

PART I:

Vaccine Manufacturing Competency Framework

PAVM TALENT DEVELOPMENT
WORKSTREAM

November 2023



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Abbreviations

AU	African Union
BARDA	Biomedical Advanced Research and Development Authority
BSc	Bachelor(s) of Science
BTech	Bachelor(s) of Technology
CAPAs	Corrective and preventive actions
CBM	Condition-based monitoring
CCS	Contamination control strategy
CDC	Centre for Disease Control and Prevention
CDMO(s)	Contract development and manufacturing organisation(s)

CEO	Chief Executive Officer
CEPI	Coalition for Epidemic Preparedness Innovations
cGMP	Current good manufacturing practices
cGXP	Current good standard practices
CI	Continuous improvement
CMC	Chemistry, manufacturing and controls
CMO(s)	Contract manufacturing organisation(s)
DCVMs	Developing country vaccine manufacturers
DMAIC	Define, measure, analyse, improve and control
DP	Drug production
DS	Drug substance
DSP	Downstream processing
eCTD	Electronic common technical documents
EHS	Electronic health system
EPR	Employee performance rating
ERP	Enterprise resource planning
EWI	Electronic work instruction
FEED	Front end engineering design
FMEA	Failure model and effects analysis
FTEs	Full-time equivalent
GDP	Good distribution practices
GLP	Good laboratory practices
GMP	Good manufacturing practices
GxP	Good practices
HPLC	High-performance liquid chromatography
HR	Human resources
HRIS	Human resource information systems
HVAC	Heating, ventilation and air conditioning
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organisation for Standardisation

IT	Information technology
IVI	International Vaccine Institute
KPIs	Key performance indicators
KQIs	Key quality indicators
LIMS	Laboratory information management systems
MNC	Multinational company
MSAT	Manufacturing science and technology
MTBF	Mean time between failures
NRA	National Regulatory Agency
NCTM	National Center for Therapeutics Manufacturing
OE	Operational excellence
OEM	Original equipment manufacturer
OJTs	On-the-job training
OND	Ordinary National Diploma
P&L	Profit and loss
PAVM	Partnerships for African Vaccine Manufacturing
PIP	Project investment proposal
PLC's	Programmable logic controllers
PO	Purchase order
QA	Quality assurance
QMS	Quality management system
R&D	Research and development
ROI	Return on investment
S&OP	Sales and operations planning process
SEM	Search engine marketing
SLAs	Service level agreements
SOP's	Standard operating procedures
TFF	Tangential flow filtration
Vx	Vaccine(s)



Executive Summary

The African Union and the African Centres for Disease Control and Prevention are working towards a New Public Health Order to enhance the continent's health and economic security. A central part of this initiative is the expansion of local vaccine, diagnostics and therapeutics manufacturing. Currently, the continent manufactures less than 1% of the vaccines it administers. This imposes significant strains on African nations' healthcare systems and diminishes their capacity to respond to pandemics and health crises.

In response to this pressing challenge, Partnerships for African Vaccine Manufacturing (PAVM) was established in 2021 under the auspices of the African Union (AU) and the African Centres for Disease Control and Prevention (Africa CDC). PAVM has set an ambitious objective: to empower the African vaccine manufacturing industry to develop, produce and supply over 60% of the total vaccine doses required on the continent by 2040. This marks a substantial increase from the fewer than 1% currently produced in Africa, with interim targets of 10% by 2025 and 30% by 2030.

A principal challenge in realizing PAVM's 2040 ambitions is the scarcity of vaccine development and manufacturing talent in Africa. Currently, there is a total workforce of between 2,000 and 3,000 full-time employees (FTEs), many of whom are associated with research and development entities that are not exclusively vaccine-focused. Importantly, there is a dearth of critical manufacturing capabilities. At present, talent development in Africa relies heavily on programmes offered outside the continent, incurring significant cost.

To address this, PAVM has developed competency frameworks for vaccine manufacturing and research and development (R&D) in the vaccine industry in Africa. These competency frameworks are designed to address the lack of clarity regarding training needs, the absence of a comprehensive training needs catalogue and the inconsistency in nomenclature used by various training programmes. These frameworks will serve as essential tools for ongoing training needs assessment, curricula development and transparency of course offerings. They are designed to benefit both training providers and vaccine manufacturers and research organisations by enabling better hiring decisions, capability assessments and internal and external training selection.

This document lays out one of these two frameworks; the vaccine manufacturing framework. This framework was created based on data analysis and expert reviews. It defines the roles of staff in the vaccine manufacturing industry. It also prescribes the knowledge and skills required for the adequate performance of a given role.

Publication of the framework will be both in “paper” as well as in virtual format on the AfricaCDC website to ensure access across the continent as reference for manufacturers, curricula developers and other stakeholders. It also served as the basis for the vaccine manufacturing needs assessment. PAVM will conduct regular needs assessments to prioritise immediate training needs in respect of manufacturers and researchers on the continent along the capabilities identified in the competency frameworks to help inform curriculum development (i.e., for which roles training is most required, and in which capabilities/skills).

In conclusion, these competency frameworks represent a crucial step in realising Africa's ambitious vaccine manufacturing goals, enabling talent development and strengthening the capabilities of the local healthcare sector.

Introduction

The AU and Africa CDC have called for a New Public Health Order which will safeguard the health and economic security of the continent as it strives to meet the aspirations of Agenda 2063. A key pillar of this mandate is the expansion of the local manufacture of vaccines, diagnostics and therapeutics. Fewer than one percent of vaccines administered on the continent are manufactured locally. This places a great burden on Africa's health systems and reduces their ability to respond to pandemics and other health crises. PAVM, with its secretariat within Africa CDC, was established in 2021 by the AU to achieve a bold goal: enabling the African vaccine manufacturing industry to develop, produce and supply more than 60 percent of the total vaccine doses required on the continent by 2040 (with interim goals of 10 percent by 2025 and 30 percent by 2030).





Challenge

Scaling vaccine manufacturing and R&D across the continent to meet PAVM's 2040 ambitions will require quadrupling the vaccine workforce to approximately 12,500 full-time employees (FTEs). Currently, there is a scarcity of vaccine development and manufacturing talent in Africa. Today there are between 2,000 and 3,000 FTEs, of whom many are associated with R&D entities that are not fully vaccine-dedicated. The existing talent base lacks key manufacturing capabilities including drug substance (DS) and drug manufacturing (DS) R&D; in other words, research activities and process efficiency improvements performed by manufacturers in dedicated R&D departments. When it comes to R&D carried out other than by vaccine manufacturers, some 40 percent of research-centred talent is comprised of students and fewer than 25 percent are full-time academics. PAVM has developed a vision to respond to the vaccine manufacturing talent needs that is shown in Figure 1.

PAVM's vision for training sources

Training for local vaccine manufacturers across time horizons¹

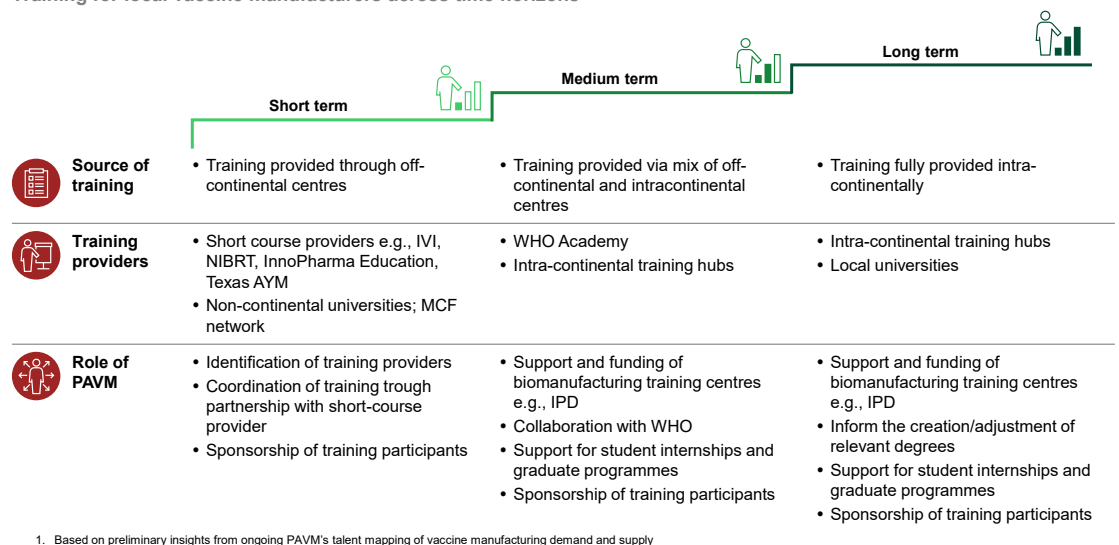


Figure 1. **PAVM's vision to respond to Africa's vaccine manufacturing talent needs**

The development of vaccine manufacturing talent in Africa currently relies on programmes offered outside the continent to satisfy the short-term needs of vaccine manufacturers and regulators. However, this approach is both expensive and unsustainable. For example, Africa CDC spent approximately US\$500,000 to support 53 trainees from Africa to attend an introductory course in vaccine manufacturing at the International Vaccine Institute (IVI) in the Republic of South Korea in 2021. A similar amount will be spent in 2023 to support trainees at Texas A&M University in the USA to gain an Advanced Certificate in Biomanufacturing, Gene Therapy, and mRNA vaccine Manufacturing.

Although a number of Africa-based training institutions are developing programmes to respond to medium- and long-term goals for localising the development of vaccine manufacturing talent, they face challenges in accessing standard curricula. The development of an appropriate curriculum requires a competency framework to define the roles of staff in the vaccine manufacturing industry. The competency framework also prescribes the knowledge and skills required for the adequate performance of a given role and thus feeds into the curriculum development process.

Objectives of the Vaccine Manufacturing Competency Framework

To enhance sustainable talent development, several information needs will need to be addressed. These are:

- A lack of clarity regarding the most pressing training needs across the continent
- The absence of a comprehensive training needs catalogue
- Inconsistent use of nomenclature used by various training programs

To address these challenges, PAVM has developed a competency framework tool to serve talent development activities going forward:

- Carrying out ongoing training needs and capability assessments to identify capability gaps and opportunities for improvement

- b. Informing curriculum development and subsequent updates
- c. Mapping course offerings (i.e., a tool for training providers)

Vaccine manufacturers can also use the tool for:

- a. Ensuring the professionals they hire for a range of roles have adequate qualifications and competencies
- b. Undertaking capability assessments to identify improvement opportunities
- c. Curating internal trainings to upskill employees across competency levels
- d. Selecting external trainings for employees

Overview of the Vaccine Manufacturing Competency Framework

The vaccine manufacturing competency framework tool has five key components:

- i. Mapping of all organisational functions and sub-functions to constituent roles
- ii. Common role nomenclature
- iii. Roles and responsibilities for each job/role within the vaccine manufacturing organisational structure
- iv. Qualifications required for each job/role (e.g., minimum experience, courses studied, etc.)
- v. Competency proficiency for each job/role (i.e., variations in capabilities between basic-skilled, semi-specialist and specialist employees)

For each unique role within a vaccine manufacturing organisation, we have defined six key metrics:

- i. Minimum number of years' experience
- ii. Minimum educational level required (e.g., high school, undergraduate degree, masters or PhD)
- iii. Courses studied (e.g., biochemistry, chemical engineering, etc.)
- iv. Roles and responsibilities
- v. Technical capabilities (e.g., business process improvement, tangential flow filtration, etc.) including variations in required proficiency between basic-skilled, semi-specialised and specialist employees)
- vi. Leadership and functional capabilities: soft skills such as team leadership, fostering collaboration, project management and communication and including variations in required proficiency between basic-skilled, semi-specialised and specialist employees)

Approach to building the Vaccine Manufacturing Competency Framework

We followed a six-step approach in building the Vaccine Manufacturing Competency Framework:

- a. We designed an end-to-end vaccine manufacturing company organisational structure by reviewing those of various company archetypes
- b. We established the unique roles that sit under various organisational functions
- c. We carried out a web-scraping exercise using two major sources of insight (i.e., LinkedIn and job postings) to acquire more than 55,000 datapoints across key output metrics (i.e., roles and

responsibilities, skills, etc.), gathering data from existing employee profiles and job postings from ~20 benchmark multinational organisations

- d. We assembled a first draft competency framework based on averages of output metrics across these 55,000 data points (typically at least five job descriptions from benchmark companies examined for each role to arrive at definitions of roles and responsibilities)
- e. Vaccine manufacturing experts reviewed a first draft
- f. Groups of experts conducted final peer reviews and suggested refinements to the competency framework.

The Vaccine Manufacturing Competency Framework was peer reviewed by 11 experts from nine organisations:

- i. African Vaccine Manufacturing Initiative
- ii. Afrigen Biologics & Vaccines
- iii. National Center for Therapeutics Manufacturing (NCTM)
- iv. The University of the Western Cape
- v. Biomedical Advanced Research and Development Authority (BARDA)
- vi. National Institute of Bioprocessing Research and Training (NIBRT)
- vii. Institut Pasteur de Dakar
- viii. BIOVAC
- ix. The United States Pharmacopeia



Implementation and Next steps

It is anticipated that the completed competency frameworks will be a catalyst for the development and localisation of vaccine manufacturing training programmes in Africa. The tools will assist in:

- i. Carrying out ongoing training needs and capability assessments, allowing for internal and external benchmarking to identify capability gaps and opportunities for improvement
- ii. Informing curriculum development and subsequent updating (in tandem with needs assessments)
- iii. Mapping course offerings and creating full transparency about training needs addressed by various courses from a range of providers

The framework is accessible via the AfricaCDC website to ensure access across the continent as reference for manufacturers, curricula developers and other stakeholders. It also served as the basis for the vaccine manufacturing needs assessment.

PAVM will conduct regular needs assessments to prioritise immediate training needs in respect of manufacturers and researchers on the continent along the capabilities identified in the competency frameworks to help inform curriculum development (i.e., for which roles training is most required, and in which capabilities/skills).

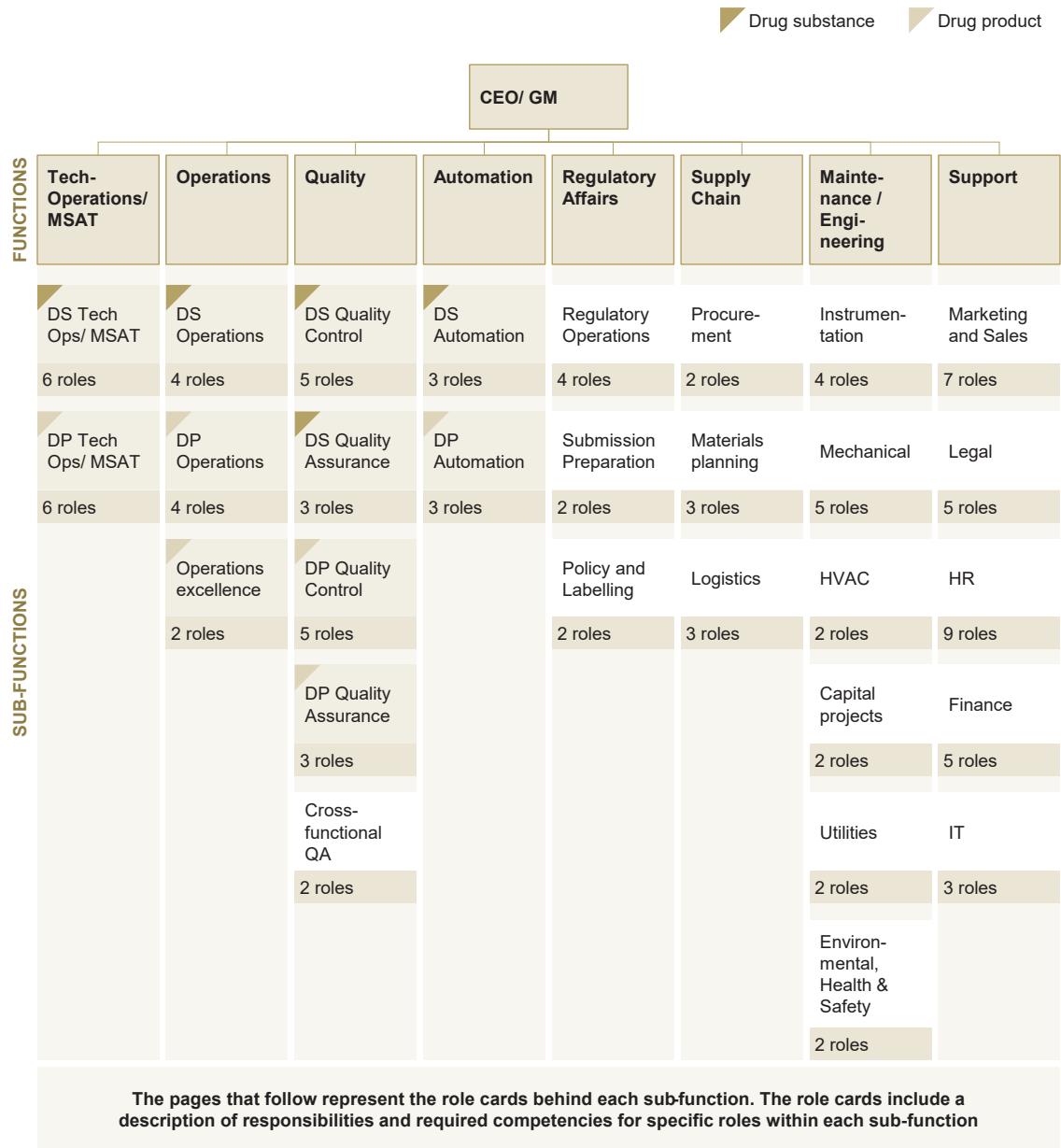
We encourage vaccine manufacturers to reach out to pavm@africacdc.org to fill out the needs assessment form to help us build a robust view of the immediate training needs of manufacturers and researchers across the continent.

A close-up photograph of a scientist in a laboratory setting. The scientist is wearing a white lab coat, a light blue surgical mask, and blue nitrile gloves. They are using a white and black pipette to transfer a yellow liquid from a small vial into a larger, clear plastic bottle with a blue cap. The bottle has volume markings (200, 150, 100, 50) and is partially filled with the same yellow liquid. In the background, another gloved hand is visible holding a small vial. The overall scene is brightly lit, emphasizing the sterile environment.

Appendix

Vaccine manufacturing competency framework

Vaccine manufacturer competency mapping



CEO / GM

Site GM


Roles and responsibilities

- Oversee day-to-day plant/ site operations
- Design overall site development plan / company strategy, liaising with various functions and sub-functions across the organization
- Contribute to site budget development and management
- Oversee the recruitment, training, motivation, and development of site staff
- Evaluate and oversee continuous improvement of site operations
- Direct the performance management process
- Prepare regular reports for central organizational leadership (or board) if CEO
- Ensure staff follow health and safety regulations
- Ensure staff follow quality regulations
- Ensure optimal collaboration across various functions (e.g., Quality, MSAT, Operations, Automation etc.)
- Owner of the site risk management plan
- Be the primary spokesperson for the company
- Raise funds from investors to sustain the company's operations

Minimum years of experience required	15
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Biotechnology, Pharmacy, Mechanical Engineering, Chemical Engineering, Biochemical Engineering, Biochemistry, Microbiology, Electrical Engineering, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Process development • Technology transfer • Quality management • Regulatory requirements • Product lifecycle management • Business process improvement • Biochemical assays • Good manufacturing practices (GMP) • Project management • Risk management • Budgeting • Innovation
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion

MSAT

DS MSAT/Tech Ops

Head, Drug Substance MSAT

Roles and responsibilities

- Contribute to develop strategy to ensure that processes for the new products are robust and efficient; help to develop and use tools such as statistical analysis and process robustness techniques to drive ongoing quality and process improvements (with emphasis on development of second-generation DS processes and associated control strategies)
- Lead a team of MSAT engineers and scientists responsible for maintaining process information, documentation of process parameters and tracking process performance as subject matter experts.
- Oversee investigations and robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Oversee development of industrial processes, including fermentation and purification
- Introduce and expand the use of statistical and scientific analysis methods to improve process robustness and efficiency
- Lead reviews of existing processes and systems and generates actions to drive improvement and ensure appropriate standards are met
- Oversee and direct department to build organisational capacity and ensure area goals are met
- Leadership of the Site MSAT organisation - including resource planning, targets, deliverables, budget management, compliance, capability, safety and more
- Leadership of commercial lifecycle improvements, including definition of relevant standards and practices, network alignment, identification, and capitalisation of opportunities
- Meet staffing and talent needs by coaching and developing existing staff while supporting recruitment and development of new talent to fill competency gaps
- Pipeline support - Enable fast pace of Chemistry, Manufacturing and Controls (CMC) development of new products to launch by providing stage appropriate input such as manufacturability, risk assessment, control strategy, process validation, dossier review and post approval change management strategies during development of new biological products
- Represent DS function in key technical review forums for new product Chemistry, Manufacturing and Controls (CMC) development.
- Support new capital projects as required
- Keep up to date with latest technology trends in biomanufacturing

Minimum years of experience required	10 years with Bachelors; 5-8 years with Masters
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biochemical Engineering, Industrial Biotechnology, Pharmaceutical Technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Process development • Business process improvement • Technology transfer • Product lifecycle management • Good manufacturing practices (GMP) • Regulatory requirements • CAPAs • Cell cultures • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

Manager, Process Engineering

Roles and responsibilities

- Design, plan and support execution of scale up/ scale down and implementation studies at laboratory or pilot scale, using best practices methodologies, to ensure robust and predictable process operation during drug substance manufacturing at a client facility.
- Leading a team of scientists and engineers responsible for technical floor support of ongoing manufacturing.
- Managing a team dedicated to the management and analysis of critical manufacturing data and process modelling
- Provide guidance and leadership in the diagnosis and resolution of complex production problems.
- Drive development of industrial processes, including fermentation and purification
- Drive investigations and robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Lead a team of Tech Transfer and Validation specialists responsible for effective transfer of processes and technology from the Process Development group into a cGMP Manufacturing environment.
- Review & author Standard Operating Procedures (SOP's) & other documents, as required.
- Direct a lab-based group of engineers/ scientists on performing scale-down models of cell culture processes with associated analytical methods to support on-going process investigations, changes, validation, and process improvement initiatives.
- Develop and test the feasibility of new manufacturing technologies and their introduction into a cGMP environment.
- Liaise with site functions such as Manufacturing, Planning, QA, QC, Operations, and Regulatory Affairs as well as off-site functions such as R&D to facilitate efficient technology transfer of new production processes and change control.
- Provide project management oversight to ensure effective resource utilisation, planning, and execution of projects that are in alignment with site objectives.
- Responsible for ensuring top performance management by personnel in the MSAT organisation in delivering high quality work to meet the demands of the site.
- Recruit, direct, coach and develop talent in the MSAT organisation to maintain a high level of technical expertise that works collaboratively with key partners.

Minimum years of experience required	7 years with Bachelors; 4-5 years with Masters
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Bioprocess technology, Industrial biotechnology, Pharmaceutical technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Process development • Business process improvement • Regulatory requirements • Technology transfer • Product lifecycle management • Good manufacturing practices (GMP) • CAPAs • Change control • Risk analysis • Statistics • Cell cultures • Aseptic technique • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Process Engineer




Roles and responsibilities

- Process monitoring and root cause investigation
- Carrying out change assessments, de-bottlenecking, and continuous improvement
- Process design for upstream techniques
- Provide input and coordinates support from process development teams.
- Provide technical/ scientific support, expertise, and guidance to manufacturing and quality
- Develop industrial processes, including fermentation and purification
- Reviews manufacturing processes and/or development and production data.
- Execute investigations and robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Support documentation preparation for regulatory purposes and stay up to date on regulatory requirements that have impact on manufacturing processes and evaluate/ implement changes if required
- Provide Chemistry, Manufacturing and Controls (CMC) support and guidance for product lifecycle management.
- Attend development and scientific meetings to remain current with technology and regulatory guidelines.
- Supporting tech transfer activities and the development of process improvements for existing commercial products using small scale upstream processing models
- Develop and track continuous improvement projects
- Design and implement experimental protocols to understand process sensitivity and solve operational issues with minimal direction

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Bioprocess Engineering, Biochemical Engineering, Bioprocess technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Process monitoring • Process design • Business process improvement • Good manufacturing practices (GMP) • Regulatory requirements • CAPAs • Research • Statistics • Data analysis • Risk analysis • Root cause analysis • Change control • Process control • Cell cultures • Aseptic technique • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Safety principles • Packing 	 <ul style="list-style-type: none"> • Process development • Technology transfer • Product lifecycle management • Innovation 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Production Technician

Roles and responsibilities

- If required, be able to fulfill typical operations duties, including but not limited to set up, operate, monitor & control equipment, systems & processes within assigned area.
- Perform equipment maintenance, including restoration of lost function, predictive & preventative maintenance.
- Perform industrial processes, including fermentation and purification
- Perform corrective maintenance and troubleshooting for vaccine processing and packaging equipment utilizing diagnostic equipment and programmable logic controllers (PLC's) as necessary.
- Participate in new equipment installations by interfacing with equipment vendors, recommending spare parts, assisting process-project engineers, assisting qualification, and performing initial debug for vaccines processing and packaging equipment.
- Author Standard Operating Procedures (SOP's) & other documents, as required.
- Train fellow employees in areas of expertise & aggressively learn systems & equipment outside of own area of expertise
- Support MSAT design of experiments activities in the lab or on the shopfloor

Minimum years of experience required	5
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Engineering, Pharmacy, Mechanical Services, Trade craft (e.g., Electrical, Plumbing, HVAC)

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Safety principles • Business process improvement • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Root cause analysis • Good manufacturing practices (GMP) • Regulatory requirements • Equipment operation and maintenance • Standard operating procedures • Aseptic technique • Cell cultures • Research • Packing 	<ul style="list-style-type: none"> • ERP applications • Logbooks • Environmental monitoring 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Manager, Process Validation

Roles and responsibilities

- Provide overall leadership to the DS validation team, including but not limited to prioritization of workload, troubleshooting validation activities, completion of training requirements, group problem solving
- Defining process validation strategies
- Generating and executing validation protocols and writing final reports on adherence to protocols
- Sampling, as required
- Support regulatory affairs function in the generation of regulatory submission documents
- Project management of overall and individual process validation projects and activities
- Write impact assessments for investigations
- Perform and lead gap analyses and risk assessments for tech transfers
- Write justifications for the assessment of change controls for process impact.
- Ability to manage multiple projects and activities of moderate complexity simultaneously.
- Liaise with site functions such as Manufacturing, Planning, QA, QC, Operations, and Regulatory Affairs as well as off-site functions such as R&D to facilitate efficient technology transfer of new production processes and change control.
- Support Regulatory Affairs function with regulatory inspections through the preparation, defense and interaction with auditors in areas related to process and cleaning validation.
- Provide expertise for troubleshooting and resolution of process and cleaning issues.
- Work to implement a culture of Right-First Time and continuous improvement relative to cleaning and process procedures and systems.

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Process development • Process control • Process design • CAPAs • Technology transfer • Aseptic technique • Cell cultures • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Sampling • Business process improvement • Risk analysis • Statistics • Change control • Simulations • Process equipment and facility validation • Regulatory requirements • Good manufacturing practices (GMP)
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Process Validation Engineer




Roles and responsibilities

- Create and execute validation protocols for scale-up, optimization studies, and process validation.
- Review process design documents and development reports
- Identify potential quality and compliance risks associated with technology transfer and scale-up
- Propose solutions to mitigate risk.
- Support process changes through contributing to the generation of necessary validation documentation and change control activities
- Determine the impact of proposed process changes
- Provide technical guidance and assessment for process validation regulatory requirements
- Perform process monitoring
- Identify process capability and capacity
- Perform statistical analysis
- Develop, review, and approve equipment and process related engineering studies
- Create summary reports on adherence to validation protocols during external and internal audits

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Pharmacy

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Process design • Process control • Regulatory requirements • Change control • CAPAs • Materials management • Good manufacturing practices (GMP) • Process monitoring • Risk analysis • Data analysis • Statistics • Sampling • Cell cultures • Aseptic technique • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) 	 <ul style="list-style-type: none"> • Simulations • Technology transfer • Process development • Process equipment and facility validation 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

DP MSAT/Tech Ops

Head, DP Tech Ops/MSAT

Roles and responsibilities

- Lead drug product Drug Product MSAT responsible for cGMP support for internal aseptic drug product manufacturing
- Contribute to and develop strategy to ensure that processes for the new products are robust and efficient, helping to develop and use tools such as statistical analysis and process robustness techniques to drive ongoing quality and process improvements
- Work closely with Drug Product Process Development, Manufacturing, and Quality and external Contract Manufacturing Organisations (CMO) to successfully implement and sustain cGMP drug product manufacturing processes
- Oversee development of industrial processes, including Formulation, Filling, Lyophilisation and Inspection
- Lead a team of MSAT engineers and scientists responsible for maintaining process information, documentation of process parameters and tracking process performance as subject matter experts.
- Ensure robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Introduce and expand the use of statistical and scientific analysis methods to improve process robustness and efficiency
- Lead reviews of existing processes and systems and generates actions to drive improvement and ensure appropriate standards are met
- Oversee and direct department to build organisational capacity and ensure area goals are met
- Leadership of the Site MSAT organisation - including resource planning, targets, deliverables, budget management, compliance, capability, safety and more
- Implementation of commercial lifecycle improvements, including definition of relevant standards and practices, network alignment, identification, and capitalisation of opportunities
- Meet staffing and talent needs by coaching and developing existing staff while supporting recruitment and development of new talent to fill competency gaps
- Contributes to Chemistry, Manufacturing and Controls (CMC) development cycles of individual products
- Provides input into Commercial Process Design, Process Failure Model and Effects Analysis (FMEA), Process Characterisation Studies, Control Strategies, dossier and responses to agencies questions, as well driving Medical Device Combination regulation compliance
- Support capital projects as necessary
- Keep up to date with latest technology trends in biomanufacturing

Minimum years of experience required	10 years with Bachelors; 5-8 years with Masters
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biochemical Engineering, Industrial Biotechnology, Pharmaceutical Technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • P Process development • Business process improvement • Product lifecycle management • Good manufacturing practices (GMP) • Regulatory requirements • CAPAs • Technology transfer • Change control • Formulation • Filling • Cell cultures • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

Manager, Process Engineering

Roles and responsibilities

- Design, plan and support execution of scale up/ scale down and implementation studies at laboratory or pilot scale, using best practices methodologies, to ensure robust and predictable process operation during drug product manufacturing at a facility.
- Leading a team of scientists and engineers responsible for technical floor support of ongoing manufacturing.
- Lead development of industrial processes, including Formulation, Filling, Lyophilisation, Primary packing and Inspection
- Managing a team dedicated to the management and analysis of critical manufacturing data and process modelling
- Review Standard Operating Procedures (SOP's) & other documents, as required.
- Provide guidance and leadership in the diagnosis and resolution of complex production problems.
- Drive investigations and robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Lead a team of Tech tTransfer and Validation specialists responsible for effective transfer of processes and technology from the Process Development group into a cGMP Manufacturing environment.
- Direct a lab-based group of engineers/ scientists on performing scale-down models of cell culture and purification processes with associated analytical methods to support on-going process investigations, changes, validation, and process improvement initiatives.
- Develop and test the feasibility of new manufacturing technologies and their introduction into a cGMP environment.
- Liaise with site functions such as Manufacturing, Planning, QA, QC, Operations, and Regulatory Affairs as well as off-site functions such as R&D to facilitate efficient technology transfer of new production processes and change control.
- Provide project management oversight to ensure effective resource utilisation, planning, and execution of projects that are in alignment with site objectives.
- Responsible for ensuring top performance management by personnel in the MSAT organisation in delivering high quality work to meet the demands of the site.
- Recruit, direct, coach and develop talent in the MSAT organisation to maintain a high level of technical expertise that works collaboratively with key partners.
- Develop risk-based strategies for organisation technical oversight accounting for product life cycle, technical complexity and site capabilities.

Minimum years of experience required	7 years with Bachelors; 4-5 years with Masters
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Bioprocess technology, Industrial biotechnology, Pharmaceutical technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Process development • Business process improvement • Product lifecycle management • Regulatory requirements • Good manufacturing practices (GMP) • Technology transfer • Risk analysis • Change control • CAPAs • Statistics • Aseptic technique • Formulation • Filling • Cell cultures • Lyophilisation • Purification • Chromatography • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Process Engineer


Roles and responsibilities

- Process design for Tangential Flow Filtration (TFF) and chromatography systems
- Provide support for filtration-based purification technologies as needed
- Contributing to initial process validation and process control strategy
- Introduction of new products and processes at manufacturing scale
- Process monitoring and root cause investigation
- Execute investigations and robust resolution of technical deviations through root cause analysis and subsequent Corrective and Preventive Actions (CAPAs) that resolve the issue
- Development of industrial processes, including Formulation, Filling, Lyophilisation, Primary Packing and Inspection
- Carrying out change assessments, de-bottlenecking, and continuous improvement
- Supporting tech transfer activities and the development of process improvements for existing commercial products using small scale downstream processing (DSP) models
- Design and implement experimental protocols to understand process sensitivity and solve operational issues with minimal direction.
- Train operators on Resin column packing

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Bioprocess Engineering, Biochemical Engineering, Bioprocess technology, Chemistry, Biological Sciences, Biochemistry, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Process design • Business process improvement • Regulatory requirements • Good manufacturing practices (GMP) • Research • Change control • CAPAs • Data analysis • Risk analysis • Statistics • Root cause analysis • Process control • Cell cultures • Process monitoring • Formulation • Filling • Chromatography • Purification • Tangential flow filtration (TFF) • Aseptic technique • Packing 	<hr/> <ul style="list-style-type: none"> • Process development • Technology transfer • Product lifecycle management • Innovation 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	<hr/> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Production Technician

Roles and responsibilities

- If required, be able to fulfill typical operations duties, including but not limited to set up, operate, monitor & control equipment, systems & processes within assigned area.
- Perform equipment maintenance, including restoration of lost function, predictive & preventative maintenance.
- Perform industrial processes, including Formulation, Filling, Lyophilisation, Primary Packing and Inspection
- Perform corrective maintenance and troubleshooting for vaccine processing and packaging equipment utilizing diagnostic equipment and programmable logic controllers (PLC's) as necessary.
- Participate in new equipment installations by interfacing with equipment vendors, recommending spare parts, assisting process-project engineers, assisting qualification, and performing initial debug for vaccines processing and packaging equipment.
- Author Standard Operating Procedures (SOP's) & other documents, as required.
- Train fellow employees in areas of expertise & aggressively learn systems & equipment outside of own area of expertise
- Support MSAT design of experiments activities in the lab or on the shopfloor

Minimum years of experience required	5
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Engineering, Pharmacy, Mechanical Services, Trade craft (e.g., Electrical, Plumbing, HVAC)

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Safety principles • Business process improvement • Regulatory requirements • Good manufacturing practices (GMP) • Equipment operation and maintenance • Standard operating procedures • Root cause analysis • Aseptic technique • Research • Formulation • Cell cultures • Filling • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	<ul style="list-style-type: none"> • ERP applications • Logbooks • Environmental monitoring 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Manager, Process Validation

Roles and responsibilities

- Provide overall leadership to the DP validation team, including but not limited to prioritization of workload, troubleshooting validation activities, completion of training requirements, group problem solving
- Defining process validation strategies
- Generating and executing validation protocols and writing final reports
- Sampling
- Supporting the development and validation of industrial processes including Formulation, Filling, Lyophilization, Primary packing and Inspection
- Support regulatory affairs function in the generation of regulatory submission documents
- Project management of overall and individual process validation projects and activities
- Write impact assessments for investigations
- Perform and lead gap analyses and risk assessments for tech transfers
- Write justifications for the assessment of change controls for process impact.
- Ability to manage multiple projects and activities of moderate complexity simultaneously.
- Liaise with site functions such as Manufacturing, Planning, QA, QC, Operations, and Regulatory Affairs as well as off-site functions such as R&D
- Support regulatory inspections through the preparation, defense and interaction with auditors in areas related to process and cleaning validation.
- Provide expertise for troubleshooting and resolution of process and cleaning issues.
- Work to implement a culture of Right-First Time and continuous improvement relative to cleaning and process procedures and systems.
- Sterile Filtration validation

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Process development • Process control • Process design • Sampling • Business process improvement • CAPAs • Technology transfer • Process equipment and facility validation • Risk analysis • Statistics • Change control • Regulatory requirements • Good manufacturing practices (GMP) • Formulation • Filling • Cell cultures • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Process Validation Engineer

Roles and responsibilities

- Supporting the development and validation of industrial processes including Formulation, Filling, Lyophilisation, Primary Packing and Inspection
- Create and execute validation protocols for scale-up, optimisation studies, and process validation.
- Review process design documents and development reports
- Identify potential quality and compliance risks associated with technology transfer and scale-up
- Propose solutions to mitigate risk.
- Support regulatory affairs function in the generation of regulatory submission documents
- Support changes through the provision of necessary validation documentation and change control activities
- Determine the impact of proposed process changes
- Provide technical guidance and assessment for process regulatory requirements
- Perform process monitoring
- Identify process capability
- Perform statistical analysis
- Develop, review, and approve equipment and process related engineering studies
- Create summary reports during external and internal audits

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Pharmacy

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Process design • Process control • Regulatory requirements • Business process improvement • CAPAs • Change control • Materials management • Process monitoring • Data analysis • Statistics • Sampling • Aseptic technique • Cell cultures • Formulation • Filling • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	<ul style="list-style-type: none"> • Simulations • Technology transfer • Process development • Process equipment and facility validation 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Operations

DS Operations

Head of DS Operations

Roles and responsibilities

- Develop a unified short and long-term operational plan for the site in partnership with the site GM/ CEO and site leadership team across all drug substance operational areas i.e., project management, maintenance, finance, supply chain, MSAT, and other stakeholders
- Collaborate with the Head of Drug Product Operations and other stakeholders to ensure seamless integration and coordination between drug substance and drug product operations.
- Build and maintain a comprehensive understanding of all site functions and apply that knowledge to effectively manage strategic and tactical initiatives according to strategic plans.
- Coordinate site services areas and key site stakeholders
- Take lead in strategic workforce planning
- Oversee development and implementation of business continuity and disaster recovery plans for sites to support uninterrupted product supply.
- Lead site operations with a large focus on continuous improvement programs, development of KPIs, business problem resolution, and reviewing key initiative plans
- Financial analysis of certain initiatives including new business opportunities for site as needed.
- Development of operating budget
- Ability to identify critical business opportunities and effectiveness needs, develop and implement effective strategies that drive optimal operations performance, long-term growth, and productivity priorities
- Support site vision while ensuring the implementation of the change efforts to achieve the vision.
- Support team development and growth, including hiring, coaching, mentoring of team members
- Co-operate with other departments to obtain consensus and achieve site and operational goals.
- Ensure that quality standards and procedures are in place and adhered to across all operational areas. This includes overseeing the implementation of quality management systems, ensuring compliance with regulatory requirements, and managing deviations, investigations, and corrective actions.

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters or PhD preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering, Project Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Business process improvement • Technology transfer • Regulatory requirements • Good manufacturing practices (GMP) • CAPAs • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

Manager, DS Operations


Roles and responsibilities

- Review and approve technical and quality related documentation. (Process and Instrumentation Diagrams, validations, and design documents)
- Provide troubleshooting and problem-solving guidance for daily project and manufacturing issues
- Implement preventative/corrective actions
- Develop and execute production schedules from project through full scale manufacturing, ensure that project support and production activities are executed as per defined schedules
- Lead operations team execution on the shop floor for equipment, processes, and facilities. Monitor and communicate team and project performance with respect to deliverables using visible metrics
- Support development of operating budget and staffing for operations and project related activities.
- Develop communication approach for operations topics to ensure project milestones are met (escalation, cascading).
- Ensure compliance with GMP requirements, develop quality continuous improvement initiatives, develop staff quality culture, and GMP knowledge.
- Ensure that all operating procedures, training plans, and manufacturing documentation are current, developed in adherence to global and site policies, and completed in a timely manner
- Through appropriate shop floor oversight, ensure that facilities & equipment are compliant, and that process deviations and environmental incidences are addressed in a compliant manner.
- Support internal and external regulatory audits/inspections and coordinate appropriate responses.
- Organize and develop staff to ensure a high performing team. Provide individual feedback on staff objectives and development, coaching each team member on personal development milestones.
- Co-operate with other departments to obtain consensus and achieve site, department, and operational goals.

Minimum years of experience required	7
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering, Project Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Business process improvement • Regulatory requirements • Safety principles • Technology transfer • Maintenance • Automation systems • Quality Management Systems • Deviation Investigation • CAPAs • Change control • Good manufacturing practices (GMP) • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Cell cultures • Aseptic technique
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Supervisor, DS Operations

Roles and responsibilities

- Lead the safe operation of the shift and facilitate team of operators to ensure timely completion of all process activities
- Ensure cGMP compliance and being audit ready at all times
- Coordinate the workload of your team to ensure batch loss and material loss is prevented, business objectives are met
- Input into development of production plans, capacities and staffing to ensure schedule adherence and execution of plan based on Standard Work
- Lead cross-functional working groups to troubleshoot any issues and to identify preventative actions
- Drive operational changes to improve supply and quality of the product
- Coach operations technicians in ways of working, problem solving, and continuous improvement projects
- Facilitating and supporting new product introduction.
- Engaging and consulting with senior leaders, analyzing organisational challenges
- Ensure process documentation is completed properly and per cGMP guidance
- Monitors safety of team members and working conditions, escalates safety issues according to EHS policies

Minimum years of experience required	5
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Business process improvement • Regulatory requirements • Safety principles • Technology transfer • Maintenance • Scheduling • Automation systems • Quality Management Systems • Deviation Investigation • CAPAs • Change control • Good manufacturing practices (GMP) • Standard operating procedures • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Cell cultures • Aseptic technique • ERP applications 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Technician, DS Operations

Roles and responsibilities

- Maintains a safe working environment and reporting of incidents/accidents to Manufacturing management.
- Effectively demonstrates understanding of GMPs and how they apply to specific responsibilities.
- Follows verbal and written procedures in operating production and equipment and performing processing steps; accurately completes appropriate production documentation.
- Maintains cleanliness and orderliness in process area.
- Ensures production area is stocked with supplies.
- Performs EWI (Electronic Work Instruction) revisions and work order generation.
- Interacts with other support functions such as Quality Assurance, Quality Control, MSAT etc.
- Utilizes manufacturing knowledge to improve process operations and affect positive change.
- Perform in-process testing of batch samples utilizing various physical testing instruments.
- Operate material handling equipment such as forklifts, drum lifters, and pallet jacks.
- Demonstrates ability to troubleshoot basic mechanical operations.
- Collect samples of raw materials, intermediates and finished products utilizing appropriate sampling tools and techniques
- Contributes to continual improvement of all manufacturing documentation (SOPs, EWIs, MBRs, OJTs) to ensure they are current, accurate, and clear.
- Supports plant floor continuous improvement initiatives.
- Document production activities in real-time, including batch records, logbooks, and other production documentation in accordance with Good Documentation Practices

Minimum years of experience required	0 - 3 years
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> Regulatory requirements Safety principles Quality Management Systems Maintenance Automation systems Standard operating procedures Fermentation Chromatography Purification Tangential flow filtration (TFF) Packing Cell cultures Aseptic technique Computer literacy 	<ul style="list-style-type: none"> Business process improvement Deviation Investigation CAPAs Good manufacturing practices (GMP) ERP applications 		
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Teamwork Problem solving Interpersonal skills 	<ul style="list-style-type: none"> Decision making Presentation Coaching and mentoring 		

DP Operations

Head of DP Operations

Roles and responsibilities

- Develop a unified short and long-term operational plan for the site in partnership with the site GM/ CEO and site leadership team across all drug product operational areas i.e., project management, maintenance, finance, supply chain, MSAT, and other stakeholders
- Build and maintain a comprehensive understanding of all site functions and apply that knowledge to effectively manage strategic and tactical initiatives according to strategic plans.
- Coordinate site services areas and key site stakeholders
- Take lead in strategic workforce planning
- Oversee development and implementation of business continuity and disaster recovery plans for sites to support uninterrupted product supply.
- Lead site operations with a large focus on continuous improvement programs, development of KPIs, business problem resolution, and reviewing key initiative plans
- Financial analysis of certain initiatives including new business opportunities for site as needed.
- Development of operating budget
- Ability to identify critical business opportunities and effectiveness needs, develop and implement effective strategies that drive optimal operations performance, long-term growth, and productivity priorities
- Support site vision while ensuring the implementation of the change efforts to achieve the vision.
- Support team development and growth, including hiring, coaching, mentoring of team members
- Co-operate with other departments to obtain consensus and achieve site and operational goals.
- Ensure that quality standards and procedures are in place and adhered to across all operational areas. This includes overseeing the implementation of quality management systems, ensuring compliance with regulatory requirements, and managing deviations, investigations, and corrective actions.

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters or PhD preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering, Project Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Business process improvement • Regulatory requirements • Technology transfer • Aseptic technique • Formulation • Filling • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Good manufacturing practices (GMP) 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

Manager, DP Operations


Roles and responsibilities

- Manage the procurement process and readiness of small equipment within Operations for engineering runs and start-up.
- Review and approve technical and quality related documentation.
- Provide troubleshooting and problem-solving guidance for daily project and manufacturing issues
- Lead implementation of preventative/corrective actions.
- Participate and support the incorporation of digital technology (e.g., electronic batch record and e-logbooks) into manufacturing process in the new facility to reduce costs and to improve quality and delivery capability.
- Develop and execute production schedules from project through full scale manufacturing, ensure that project support and production activities are executed as per defined schedules.
- Lead operations team execution on the shop floor for equipment, processes, and facilities.
- Monitor and communicate team and project performance with respect to deliverables using visible metrics.
- Support development of operating budget and staffing for operations and project related activities from design to start-up
- In collaboration with the site Quality team, ensure compliance with GMP requirements, develop quality continuous improvement initiatives, develop staff in quality culture and GMP knowledge.
- Ensure that all operating procedures, training plans, and manufacturing documentation are current, developed in adherence to global and site policies, and completed in a timely manner.
- Support internal and external regulatory audits/inspections and coordinate appropriate responses.
- Identify and lead initiatives to increase process efficiency, quality and/or yield. Implement solutions or changes via change control, plan and manage site, department, and organisation improvements.

Minimum years of experience required	7
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering, Project Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Business process improvement • Regulatory requirements • Technology transfer • Maintenance • Automation systems • Quality Management Systems • Deviation Investigation • CAPAs • Change control • Formulation • Filling • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Good manufacturing practices (GMP)
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Supervisor, DP Operations

Roles and responsibilities

- Lead the safe operation of the shift and facilitate team of operators to ensure timely completion of all process activities
- Ensure cGMP compliance and being audit ready at all times
- Coordinate the workload of your team to ensure batch loss and material loss is prevented, business objectives are met
- Input into development of production plans, capacities and staffing to ensure schedule adherence and execution of plan based on Standard Work
- Lead cross-functional working groups to troubleshoot any issues and to identify preventative actions
- Drive operational changes to improve supply and quality of the product
- Coach operations technicians in ways of working, problem solving, and continuous improvement projects
- Facilitating and supporting new product introduction.
- Engaging and consulting with senior leaders, analyzing organisational challenges
- Monitors safety of team members and working conditions, escalates safety issues according to EHS policies

Minimum years of experience required	5
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Business process improvement • Regulatory requirements • Technology transfer • Maintenance • Scheduling • Automation systems • Quality Management Systems • Deviation Investigation • CAPAs • Change control • Good manufacturing practices (GMP) • Standard operating procedures • Aseptic technique • Formulation • Filling • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Technician, DP Operations




Roles and responsibilities

- Maintains a safe working environment and reporting of incidents/accidents to Manufacturing management.
- Effectively demonstrates understanding of GMPs and how they apply to specific responsibilities.
- Follows verbal and written procedures in operating production and equipment and performing processing steps; accurately completes appropriate production documentation.
- Maintains cleanliness and orderliness in process area.
- Ensures production area is stocked with supplies.
- Performs EWI (Electronic Work Instruction) revisions and work order generation.
- Interacts with other support functions such as Quality Assurance, Quality Control, MSAT etc.
- Utilizes manufacturing knowledge to improve process operations and affect positive change.
- Perform in-process testing of batch samples utilizing various physical testing instruments.
- Operate material handling equipment such as forklifts, drum lifters, and pallet jacks.
- Demonstrates ability to troubleshoot basic mechanical operations.
- Collect samples of raw materials, intermediates and finished products utilizing appropriate sampling tools and techniques
- Contributes to continual improvement of all manufacturing documentation (SOPs, EWIs, MBRs, OJTs) to ensure they are current, accurate, and clear.
- Supports plant floor continuous improvement initiatives.
- Document production activities in real-time, including batch records, logbooks, and other production documentation in accordance with Good Documentation Practices

Minimum years of experience required	0 - 3 years
Minimum educational level required	High School (Bachelors preferred)
Degree majors typically studied	Chemistry, Biological Sciences, Biochemistry, Medicine, Chemical Engineering, Mechanical Engineering, Industrial Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Safety principles • Regulatory requirements • Quality Management Systems • Maintenance • Automation systems • Standard operating procedures • Aseptic technique • Formulation • Filling • Lyophilisation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Computer literacy 	 <ul style="list-style-type: none"> • Business process improvement • Deviation Investigation • CAPAs • Good manufacturing practices (GMP) • ERP applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Operations Excellence

Operations Excellence Manager

Roles and responsibilities

- Drive continued deployment of continuous improvement (CI) culture at the site, to include specific actions to address identified improvement opportunities in alignment with the site masterplan and maturity assessments.
- Conduct, lead and/or facilitate workshops to uncover continuous improvement opportunities (for example, value stream mapping to identify bottlenecks and areas of improvement).
- Design Key Performance Indicators (KPIs) and dashboards, design collection/reporting processes and lead administrative teams in gathering and reporting site KPIs.
- Utilize digitisation opportunities to reduce lean waste in the site processes, drive simplification for the customer, and leverage and create electronic visual management tools.
- Build site/ function CI capabilities at different Lean / Six Sigma expertise levels in line with the site masterplan.
- Apply, adapt and develop advanced, expert Lean Six Sigma methods and tools to drive initiatives that will increase utilisation, reduce waste, improve profitability, and improve general ways of working.
- Lead, motivate and facilitate cross-functional teams to commit to, and deliver results.
- Employ benchmarking techniques, both within and outside organisation, to leverage best practices, share knowledge, and deploy best known methods, as appropriate.
- Design, plan and facilitate effective, efficient meetings and workshops, and mentor others in meeting planning and facilitation.

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters)
Degree majors typically studied	Business Administration, Statistics, Mathematics, Finance, Humanities, Engineering, Biology, Chemistry, Supply Chain Management, Project Management, Risk Management, Regulatory Compliance, Lean Six Sigma

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Six sigma methodologies • Business process improvement • Lean production systems • Statistics • Root cause analysis • Process control 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Operations Excellence Specialist



Roles and responsibilities

- Support continued deployment of continuous improvement (CI) culture at the site, to include specific actions to address identified improvement opportunities in alignment with the site masterplan and maturity assessments.
- Conduct/ facilitate workshops to uncover continuous improvement opportunities (for example, value stream mapping to identify bottlenecks and areas of improvement).
- Support design of Key Performance Indicators (KPIs) and dashboards, design collection/reporting processes and lead administrative teams in gathering and reporting site KPIs.
- Utilize digitisation opportunities to reduce lean waste in the site processes, drive simplification for the customer, and leverage and create electronic visual management tools.
- Build site/ function CI capabilities at different Lean / Six Sigma expertise levels in line with the site masterplan.
- Apply, adapt and develop advanced, expert Lean Six Sigma methods and tools to drive initiatives that will increase utilisation, reduce waste, improve profitability, and improve general ways of working.
- Employ benchmarking techniques, both within and outside organisation, to leverage best practices, share knowledge, and deploy best known methods, as appropriate.
- Design, plan and facilitate effective, efficient meetings and workshops, and mentor others in meeting planning and facilitation.

Minimum years of experience required	4
Minimum educational level required	Lean Six Sigma Green/ Black Belt certification (Bachelors preferred)
Degree majors typically studied	Business Administration, Statistics, Mathematics, Finance, Humanities, Engineering, Biology, Chemistry, Regulatory Compliance, Lean Six Sigma

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Six sigma methodologies • Business process improvement • Lean production systems • Statistics • Root cause analysis • Process control 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	 <ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Quality

Site Quality Director

Roles and responsibilities

- Achieves Quality and Business results through partnerships across site
- Achieves and maintains compliance against national and international standards, as appropriate.
- Quality Plans: Ensures the creation and execution of the Site Quality Master Plan and Site Quality and Compliance annual business plan.
- Oversee the management of training, motivation and development of a team of Quality professionals
- Lead a Quality Team in support of the manufacturing of Drug substance and Drug Product manufactured at the site.
- Lead the design, implementation, maintenance and continuous improvement of the quality requirements of clinical drug substance and drug product manufacture and release.
- Ensure change controls, quality deviations, out of specification results, complaints, recalls, management of suppliers and quality / business risks associated with area of responsibility are appropriately investigated, reviewed, mitigated and closed out.
- KPIs reporting and periodic review of quality systems
- Establish systems and processes within Quality and wider analytical platform to ensure that QA and QC procedures, systems, data and documentation comply with cGMP, data integrity requirements and regulations.
- Review or approve data and commentary generated for regulatory submissions as required.
- Ensure that quality systems and processes are aligned with the rest of the drug substance and drug product platforms for project development, manufacture and supply.
- Represent Quality during internal audits and regulatory inspections.
- Issue Resolution: Ensure clear and timely action plans for issue resolution with appropriate escalation, communication, and closure.
- Stability Testing: Ensure that all marketed product stability testing is completed/reviewed in a timely manner; meets NRA expectations regarding timely notification of events
- Product Disposition: Ensures independent and timely product disposition using validated processes, batch records data reviews ,analytical methods, and documented decision-making processes.
- Technology and Science: Holds self and others accountable for making decisions, solving problems, or driving improvements through a sound understanding of the technology and science of the products.
- Operational Excellence: Drives innovation and continuous improvement through Operational Excellence (OE) in all Quality activities, and supports OE throughout site

Minimum years of experience required	15
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Quality management • Quality management systems • Regulatory requirements • ISO standards • Inspections • Quality auditing • Business process improvement • Analytical method development and validation • Chromatography • Mass spectrometry • Biochemical assays • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Next generation sequencing and multi-omics analysis • Upstream processing • Downstream processing • Aseptic technique • Cell cultures 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

DS Quality Control

QC Department Head

Roles and responsibilities

- Oversee the management of training, motivation and development of a team of Quality Control professionals
- Lead a Quality Control Team in support of the manufacturing of Drug substance manufactured at the site.
- Lead the design, implementation, maintenance and continuous improvement of the quality control requirements of clinical drug substance manufacture and release.
- Ensure change controls, quality deviations, out of specification results, and quality / business risks associated with area of responsibility are appropriately investigated, reviewed, mitigated and closed out.
- Monitoring of KPIs
- Establish systems and processes within QC and wider analytical platform to ensure that QC procedures, systems, data and documentation, comply with cGMP, data integrity requirements and regulations.
- Review or approve data and commentary generated for regulatory submissions as required.
- Ensure that quality control systems, performance and processes are aligned with the rest of the drug substance platform for project development, manufacture and supply.
- Represent Quality Control during internal audits and regulatory inspections.
- Issue Resolution: Ensure clear and timely action plans for issue resolution with appropriate escalation, communication, and closure.
- Stability Testing: Ensure that all marketed product stability testing is completed/reviewed in a timely manner; meets NRA expectations regarding timely notification of events
- Release of raw materials and artworks
- Ensure introduction of new QC techniques and technology in a fit for purpose and validated manner.

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Business process improvement • Analytical method development and validation • Aseptic technique • Chromatography • Mass spectrometry • Biochemical assays • Cell cultures • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Next generation sequencing and multi-omics analysis • Budgeting 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 	

QC Manager

Roles and responsibilities

- Accountable for ensuring on time delivery of completed test certificates & documentation.
- Ensures test results accuracy and compliance with cGMP.
- Ensure documentation is expedited in a timely manner to facilitate the release of product to market.
- Monitor and track requirements for test approvals to ensure on time release of test results.
- Review and approval of critical reagent qualification and expiry date extension reports.
- Responsible for ensuring monthly review of logbooks completion .
- Responsible for accurately compiling data for tests, products, trending for statistical reports, to support regulatory questions and/or submissions as required, Perform Laboratory Information Management Systems (LIMS) queries as required
- Responsible for organizing and management of documents in accordance with department and corporate policies.
- Reviews existing SOPs and initiate revisions/ approvals of existing or new SOPs, protocols, reports and test summaries as required.
- Manages activities related to Change Control and CAPA, as required.
- Responsible for notifying Department Head of any laboratory non conformances.
- Leads investigations and provides required support documentation to expedite closure of deviations.
- Compile data to support regulatory submissions, audits, and root cause analysis as required.
- Accountable to ensure the timely filing, and completion of all GxP documents associated.
- Support LIMS related test analysis updates.
- Assists with equipment commissioning and decommissioning, qualification and validation.
- Ensure appropriate test periodic validation where necessary
- Coordinating maintenance and re-certification/recalibration of equipment.

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Standard operating procedures • Business process improvement • Aseptic technique • Biochemical assays • Cell cultures • Chromatography • Mass spectrometry • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Budgeting • Analytical method development and validation • Next generation sequencing and multi-omics analysis 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

QC Supervisor

Roles and responsibilities

- Effectively coordinate the execution of QC methods
- Conduct technical assessments of deviations and investigations
- Collaborate effectively across all departments to meet key objectives
- Assist in development, implementation, and maintenance of general laboratory operational systems in accordance with cGMP requirements
- Write/ revise SOPs, technical protocols, and reports
- Work with the quality control team to continuously improve the quality, compliance and efficiency of QC operations
- Coordinate accurate compiling of data for tests, products and trending for statistical reports, to support regulatory questions and/or submissions as required, Perform Laboratory Information Management Systems (LIMS) queries as required
- Effectively communicate internal issues related to performance, processes, and procedures
- Establish and maintain a safe laboratory working environment
- Act as designee for the Quality Control Manager as appropriate
- Trains other laboratory staff on method execution and troubleshooting
- Provides support to audit teams for internal and vendor audits
- Ensure introduction of new QC techniques and technology in a fit for purpose and validated manner

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Business process improvement • Testing • Sampling • Aseptic technique • Chromatography • Mass spectrometry • Biochemical assays • Cell cultures • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Standard operating procedures • Instrumentation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

QC Technician

Roles and responsibilities

- Assure that equipment is operating properly, report and correct malfunctions, and assist others in complex set up/ repair operations.
- Pull samples for identification/ testing, and perform routine product/ process functional tests and complete a variety of accountability reports.
- Execute various test methods e.g., HPLC, viral load tests, sterility tests etc.
- Ensure compliance with all plant safety rules in the area of responsibility in line with Good Manufacturing Practices for products and processes.
- Maintain area housekeeping standards and environmental specifications by using a variety of sanitizing aids.
- Support implementation of new technology for process execution and/or analysis.
- Maintain current training status on all applicable standard operating procedures.
- Execute Standard Operating Procedures for testing operations

Minimum years of experience required	4
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Safety principles • Regulatory requirements • Cell cultures • Maintenance • Testing • Sampling • Chromatography • Mass spectrometry • Aseptic technique • Instrumentation • Standard operating procedures 	<div>→</div> <ul style="list-style-type: none"> • Biochemical assays • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Business process improvement • ISO standards • ERP applications 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

QC Analyst

Roles and responsibilities

- To test samples utilizing a range of chemical, biochemical and biological tests in accordance with regulatory requirements and agreed schedules.
- To apply knowledge of physiochemical testing to product testing and stability data.
- To test specifications and sampling regimes, and the impact they may have on the product.
- To work with the QC supervisor/ manager to interpret test results as required.
- Work in a safe manner and in compliance with Safety Codes of Practice and policies.
- To maintain detailed laboratory records in compliance with cGMPs using controlled pro-forma/ laboratory notebooks.
- To ensure that all records and test results are accurately prepared & peer reviewed prior to submission for approval and authorisation according to company, customer and regulatory requirements.
- Record deviations from the normal practice appropriately, report them to the QC Supervisor/ Manager, and develop appropriate CAPAs
- Assist with product investigations and test anomalies.
- Responsible for Quality Management Systems (QMS) records
- Responsible for routine maintenance of laboratory equipment, and ensuring records are adequately maintained.
- Ensure that the department is kept in a safe, clean and orderly fashion and maintained in an inspection ready state.
- To facilitate the ordering of laboratory consumables to ensure efficient running of the laboratory.
- To record incoming samples according to the appropriate SOPs.
- To ensure all samples and materials are handled safely following departmental procedures.
- To participate in the validation of test methods and equipment used in analysis to meet regulatory requirement
- Implements new technologies/instrumentation in the QC laboratory

Minimum years of experience required	1
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Safety principles • Regulatory requirements • Cell cultures • Maintenance • Testing • Sampling • Chromatography • Mass spectrometry • Aseptic technique • Instrumentation • Standard operating procedures 	<div>→</div> <ul style="list-style-type: none"> • Biochemical assays • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Business process improvement • ISO standards • ERP applications 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

DS Quality Assurance

QA Department Head


Roles and responsibilities

- Achieves Quality and Business results through partnerships across site
- Creates a high-performance Quality team culture with goals and values aligned with broader organisation, including creation of a collaborative team environment
- Oversees the conduct of Talent Management programs to develop future site leaders, including the creation of robust succession plans for the Site.
- Directs, oversees, and participates in the recruitment, selection, promotion, termination, and performance management of site personnel in leadership and critical roles.
- Issue resolution: Ensures the creation and implementation of clear and timely action plans for issue resolution with appropriate escalation, communication, and closure.
- Regulatory Excellence: Ensures sustainable regulatory excellence through systems, science, people, and continuous process improvements.
- Ensures a favorable site regulatory profile through constant inspection readiness programs
- Creates effective relationships with Regulatory agencies to create trust and credibility.
- Prepares the site for changes to regulations
- Quality Systems: Ensures compliant site Quality Systems and marketing authorisations.
- Quality Plans: Ensures the creation and execution of the Site Quality Master Plan and Site Quality and Compliance annual business plan.
- Industry Standards: Drives understanding of relevant International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards, and other appropriate industry standards across the site organisation.
- Actively follows and anticipates impact of emerging regulations on site operations and prepares site for implementation and change, as appropriate.
- Product Disposition: Ensures independent and timely product disposition using validated processes, analytical methods, and documented decision-making processes.
- Technology and Science: Holds self and others accountable for making decisions, solving problems, or driving improvements through a sound understanding of the technology and science of the products.
- Operational Excellence: Drives innovation and continuous improvement through Operational Excellence (OE) in all Quality activities, and supports OE throughout site

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Product disposition • Aseptic technique • Documentation • Regulatory requirements • Standard operating procedures • Quality indicators • Analytical method development and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP)
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion

QA Manager


Roles and responsibilities

- Managing the Quality Department team that covers all GMP/GDP quality tasks
- Contribute to compliance and quality gap analysis
- Deliver Quality Agreement plan between appropriate internal and external stakeholders and signatories
- Manage quality activities for product transfers to external suppliers from sites according to the project plans.
- Implementing a Quality Management System (QMS) based on company standards and procedures, international and local applicable GMP and Good Distribution Practices (GDP) regulations
- Implement a quality risk management process on the QMS
- Ensure quality systems, processes, specifications, and SOPs are designed to be appropriate for the development, manufacture, testing, timely release, and distribution of quality product, consistent with quality strategy and meeting all relevant regulatory requirements and guidance.
- Ensure products are manufactured in accordance with cGMPs, internal policies/ procedures and applicable regulatory requirements and guidance.
- Report status of quality systems implementation, key quality indicators (KQIs), and quality issues
- Identify and manage Quality and Compliance risks that arise from projects
- Understand and support review of investigations, root cause analysis and review and approval of major/critical deviations, complaints and change controls with process and product impact.
- Ensure business continuity in a changing environment
- Encourage collaboration across the organization to ensure cross-functional input to key decisions and initiatives
- Proactively drive a mindset of continuous improvement of processes, value creation and cost savings without compromising compliance, quality, or customer service across the team
- Build quality awareness across management and ensure that management of other functions fulfil their role regarding quality requirements as defined in the applicable regulations
- Manage quality related aspects of company GMP/ GDP vendors
- Interact with regulatory authorities as it pertains to company's licenses and regulatory activities.
- Support review of regulatory filing information to ensure data integrity and regulatory compliance
- Perform audits of suppliers, contract testing and contract manufacturing organizations, and support health authority inspections.

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Risk analysis • Product disposition • Aseptic technique • Documentation • Maintenance • Regulatory requirements • Standard operating procedures • Quality indicators • Analytical method development and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • ERP applications
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

QA Analyst

Roles and responsibilities

- Responsible for maintenance of cGMPs (current Good Manufacturing Processes) within assigned areas in compliance with company policies and NRA regulations.
- As needed reviews and approves batch records
- Carries out investigations, process qualification and validation studies, and participates in quality audits of the manufacturing areas to ensure compliance to cGMPs
- Support pre-approval inspection and regulatory filing related activities.
- Support sampling requirements, perform material control functions and accountability reviews.
- Makes decisions using cGMP/ process knowledge, and work to resolve problems and meet the needs of Quality and Production.
- Follow site safety requirements
- Author, review, and approve data and documents such as methods, procedures, and protocols.
- Complete assigned projects and tracks/reports metrics.

Minimum years of experience required	4
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Risk analysis • Product disposition • Aseptic technique • Documentation • Maintenance • Regulatory requirements • Standard operating procedures 	<div>→</div> <ul style="list-style-type: none"> • Quality indicators • Analytical method development and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • ERP applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

DP Quality Control

QC Department Head

Roles and responsibilities

- Oversee the management of training, motivation and development of a team of Quality Control professionals
- Lead a Quality Control Team in support of the manufacturing of Drug substance manufactured at the site.
- Lead the design, implementation, maintenance and continuous improvement of the quality control requirements of clinical drug substance manufacture and release.
- Ensure change controls, quality deviations, out of specification results, and quality / business risks associated with area of responsibility are appropriately investigated, reviewed, mitigated and closed out.
- Establish systems and processes within QC and wider analytical platform to ensure that QC procedures, systems, data and documentation follow cGMP, data integrity requirements and regulations.
- Manages activities related to Change Control and CAPAs as required.
- Review or approve data and commentary generated for regulatory submissions as required.
- Ensure that quality control systems and processes are aligned with the rest of the drug substance platform for project development, manufacture and supply.
- Represent Quality Control during internal audits and regulatory inspections.
- Issue Resolution: Ensure clear and timely action plans for issue resolution with appropriate escalation, communication, and closure.
- Stability Testing: Ensure that all marketed product stability testing is completed/reviewed in a timely manner; meets NRA expectations regarding timely notification of events
- Ensure that test methods related to Quality Control are validated and/or verified as per the latest pharmacopoeia or national and/or /international guidelines
- Coordinate the analytical components of Technology Transfer of new Drug Products

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Business process improvement • Analytical method development and validation • Aseptic technique • Chromatography • Mass spectrometry • Biochemical assays • Cell cultures • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Next generation sequencing and multi-omics analysis • Budgeting 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion 		

QC Manager

Roles and responsibilities

- Accountable for ensuring on time delivery of completed test documentation.
- Ensure accuracy and compliance with cGMP.
- Ensure documentation is expedited in a timely manner to facilitate the release of product to market.
- Monitor and track requirements for test approvals to ensure on time release of test results.
- Review and approval of critical reagent qualification and expiry extension reports.
- Responsible for ensuring monthly review of logbooks are completed.
- Responsible for accurately compiling data for tests, products, trending for statistical reports, to support regulatory questions and/or submissions as required, Perform Laboratory Information Management Systems (LIMS) queries as required
- Responsible for organizing and management of documents in accordance with department and corporate policies.
- Reviews existing SOPs and initiate revisions/ approvals of existing or new SOPs, protocols, reports and test summaries as required.
- Manages activities related to Change Control and CAPA, as required.
- Responsible for notifying Department Head of any laboratory non conformances.
- Leads investigations and provides required support documentation to expedite closure of deviations.
- Compile data to support regulatory submissions, audits, and root cause analysis as required.
- Accountable to ensure the timely filing, and completion of all GxP documents associated.
- Support LIMS related test analysis updates.
- Assists with equipment commissioning and decommissioning, qualification and validation.
- Coordinating maintenance and re-certification/recalibration of equipment.
- Managing Laboratory operational expenditure

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Standard operating procedures • Business process improvement • Aseptic technique • Biochemical assays • Cell cultures • Chromatography • Mass spectrometry • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Budgeting • Analytical method development and validation • Next generation sequencing and multi-omics analysis 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

QC Supervisor

Roles and responsibilities

- Effectively coordinate the execution of QC methods
- Conduct technical assessments of deviations and investigations
- Collaborate effectively across all departments to meet key objectives
- Assist in development, implementation, and maintenance of general laboratory operational systems in accordance with cGMP requirements
- Write/ revise SOPs, technical protocols, and reports
- Work with the quality control team to continuously improve the quality, compliance and efficiency of QC operations
- Coordinate accurate compiling of data for tests, products and trending for statistical reports, to support regulatory questions and/or submissions as required, Perform Laboratory Information Management Systems (LIMS) queries as required
- Manages activities related to Change Control and CAPA, as required.
- Responsible for notifying QC Manager/ QC Department Head of any laboratory non- conformities.
- Leads investigations and provides required support documentation to expedite closure of deviations
- Assist in validations and transfers of analytical methods
- Effectively communicate internal issues related to performance, processes, and procedures
- Establish and maintain a safe laboratory working environment
- Accept, complete, and report on special assignments within the agreed upon timeframe
- Act as designee for the Quality Control Manager as appropriate
- Trains other laboratory staff on method execution and troubleshooting
- Provides support to audit teams for internal and vendor audits

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • ISO standards • Safety principles • Business process improvement • Testing • Sampling • Aseptic technique • Chromatography • Mass spectrometry • Biochemical assays • Cell cultures • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Standard operating procedures • Instrumentation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

QC Technician


Roles and responsibilities

- Assure that equipment is operating properly, report and correct malfunctions, and assist others in complex set up/ repair operations.
- Complete a variety of accountability reports, pull samples for identification/ testing, and perform routine product/ process functional tests.
- Ensure adherence to all plant safety rules in the area of responsibility in line with Good Manufacturing Practices for products and processes.
- Maintain area housekeeping standards and environmental specifications by using a variety of sanitizing aids.
- Support implementation of new technology for process execution and/or analysis.
- Maintain current training status on all applicable standard operating procedures.
- Execute Standard Operating Procedures for unit operations
- Participation in notifying QC Manager /QC Department Head of any laboratory non-conformities.
- Participation in investigations and provision of required support documentation to expedite closure of deviations
- Participation in the validation of test methods and equipment used in analysis to meet regulatory requirement
- Implements new technologies/instrumentation in the QC laboratory
- Assist in transfer of analytical methods

Minimum years of experience required	4
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Microbiology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Safety principles • Regulatory requirements • Cell cultures • Maintenance • Testing • Sampling • Chromatography • Mass spectrometry • Aseptic technique • Instrumentation • Standard operating proceduresU 	<hr/> <ul style="list-style-type: none"> • Biochemical assays • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Business process improvement • ISO standards • ERP applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<hr/> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

QC Analyst




Roles and responsibilities

- To test samples utilizing a range of chemical, biochemical and biological tests in accordance with regulatory requirements and agreed schedules.
- To apply knowledge of physiochemical testing to product testing and stability data.
- To test specifications and sampling regimes, and the impact they may have on the product.
- Complete a variety of accountability reports, pull samples for identification/ testing, and perform routine product/ process functional tests.
- Execute various test methods e.g., HPLC, viral load tests, sterility tests etc.
- To work with the QC supervisor/ manager to interpret test results as required.
- Work in a safe manner and in compliance with Safety Codes of Practice and policies.
- To maintain detailed laboratory records in compliance with cGMPs using controlled pro-forma/ laboratory notebooks.
- To ensure that all records and test results are accurately prepared & peer reviewed prior to submission for approval and authorisation according to company, customer and regulatory requirements.
- Record deviations from the normal practice appropriately, report them to the QC Supervisor/ Manager, and develop appropriate CAPAs
- Assist with product investigations and test anomalies.
- Responsible for Quality Management Systems (QMS) records
- Responsible for routine maintenance of laboratory equipment, and ensuring records are adequately maintained.
- Ensure that the department is kept in a safe, clean and orderly fashion and maintained in an inspection ready state.
- To facilitate the ordering of laboratory consumables to ensure efficient running of the laboratory.
- To record incoming samples according to the appropriate SOPs.
- To ensure all samples and materials are handled safely following departmental procedures.
- To participate in the validation of test methods and equipment used in analysis to meet regulatory requirement
- Implements new technologies/ instrumentation in the QC laboratory

Minimum years of experience required	1
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Biochemistry, Medicine, Biotechnology, Pharmacy, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Safety principles • Regulatory requirements • Cell cultures • Maintenance • Testing • Sampling • Chromatography • Mass spectrometry • Aseptic technique • Instrumentation • Standard operating procedures 	 <ul style="list-style-type: none"> • Biochemical assays • Analytical method development and validation • Next generation sequencing and multi-omics analysis • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Business process improvement • ISO standards • ERP applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

DP Quality Assurance

QA Department Head

Roles and responsibilities

- Oversee the management of training, motivation and development of a team of Quality Control professionals
- Lead a Quality Control Team in support of the manufacturing of Drug substance manufactured at the site.
- Lead the design, implementation, maintenance and continuous improvement of the quality control requirements of clinical drug substance manufacture and release.
- Ensure change controls, quality deviations, out of specification results, and quality / business risks associated with area of responsibility are appropriately investigated, reviewed, mitigated and closed out.
- Establish systems and processes within QC and wider analytical platform to ensure that QC procedures, systems, data and documentation follow cGMP, data integrity requirements and regulations.
- Manages activities related to Change Control and CAPAs as required.
- Review or approve data and commentary generated for regulatory submissions as required.
- Ensure that quality control systems and processes are aligned with the rest of the drug substance platform for project development, manufacture and supply.
- Represent Quality Control during internal audits and regulatory inspections.
- Issue Resolution: Ensure clear and timely action plans for issue resolution with appropriate escalation, communication, and closure.
- Stability Testing: Ensure that all marketed product stability testing is completed/reviewed in a timely manner; meets NRA expectations regarding timely notification of events
- Ensure that test methods related to Quality Control are validated and/or verified as per the latest pharmacopoeia or national and/or /international guidelines
- Coordinate the analytical components of Technology Transfer of new Drug Products

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	← Capabilities of previous competency level(s) included →		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Product disposition • Aseptic technique • Documentation • Regulatory requirements • Standard operating procedures • Quality indicators • Analytical method development and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP)
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion

QA Manager

Roles and responsibilities

- Managing the Quality Department team that covers all GMP/GDP quality tasks
- Contribute to compliance and quality gap analysis
- Negotiation of Quality Agreement plan
- Deliver Quality Agreement plan between appropriate internal and external stakeholders and signatories
- Manage quality activities for product transfers to external suppliers from sites according to the project plans.
- Implementing a Quality Management System (QMS) based on company standards and procedures, international and local applicable GMP and Good Distribution Practices (GDP) regulations
- Implement a quality risk management process on the QMS
- Ensure quality systems, processes, specifications, and SOPs are designed to be appropriate for the development, manufacture, testing, timely release, and distribution of quality product, consistent with quality strategy and meeting all relevant regulatory requirements and guidance.
- Ensure products are manufactured in accordance with cGMPs, internal policies/ procedures and applicable regulatory requirements and guidance.
- Report status of quality systems implementation, key quality indicators (KQIs), and quality issues
- Identify and manage Quality and Compliance risks that arise from projects
- Understand and support review of investigations, root cause analysis and review and approval of major/critical deviations, complaints and change controls with process and product impact.
- Ensure business continuity in a changing environment
- Encourage collaboration across the organisation to ensure cross-functional input to key decisions and initiatives
- Proactively drive a mindset of continuous improvement of processes, value creation and cost savings without compromising compliance, quality, or customer service across the team
- Build quality awareness across management and ensure that management of other functions fulfil their role regarding quality requirements as defined in the applicable regulations
- Manage quality related aspects of company GMP/ GDP vendors
- Interact with regulatory authorities as it pertains to company's licenses and regulatory activities.
- Support review of regulatory filing information to ensure data integrity and regulatory compliance
- Perform audits of suppliers, contract testing and contract manufacturing organisations, and support health authority inspections.
- Ensure the Vendor management Program is maintained and managed
- Ensure that a Validation master plan is in place and managed
- Participate in the design and implementation of Aseptic Process simulation (Media Fill)
- Participate in the implementation of the Site Contamination control Strategy

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Risk analysis • Product disposition • Aseptic technique • Documentation • Document maintenance • Regulatory requirements • Standard operating procedures • Quality indicators • Analytical method dlpt and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • ERP applications
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

QA Analyst

Roles and responsibilities

- Responsible for maintenance of cGMPs (current Good Manufacturing Processes) within assigned areas in compliance with company policies and NRA regulations.
- Ensuring cGMPs are utilized for all batch/ facility cleaning documentation, change control and day-to-day operations for a bulk sterile/ aseptic process.
- As needed reviews and approves batch records,
- Carries out investigations, process qualification and validation studies, and participates in quality audits of the manufacturing areas/ service providers to ensure compliance to cGMPs
- Support pre-approval inspection and regulatory filing related activities.
- Support sampling requirements, perform material control functions and accountability reviews.
- Makes decisions using cGMP/ process knowledge, and work to resolve problems and meet the needs of Quality and Production.
- Follow site safety requirements.
- Author, review, and approve data and documents such as methods, procedures, and protocols.
- Complete assigned projects and tracks/ report metrics.
- Reviews and approves Minor deviations, Change controls and CAPAs
- Perform statistical analysis and scientific report writing as needed
- Participate in Quality Continuous improvement activities

Minimum years of experience required	4
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Chemical Engineering, Medicine, Pharmacy, Biotechnology, Microbiology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Quality auditing • Inspections • Risk analysis • Product disposition • Aseptic technique • Documentation • Document maintenance • Regulatory requirements • Standard operating procedures 	<div>→</div> <ul style="list-style-type: none"> • Quality indicators • Analytical method development and validation • Business process improvement • Process monitoring • Process validation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • ERP applications 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Cross-functional QA

QA IT Compliance Manager

Roles and responsibilities

- Application support and maintenance activities for the QMS, including user access, system troubleshooting, end-user process support, and change control
- Troubleshoot interface issues with QMS, ERP, and other Quality IT tools/ systems
- Participate in ongoing technical training for the development of skills with emphasis on compliance and QMS platform.
- Computer System Validation:
- Take an active project role, working with business resources, to develop needed capabilities using QMS
- Develop validation documentation and drive validation activities to completion. This may include writing documentation, protocol development, test execution and event resolution, communication, SOPs and Training.
- Execution support for changes to existing applications
- Creation and delivery of QMS training
- Provide guidance and oversight for global computerized systems in terms of governance, validation, quality review or other activities.
- Provide site and regional support for metrics through QMS and other quality IT tools

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Information Technology, Software Engineering, Computer Science, Computer Engineering, Business Management, Life Sciences

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Quality Management • Quality Management Systems • Regulatory requirements • Standard operating procedures • Documentation • ERP applications • Business software • Change control • Computer security • Automation • Configuration management • Electronic filing systems • Data integrity 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

QA Documentation Specialist

Roles and responsibilities

- Responsible for the organisation of cGXP controlled documents in Document Archives and electronic filing systems to ensure that records are readily retrievable.
- Issue production batch records to support manufacturing operations.
- Provide support for implementation of upgrades or new QMS platforms.
- Maintain KPIs for QMS pertaining to Document Control.
- Work with authors to coach them on generation of ALCOA compliant documents
- Maintain audit readiness for document control
- Provides support for corporate and regulatory audits.
- Reviews SOPs, determines gaps and provides input to as it relates to documentation management.
- Write and revise internal procedures to provide closure to process gaps and/or as part of continuous improvement projects.
- Understands electronic documentation and/or database system processes and communicates systems discrepancies that may arise, including providing suggestions to management to help rectify or improve the systems

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Biological sciences, Chemistry, Pharmacy, Biotechnology, Technical services, Humanities

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • Documentation • Document maintenance • Electronic filing systems • Regulatory requirements • Quality Management • Quality Management Systems • Data integrity • Quality auditing • Business process improvement • Good manufacturing practices (GMP) • Good laboratory practices (GLP) • Standard operating procedures • ERP applications 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<ul style="list-style-type: none"> • Stakeholder management • Persuasion 	→

IT System Administrator

Roles and responsibilities

- Create, edit, and manage policies and procedures related to the administration of assigned systems
- Ensure system documentation is maintained to be accurate and in compliance with company policies and cGMP requirements
- Develop and implement systems diagnostics and maintenance tools to ensure the availability and functionality of systems required to support organisational objectives
- Manage the installation of software and hardware, systems fixing, updates and enhancement, and account administration.
- Optimize the functionality of networks and systems, including diagnosing and recovering failed systems.
- Participate in cyber security related initiatives as directed including backups testing and Disaster Recovery planning and testing.
- Act as single point of contact for staff requesting additions and changes to the system or data retrieved from the system.
- Coordinate, create and retain all submittal requests associated with the system.
- Develop and implement alarm management program for all alarms defined in the system.
- Assist in developing master plan for assigned system.
- Directs the work activities and priorities of supporting vendors, directly or through the designated vendor contract manager as required.
- Audit vendors supporting field maintenance of the system.
- Coordinate and approve engineering changes done on existing and new site systems

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Process automation • Automation systems • Scripting • Systems security • Account access management • Hardware management • Systems maintenance 	<div>→</div> <ul style="list-style-type: none"> • Change control • Cloud computing 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Automation

DS Automation

Automation Manager


Roles and responsibilities

- Develop and implement a technology roadmap for Automation of manufacturing processes and supporting systems to improve safety, compliance, efficiency, and reliability.
- Identify vendor platforms that can scale across manufacturing and lab sites with flexible configurations of instrumentation that can be changed to suit different process needs i.e., modular & adaptable
- Develop solutions to improve operational workflow and reduce manual repetitive tasks e.g., MES/ eForms
- Lead gathering of project information during definition and setup stage of strategic projects, and partner with product management to build project business cases.
- Lead end-to-end Robotics Process Automation & AI efforts to deliver projects within the developed budget
- Track project revenue and non-revenue metrics compared to plan, and proactively escalate/ update sponsor as needed.
- Facilitate effective team dynamic between project stakeholders and contributors.
- Effectively manage timely identification of execution issues and roadblocks and facilitate their resolution.
- Partner with QA, Operations, and MSAT teams to develop and execute validation protocols that deliver the intended compliance.
- Design an Automation Asset Management Strategy to ensure business continuity and to reduce the total cost of ownership.
- Design, implement, modify, and improve asset maintenance plans based on failure modes, mean time between failures (MTBF), data analysis, throughput, condition monitoring, and statistics to improve processes to reduce and/ or eliminate equipment and process failures.
- Work closely with project sponsors to execute assigned strategic projects.

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Computer Science, Electrical Engineering, Chemical Engineering, Mechanical Engineering, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Process automation • Technology roadmaps • Automation systems • Scripting • Systems maintenance • Systems security • Data analysis • Statistics • Troubleshooting • Process monitoring • Business process improvement • Control Systems • Change control • Regulatory requirements
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Automation Engineer

Roles and responsibilities

- Understand and support all GMPs, safety, and environmental regulations
- System upgrades, troubleshooting issues, identifying trends, process monitoring, system administration, documentation updates, data querying, operator training and participating in deviation investigations.
- Ensure automation documents are in an inspection-ready state
- Perform preventive maintenance and periodic reviews
- Support process automation inquiries during internal and external audits/ inspections and must, therefore, be able to speak knowledgeably about automation, process and cGMP details of the manufacturing operations
- Evaluate automated and information technology systems and develop strategies to optimize and ensure the quality and stability of automation systems through future expansion, replacement, or upgrade
- Use their technical knowledge to assure the efficient operation of a variety of automated processing, information technology systems and regulatory compliance
- Develop solutions for automation problems
- Participate and contribute to investigations of automation anomalies to prevent a recurrence, which includes on-the-floor support of manufacturing activities
- Develop technical requirements, keeping in mind the associated technology needs, benefits, and risks
- Develop control strategies and applying computerized tools that will deliver tangible improvements to overall production unit performance
- Communicate daily with the business, technical, and quality representatives within the area of support through the tier process
- Familiar with lean manufacturing principles with an ability to convert business logic and requirements into detailed system requirements

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, Electrical Engineering, Chemical Engineering, Mechanical Engineering, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Process automation • Technology roadmaps • Automation systems • Scripting • Systems maintenance • Systems security • Data analysis • Statistics • Troubleshooting • Process monitoring • Business process improvement • Control Systems • Change control • Regulatory requirements 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Persuasion

IT System Administrator

Roles and responsibilities

- Create, edit, and manage policies and procedures related to the administration of assigned systems
- Ensure system documentation is maintained to be accurate and in compliance with company policies and cGMP requirements
- Develop and implement systems diagnostics and maintenance tools to ensure the availability and functionality of systems required to support organisational objectives
- Manage the installation of software and hardware, systems fixing, updates and enhancement, and account administration.
- Optimize the functionality of networks and systems, including diagnosing and recovering failed systems.
- Participate in cyber security related initiatives as directed including backups testing and Disaster Recovery planning and testing.
- Act as single point of contact for staff requesting additions and changes to the system or data retrieved from the system.
- Coordinate, create and retain all submittal requests associated with the system.
- Develop and implement alarm management program for all alarms defined in the system.
- Assist in developing master plan for assigned system.
- Directs the work activities and priorities of supporting vendors, directly or through the designated vendor contract manager as required.
- Audit vendors supporting field maintenance of the system.
- Coordinate and approve engineering changes done on existing and new site systems

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Process automation • Automation systems • Scripting • Systems security • Account access management • Hardware management • Systems maintenance 	<div>→</div> <ul style="list-style-type: none"> • Change control • Cloud computing 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

DP Automation

Automation Manager

Roles and responsibilities

- Develop, implement and monitor a technology roadmap for Automation of manufacturing processes and supporting systems to improve safety, compliance, efficiency, and reliability.
- Identify vendor platforms that can scale across manufacturing and lab sites with flexible configurations of instrumentation that can be changed to suit different process needs i.e., modular & adaptable
- Develop solutions to improve operational workflow and reduce manual repetitive tasks e.g., MES/ eForms
- Lead gathering of project information during definition and setup stage of strategic projects, and partner with product management to build project business cases.
- Lead end-to-end Robotics Process Automation & AI efforts to deliver projects within the developed budget
- Track project revenue and non-revenue metrics compared to plan, and proactively escalate/ update sponsor as needed.
- Facilitate effective team dynamic between project stakeholders and contributors.
- Effectively manage timely identification of execution issues and roadblocks and facilitate their resolution.
- Partner with QA, Operations, and MSAT teams to develop and execute validation protocols that deliver the intended compliance.
- Design an Automation Asset Management Strategy to ensure business continuity and to reduce the total cost of ownership.
- Design, implement, modify, and improve asset maintenance plans based on failure modes, mean time between failures (MTBF), data analysis, throughput, condition monitoring, and statistics to improve processes to reduce and/ or eliminate equipment and process failures.
- Work closely with project sponsors to execute assigned strategic projects.

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Computer Science, Electrical Engineering, Chemical Engineering, Mechanical Engineering, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Process automation • Technology roadmaps • Automation systems • Scripting • Systems maintenance • Systems security • Data analysis • Statistics • Troubleshooting • Process monitoring • Business process improvement • Control Systems • Change control • Regulatory requirements 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Automation Engineer

Roles and responsibilities

- Understand and support all GMPs, safety, and environmental regulations
- System upgrades, troubleshooting issues, identifying trends, process monitoring, system administration, documentation updates, data querying, operator training and participating in deviation investigations.
- Ensure automation documents are in an inspection-ready state
- Perform preventive maintenance and periodic reviews
- Support process automation inquiries during internal and external audits/ inspections and must, therefore, be able to speak knowledgeably about automation, process and cGMP details of the manufacturing operations
- Evaluate automated and information technology systems and develop strategies to optimize and ensure the quality and stability of automation systems through future expansion, replacement, or upgrade
- Use their technical knowledge to assure the efficient operation of a variety of automated processing and information technology systems
- Develop solutions for automation problems
- Participate and contribute to investigations of automation anomalies to prevent a recurrence, which includes on-the-floor support of manufacturing activities
- Develop technical requirements, keeping in mind the associated technology needs, benefits, and risks
- Develop control strategies and applying computerized tools that will deliver tangible improvements to overall production unit performance
- Communicate daily with the business, technical, and quality representatives within the area of support through the tier process
- Familiar with lean manufacturing principles with an ability to convert business logic and requirements into detailed system requirements

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, Electrical Engineering, Chemical Engineering, Mechanical Engineering, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Process automation • Technology roadmaps • Automation systems • Scripting • Systems maintenance • Systems security • Data analysis • Statistics • Troubleshooting • Process monitoring • Business process improvement • Control Systems • Change control • Regulatory requirements 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Stakeholder management • Persuasion

Regulatory Affairs

Regulatory Operations

Director, Regulatory Affairs

Roles and responsibilities

- Oversee a team of Regulatory Affairs professionals in preparation and publishing of submission documents, as well as labelling
- Develop and implement a regulatory strategy that will deliver the needs of the relevant region, while taking in to account the needs of other regions globally.
- Oversee regulatory audits
- Provide strategic regulatory input for all development stages of the product within a given product portfolio to key stakeholders.
- Lead regulatory interactions and the review processes in markets in which company is present i.e., be the point of contact to the National Regulatory Agencies (NRAs) for all assets
- Advocate scientifically sound approaches persuasively to senior leaders at company and to National Regulatory Agencies (NRAs)
- Ensure appropriate interaction with commercial teams
- Manage and lead multiple teams across Regulatory Affairs function
- Oversee the development of staff competencies and the identification and addressing of skill gaps
- Oversee compliance with relevant regulatory requirements at all stages of product life cycle.
- Oversee preparation for governance meetings, adequately representing Regulatory Affairs function and clearly outlining its progress, opportunities for improvement and help needed from broader organisation
- Have complete oversight of the manufacturing and distribution of medicines, scheduled substances in terms of the provisions of the Medical Regulations
- Build a positive external reputation for the Regulatory Affairs function by overseeing research published in high-tier journals and representing the function at scientific events
- Oversee the development of Regulatory Affairs preparation budgets
- Oversee adherence to Regulatory Affairs budgets

Minimum years of experience required	10
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Regulatory requirements • Risk management • Project management • Database management • Quality management • Document Management • Electronic Common Technical Documents (eCTD) • Submission publishing • Submission preparation • Compliance databases • Product lifecycle management • Budgeting • Labelling 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Manager, Regulatory Operations


Roles and responsibilities

- Lead the Regulatory Operations team to deliver on project milestones related to submission publishing for company's regulatory applications
- Manage the development of the electronic systems, and associated processes used by Regulatory Affairs
- Plans and manages detailed publishing timelines; provides reporting on publishing status to key stakeholders.
- Proactively escalates publishing concerns, risks, and issues that may delay/ impact submissions and presents risk mitigation for publishing strategy.
- Shape the electronic submission regulatory environment by providing input on emerging local regulations and policies
- Use process improvement tools and approaches to support Regulatory Operations effectiveness and delivery.
- Determine and author appropriate process documentation and ensure appropriate monitoring and reporting are in place
- Manage revisions and updates of regulatory work for ongoing products to meet evolving regulatory requirements, such as changes in labelling, safety information, manufacturing processes, or post-marketing surveillance, to continue their presence in the market across different geographies
- Participate in the development or implementation of clinical trial protocols
- Lead the Regulatory Operations team and provide training, coaching and mentoring including line and performance management
- Manage and ensure staff competencies are developed and skill gaps are identified and addressed
- Keeps abreast of regulatory agency submission, publishing, and validation standards to ensure compliant and valid dossiers in operating markets
- Oversees performance of regulatory activities in accordance with Good Regulatory Practices (GRP)
- Collaborates with other cross functional leads (e.g., Clinical Operations, Commercial, CMC) to develop strategies to mitigate risks to timelines and other issues
- Lead interface between the local Regulatory team and third-party submission publishing vendors
- Lead development of Regulatory Operations budgets and syndicate with Regulatory Affairs leadership
- Manage adherence to Regulatory Operations budgets

Minimum years of experience required	7
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Regulatory requirements • Database management • Quality management • Vendor management • Document Management • Electronic Common Technical Documents (eCTD) • Submission publishing • Submission preparation • Compliance databases • Product lifecycle management • Labelling • Project management • Risk management • Budgeting
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation

Regulatory Affairs Specialist

Roles and responsibilities

- Ensure timely submission and approval of all licensing applications in compliance with local and global regulatory requirements
- Ensure timely delivery of clinical trial approvals and maintenance of high regulatory compliance standards achieved through provision of local regulatory expertise.
- Prepare high quality regulatory applications and regulatory responses
- Provide regulatory input to stock and supply issues
- Conduct revisions and updates of regulatory work for ongoing products to meet evolving regulatory requirements, such as changes in labelling, safety information, manufacturing processes, or post-marketing surveillance, to continue their presence in the market across different geographies
- Ensure regulatory compliance for defined product and project responsibilities.
- Assure appropriate standards and policies are maintained for all technical aspects of the company's regulatory activities
- Liaise with labelling function to manage pack changes and ensure labelling compliance
- Proactively manage the regulatory process and effectively negotiate with regulatory agencies to provide rapid regulatory approvals with competitive labelling
- Develop professional working relationships with assessors and administrative staff within the regulatory agencies
- Support the delivery of commercial objectives, including representing Regulatory Affairs on appropriate cross-functional teams
- Maintain and establish relationships with the Regulatory units and/or other Health Authorities to ensure more effective streamlining of the company's applications when required

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> Regulatory requirements Risk management Document Management Electronic Common Technical Documents (eCTD) Submission publishing Submission preparation Product lifecycle management Labelling 	<div>→</div> <ul style="list-style-type: none"> Project management Database management Quality management Vendor management Compliance databases 		
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Attention to detail Teamwork Problem solving Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> Decision making Negotiation Presentation Coaching and mentoring 		

Medical writer

Roles and responsibilities

- Contribute to the planning, authoring, review, and approval of clinical/ regulatory documents for medical writing projects to achieve a successful outcome within the required timelines e.g., contribution to documents and activities included in registration files, authoring clinical documents supporting studies following defined templates etc.
- Ensure the consistency and quality level of all documents that are issued.
- Advise on methods for achieving accelerated timelines, including review tools and automation.
- Actively participate in all aspects of document development planning, coordination and review meetings to integrate and address stakeholder comments.
- Effectively contribute to process improvement activities in the Regulatory Operations subfunction
- Actively contribute to development of training materials for clinical document preparation; provide mentoring and/ or training on clinical documentation and submission planning to individuals or teams
- Ensure compliance of clinical/ regulatory documents with SOPs, company policies and local and global regulatory requirements
- Collaborate closely with the submission team to provide input to submission plan, timelines, document content and dependencies

Minimum years of experience required	2
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Medical writing • Editing • Regulatory requirements • Risk management • Document Management • Electronic Common Technical Documents (eCTD) 	<ul style="list-style-type: none"> • Project management • Quality management • Database management 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Negotiation • Presentation • Coaching and mentoring 		

Submission Preparation

Submission Manager, Regulatory Affairs

Roles and responsibilities

- Lead a team of submission associates in identification, planning, and execution of regulatory and safety submissions
- Utilize in-depth knowledge of regulatory submission requirements, processes and procedures, eCTD structure/ format, associated systems and planning software to ensure teams meet aggressive target submission dates by proactively focusing on critical path analysis, hand offs, scenarios, and reducing "rework" to avoid costly time delays
- Lead submission planning discussions, ensuring team is aware of upcoming deliverables, aligned on roles and responsibilities, and understands the interdependencies between submission activities and components
- Identify, assess, and actively resolve or escalate, where necessary, any risks or issues that could impact the successful execution of submissions
- Provide various visuals, reports, scorecards, etc, to facilitate awareness of key milestones, closely monitors critical path activities, and ensures transparency of submission status to stakeholders
- Ensure project data, including information used to maintain compliance and aid with submission planning, is accurately reported in databases
- For assigned products, works closely with the Regulatory Affairs Director to assess the overall program, and manage the sequencing of submissions as needed
- Actively lead and/or participate in continuous improvement activities in submission preparation including business processes, tools, systems, metrics, and analytics
- Be responsible for understanding, adhering to, and advising others on Regulatory Authority regulations and guidance associated with electronic submissions, which differs across regions and Regulatory Authorities
- Lead the Submissions Preparation team and provide training, coaching and mentoring including line and performance management
- Manage and ensure staff competencies are developed and skill gaps are identified and addressed
- Keeps abreast of regulatory agency submission, publishing, and validation standards to ensure compliant and valid dossiers in operating markets
- Oversees performance of submission preparation activities in accordance with Good Regulatory Practices (GRP)
- Participate in discussions/ meetings with Regulatory Authorities, as required, to develop and communicate submission strategies for applications
- Collaborate and support third-party vendors as needed to support submission efficiency and overall success
- Lead development of Submission preparation budgets and syndicate with Regulatory Affairs leadership
- Manage adherence to Submission preparation budgets

Minimum years of experience required	6
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	← Capabilities of previous competency level(s) included →		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Regulatory requirements • Database management • Quality management • Document Management • Electronic Common Technical Documents (eCTD) • Submission publishing • Submission preparation • Project management • Risk management • Budgeting
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation

Submission Associate, Regulatory Affairs

Roles and responsibilities

- Support achievement of Regulatory Affairs plans and delivery, utilizing content re-use strategies and applying technical expertise
- Develop submission structure strategies in accordance with Health Authority and ICH regulations, guidelines, and specifications
- Prepare and compile regional submission documentation to regulatory health authorities according to ICH / eCTD formats and regulatory authority and company standards
- Perform quality control checks for submission publishing, understanding, and addressing validation criteria in detail
- Identify and raise submission technical issues in timely manner to ensure that resolutions are realized, enabled and executed to deliver according to planned submission filing dates
- Assist in improvement efforts of publishing processes and contribute to review and updates of quality documents
- Maintain knowledge of regulatory requirements for document and submission assembly and publishing across various submission regions on a continuous basis
- Ensure end-to-end process adherence for routine compliance submissions in accordance with company and regulatory authority standards
- Collaborate and support third-party vendors as needed to support submission efficiency and overall success
- Maintenance and monitoring of existing registration dossiers (amendments and updates) including timely responses to resolutions

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> Regulatory requirements Document Management Electronic Common Technical Documents (eCTD) Submission publishing Submission preparation Risk management 	<ul style="list-style-type: none"> Project management Database management Quality management 		
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Attention to detail Teamwork Problem solving Interpersonal skills 	<ul style="list-style-type: none"> Decision making Negotiation Presentation Coaching and mentoring 		

Policy and Labelling

Manager, Labelling

Roles and responsibilities

- Lead the development and execution of the labelling strategy, in line with overall regulatory strategy for the product.
- Lead the Labelling Team in preparation and maintenance of high-quality Core Prescribing Information, and Instructions For Use (IFUs) to communicate to senior leaders for approval to achieve advantageous labelling.
- Lead the development of the Organisation's Core Datasheet for new medicines or product line extensions, including ensuring its implementation in local prescribing/ patient information.
- Respond to regulatory questions on prescribing/ patient information from Regulatory Authorities.
- Contribute to the development of labelling negotiation strategies, anticipating health authority perspectives.
- Management of Regulatory Affairs Labelling data in appropriate systems and databases (e.g., Veeva Vault)
- Develop labelling policies, procedures and SOPs.
- Evaluate, interpret, and communicate global regulations and trends on labelling, including the business impact that they have on product labelling.
- Lead the Policy and Labelling team and provide training, coaching and mentoring including line and performance management
- Manage and ensure staff competencies are developed and skill gaps are identified and addressed
- Ensure all work is performed in accordance with established procedures, regulatory requirements, and Good Practices (GxPs).
- Provide regulatory labelling expertise to the Regulatory Operations and Submission Preparation teams.
- Provide guidance regarding applicable labelling requirements and expectations to relevant stakeholders (e.g., Clinical Operations, CMC, Commercial) and proposing mitigations.
- Lead development of CMC Regulatory budgets and syndicate with Regulatory Affairs leadership
- Manage adherence to CMC Regulatory budgets

Minimum years of experience required	7
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Labelling • Product Information • Regulatory requirements • Database management • Quality management • Vendor management • Document Management • Document Management Systems • Submission preparation • Project management • Risk management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Specialist, Regulatory Affairs Labelling

Roles and responsibilities

- Author and compile Regional/ Country Product Information (PI) as per regulatory authority labelling requirements and company processes and standards.
- Author and compile market-specific supporting documentation for labelling submissions in accordance with regulatory authority requirements company processes and standards.
- Ensure that the labelling documents submitted to the Regulatory Authorities are of the highest quality
- Efficiently coordinate and manage labelling documentation and data in regulatory systems.
- Contribute to the implementation of changes to labelling processes and evaluate new regulatory authority labelling requirements.
- Be a subject-matter-expert in country/ regional labelling content and processes
- Perform work in accordance with established procedures, regulatory requirements, and Good Practices (GxPs).
- Communicate with Regulatory Agencies and third parties on behalf of Regulatory Affairs Labelling staff.
- Provide advice regarding regulatory authority labelling requirements company labelling processes and standards to the rest of the Regulatory Affairs function

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • Labelling • Product Information • Regulatory requirements • Database management • Quality management • Vendor management • Document Management • Document Management Systems • Submission preparation • Project management • Risk management 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Negotiation • Presentation • Coaching and mentoring 		

Supply Chain

Procurement

Procurement Manager

Roles and responsibilities

- Develop and propose long and short-term plans to create a robust supplier base to enhance the overall performance of the site
- Lead implementation of procurement processes, policies, guidelines & strategies, and ensure compliance
- Manage interfaces between procurement and the site, balancing the expectations of both procurement and site stakeholders
- Understand different perspectives and satisfy the needs and expectations of all stakeholders, both within procurement and the site
- Develop robust procurement strategies for local categories of spend that clearly meet business requirements
- Ensure appropriate sourcing strategies are agreed and implemented
- Ensure delivery of site objectives related to third parties
- Adapt and respond to regularly changing business requirements
- Manage the development of a long-term vision for all purchasing categories to support company growth, including ensuring approval of this long-term vision by key stakeholders
- For specific categories, actively develop, negotiate, and maintain contracts
- Reduce the Manufacturing Indirect and CAPEX costs of the site; support the reduction of end-to-end total costs of the Site
- Influence the balance sheet of the site through development and robust implementation of best procurement practices
- Co-ordinate support from multiple category teams and working within a matrix organisation
- Evaluate and mitigate risk associated with long standing suppliers and single sourcing
- Ensure that daily procurement needs and transactional activities are executed in line with company policies and SOPs
- Identify opportunities for material cost savings, testing efficiencies, meeting/ exceeding inventory reduction goals
- Support sourcing new raw materials required for new projects, products and other departments consistent with organisations sourcing strategy
- Negotiate contracts that meet business objectives

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Contract Law, Business Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Sourcing • Quotation analysis • Contract negotiation • Supplier review • Supplier development • Contracting • Cost benchmarking • Financial acumen • Business process improvement • Risk management • Vendor management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Buyer

Roles and responsibilities

- Ensure that all orders are accurately processed in a timely manner for all assigned company functions according to company policies and SOPs
- Assist in authoring and review of work instructions and SOPs to deliver a standardized level of support
- Resolve any missing Purchase Order (PO) numbers and follow up on any back orders.
- Closely monitor all invoices and accompanying processes within the agreed time frame i.e., invoice discrepancies, credit note processing, process documents, goods receipting & approval, rejection, and coding of invoices.
- Responsibility to challenge cost savings/ cost avoidance from materials planning team, and obtain bulk quotes to maximize savings, pricing & stock availability.
- Capture cost savings and cost avoidance to align with strategic sourcing and account savings initiatives
- Continuous improvement of the purchasing ways of working
- Ensure users are kept informed of progression & status of their orders.
- Use agreed procurement systems to process orders.
- Single point of contact for all purchasing enquiries.
- Provide relevant Key Performance Indicators (KPIs) to the management team on the procurement services provided to the company functions.
- Comply with all site Health & Safety regulations.
- Provide supplier with rolling 12-18 month forecast of requirements.
- Work through defective material process with supplier (returns, documentation of defect, & credits)
- Maintain ERP Vendor Master and material pricing

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Contract Law, Business Management

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • Sourcing • Quotation analysis • Contract negotiation • Supplier review • Supplier development • Contracting • Cost benchmarking • Financial acumen • Business process improvement • Risk management • Vendor management 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Negotiation • Presentation • Coaching and mentoring • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 		

Materials Planning

Manager, Materials planning

Roles and responsibilities

- Lead material planning for raw materials, chemicals, single-use components, manufacturing supplies, QC materials, etc. to support continuous production at facility.
- Focus on all aspects of inventory management and optimisation, including reconciliation, scrap/obsolescence provisions (for finance), budgeting, warehouse storage requirements, excess & obsolete analysis, and disposition.
- Establish schedules and materials status across the supply chain. Inform key stakeholders of status, issues, problems, and proposed solutions. Ensure procurement of required materials.
- Participate in inventory review meetings with production, finance, and logistics. Prepare all inventory and supply planning reports accurately reflecting the flow of materials and ensuring lot traceability. Support the sales and operations planning process (S&OP).
- Calculate and maintain safety stock targets to support the inventory plan. Make recommendations for inventory target adjustments based on changes in demand, market trends or supply variability.
- Execute materials planning strategy and work with procurement manager place purchase orders.
- Foster effective cross-functional teamwork and drive plan execution. Proactively track critical path activities, anticipate risks, and support creating contingency plans to ensure uninterrupted production and on-time delivery.
- Support placement of orders for raw materials, components and equipment necessary for manufacturing
- Provide report of organisation's schedule compliance. Provide potential backorder risks based on changes in finished product and raw material consumption rates

Minimum years of experience required	7
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Supply Chain Management • Inventory management • Materials planning • Materials forecasting • Financial acumen • Business process improvement • Record keeping • ERP applications • Risk management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Materials planner

Roles and responsibilities

- Ensure all materials procurement activities carried out comply to relevant site GMP, EHS guidelines and policies, and relevant legal requirements
- Continuous improvement
- Develop and manage materials supply plans based on customer demand.
- Create and manage measurement systems to track adoption/ progress, utilisation, and proficiency of key business value drivers
- Materials forecasting, including sending annual rolling forecast to suppliers
- Generate full year order for priority materials, agree on supply dates & monitor delivery dates depending on fluctuating demand.
- Facilitate timely and accurate reporting e.g., Deficit Reports, Materials planning detail reports, Local Packaging Reports
- Re-align supply to the fluctuating demand upon confirmation of deliveries by warehouse technicians
- Review of parameters for ordering materials
- Support Inventory optimisation.
- Manage potential risks associated with materials depletion
- Support Inventory and cost reduction Initiatives
- Operate spend control towers to reduce procurement spend
- Work with the site project teams to manage supply risks associated with proposed product, equipment, systems and/ or facility changes
- Ensure audit readiness in all Logistics and supply and interlinked operations
- Create/ change/ delete - Maintain ERP system master data such as material/item master

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • Supply Chain Management • Inventory management • Materials planning • Materials forecasting • Financial acumen • Business process improvement • Record keeping • ERP applications • Risk management 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Negotiation • Presentation • Coaching and mentoring 		

Stock Controller




Roles and responsibilities

- Forecast materials demand to prevent overstocking and stock-outs
- Place orders to replenish raw materials, components, and equipment necessary for manufacturing
- Track shipments and address any delays
- Oversee storage of products, particularly of fragile items
- Coordinate regular inventory audits
- Keep updated inventory records
- Ensure purchases do not exceed budget
- Conduct cycle counts and root cause analysis for discrepancies and implement process improvements

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Supply Chain Management • Inventory management • Materials planning • Financial acumen • Record keeping • Risk management • ERP applications 	 <ul style="list-style-type: none"> • Business process improvement • Materials forecasting 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Negotiation • Presentation • Coaching and mentoring 	

Logistics

Manager, Logistics

Roles and responsibilities

- Managing the warehouse team effectively and delivering both internal orders, and customer orders coming from the sales department to maintain high customer satisfaction level
- Ensures the execution and continuous improvement of standard logistics processes, such as replenishment, data interchange, demand management, electronic data systems administration, and related functions
- Management of order processing and on-time-in-full delivery through distributors
- Execute inventory write-offs and physical material dispositioning
- Management of inbound shipments and importation process through Import Control Tower
- Drive management systems and continuously improve performance levels in line with established objectives
- Effectively and proactively communicate information regarding demand and supply issues, root causes, impacts, and aligned action plans to management and Business Unit stakeholders
- Management of P&L and savings
- Oversight of Third-Party Logistics Services Providers and their performance management
- Risk management
- Management of safety, quality, and compliance related to logistics processes
- Work with other company functions and external parties to deliver services
- Foster continuous improvement i.e., portfolio/ inventory optimisation, cost efficiency, waste reduction"
- Risk management: Identification and escalation of potential supply risks with potential corrective actions
- Management of safety, quality, and compliance: Oversight of team's adherence to all safety, quality and compliance policies
- Work with Procurement Manager to negotiate shipping lanes
- Presentation of team's performance in accordance with established metrics and goals

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Supply Chain Management • Inventory management • Materials planning • ERP applications • Warehouse management systems • Warehouse equipment • Financial acumen • Risk management • Business process improvement • Record keeping • Vendor management • Six sigma methodologies • Regulatory requirements 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Supervisor, Logistics

Roles and responsibilities

- Accountable to ensure delivery of material and supplies in compliance with regulatory expectations and with consistency for projects.
- Managing the day-to-day business of order assembly, fulfillment, picking and packaging operations at the warehouse.
- Managing and training a team of warehouse technicians in all associated tasks related to order assembly.
- Working with business units and customer service as necessary to ensure effective and efficient flow of outbound shipments from the warehouse.
- Ensure compliance with company policies and National Regulatory Agency (NRA) requirements.
- Foster continuous improvement.
- Identify operational challenges and opportunities, analyze them and problem solve effectively.
- Manage service-level-agreements and ensure adherence to cost, quality and agreed timelines
- Manage internal deliveries.
- Contribute to the development and issuance of metrics for inventory control, supply and forecasting.
- Coordinate order processing and on-time-in-full delivery through distributors
- Support management of inventory write-offs and provisions
- Maintain warehouse locations within ERP system

Minimum years of experience required	6
Minimum educational level required	High School
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • S Supply Chain Management • Inventory management • Materials planning • ERP applications • Warehouse management systems • Warehouse equipment • Financial acumen • Risk management • Business process improvement • Record keeping • Vendor management • Regulatory requirements • Six sigma methodologies 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Negotiation • Presentation • Coaching and mentoring 		

Warehouse Technician

Roles and responsibilities

- Ensure the warehouse facility is effectively run, meeting all the required GMP and regulatory standards, general housekeeping, daily supporting checks.
- Move, stage, or receive warehouse materials and products.
- Safe loading, unloading, distribution and stowage of materials, including all necessary system transactions.
- Safe use of all mechanical handling equipment that individual technicians are licensed to operate.
- Complete appropriate documentation associated with work responsibilities using a computerized inventory system.
- Collation and packing of internal and external orders of material, to meet service-level-agreements.
- Respond to visual and audible warning indicators.
- Adhere to all SOPs (Standard Operating Procedures), cGMP (current Good Manufacturing Practices), plant safety, quality, and documentation systems requirements and participate in regulatory and customer audits.
- Ensure SAP transactions are completed in a timely manner.
- Complete required stock checks to maintain Inventory control.
- Support other warehouse activities as training allows.
- Tracking and resolving problems and leveraging warehousing expertise in analyzing technical problems.
- Identifies required delivery and process improvements that drive increased efficiency, throughput and quality.
- Actively develop and share best practices and knowledge with others in own work group and across multiple work groups.
- Ensure compliance with company & NRA requirements pertaining to facilities & processes

Minimum years of experience required	4
Minimum educational level required	High School
Degree majors typically studied	Supply Chain, Supply Chain Management, Supply Matrix Management, Business Management, Logistics

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Supply Chain Management • Inventory management • ERP applications • Warehouse management systems • Warehouse equipment • Risk management • Record keeping • Regulatory requirements 	<div>→</div> <ul style="list-style-type: none"> • Business process improvement • Vendor management 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Negotiation • Presentation • Coaching and mentoring 	

Maintenance & Engineering

Instrumentation

Instrumentation Manager

Roles and responsibilities

- Manage day to day activities of instrumentation technicians; including recruitment and selection, performance objectives, development objectives, performance feedback/ evaluations and induction related to policies and procedures.
- Develop a safety and quality mindset on the part of all electricians and instrument technicians with a goal of zero accidents, incidents, injuries, illnesses, or defects.
- Drive the building of a well-qualified team through provision of training and skill development opportunities to staff.
- Author, review, revise, and approve operational and maintenance SOPs for all relevant systems.
- Select the initial maintenance strategy for new instruments and equipment and provide updates to keep the strategy current.
- Establish the initial preventive maintenance/ calibration activities for instruments and equipment in accordance with the guidelines and specifications for that particular instrument/ equipment class.
- Provide functional expertise and develop technology forums to exchange best practices with site organisation to establish implementation of maintenance policies and standards.
- Lead performance of root cause failure analysis of instrument and equipment deficiencies, develops, changes, and/ or initiates maintenance activities such as preventive maintenance, Condition Based Monitoring (CBM), calibration, training, and spare parts strategies to improve performance and up time.
- Update reliability plans based on Root Cause Failure Analysis results to further reduce the number of failures and minimize the effects of failures that do occur.
- Manage compliance of electrical equipment and calibration systems and ensure readiness for inspection.
- Provide adequate support to inspected departments and manage CAPA process from inspections or third-party audits.
- Manage closure of deviations associated with equipment or systems within the Instrumentation function's scope of responsibility.
- Provide technical and commercial input in procedures for procurement of sub-contractors, contractors, and vendors selection.
- Manage contracts and act as key contact for electrical equipment and calibration system contractors.
- Develop short term and long-term strategy in supplier selection consistent with site strategy for maintenance and spare parts.
- Evaluate and optimize electrical systems spare parts inventory and preventative/ predictive maintenance program.
- Develop and maintain electrical safety training program for the site.
- Perform the responsibilities of the site technical authority for electrical engineering, including equipment and system specification review for electrical components and systems.
- Develop and manage annual budget for electrical maintenance and instrument calibration.
- Coordinate budgeting with the enterprise facility management contractor, as necessary.
- Perform all job responsibilities in compliance with applicable environmental health and safety (EHS) and GMP regulations, guidelines, policies, standard operating procedures, industry practice and industrial excellence initiatives.

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Electrical Engineering, Systems Engineering, Mechanical Engineering, Computer Science, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			<ul style="list-style-type: none"> • Instrumentation • Instrument reliability • Calibration • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Business process improvement • Failure modes and effects analysis • Engineering Business Systems • Maintenance Management Systems • Control systems • ERP applications • Regulatory requirements • Safety principles • DMAIC techniques • Pneumatics • Electronics • Process automation • Scheduling
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

Instrumentation Planner

Roles and responsibilities

- Plan and co-ordinate the electrical department maintenance work efficiently in conjunction with operators to minimize production downtime.
- Pre-engineer designated maintenance and project activities to meet department requirements efficiently e.g., spares, materials, site/contract labour, services.
- Liaise with ERP contracts manager and broader instrumentation function to maximize the use of resources ensuring effective use of labour, facilities, equipment, and services
- Ensure that all legislative and regulatory work is carried out according to schedule and recorded to comply with current and future regulations and cGMP requirements.
- Providing ERP system support and training in respect of end user requirements and queries.
- Source, select and procure spares/ consumables/ equipment, etc. as required to fulfil future maintenance workload.
- Generate monthly engineering KPIs with the Instrumentation/ Electrical manager for monitoring purposes.
- Assisting with continuous improvement strategies
- Review the monthly maintenance backlog to ensure effective use of resources.
- Co-ordinate and manage weekly maintenance planning meetings for operations, mechanical, electrical and instrument groups to establish the overall maintenance plan.
- Provide cover for Instrumentation manager, coordinating electrical tasks and allocating electrical labour to meet department requirements during manager's absence from site.

Minimum years of experience required	8
Minimum educational level required	Bachelors
Degree majors typically studied	Electrical Engineering, Systems Engineering, Mechanical Engineering, Computer Science, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Instrumentation • Instrument reliability • Calibration • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Business process improvement • Failure modes and effects analysis • Engineering Business Systems • Maintenance Management Systems • Control systems • ERP applications • Regulatory requirements • Safety principles • DMAIC techniques • Pneumatics • Electronics • Process automation • Scheduling 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Instrumentation Coordinator

Roles and responsibilities

- Support manufacturing operations related to equipment, maintain plant electrical/ electronic equipment, and calibration of instrumentation.
- Promote teamwork, a positive work environment and an atmosphere that enhances continuous improvement.
- Data entry on calibration test records and assisting with calibration scheduling.
- Review and approval of completed calibration test records and maintenance work orders
- Order parts as required to service and repair equipment.
- Communicate calibration and work order status with all shifts.
- Troubleshoot and repair production and plant electrical/ electronic equipment.
- Train peers and mechanics on equipment supported by the Instrumentation function.
- Designs, orders parts, and installs machine modification.
- Author, review and update work orders and SOPs.
- Assist with internal and external plant audits.
- Make recommendations on equipment upgrades.
- Assist with plant safety programs and safety awareness.
- Provision of shutdown and project support.
- Ensure all company and site engineering policies and procedures are adhered to.
- Ensure all work carried out and equipment installed is safe, effective and in compliance with the appropriate industry standards.
- Ensure all work undertaken is reflected accurately in work order documentation and/ or up to date engineering / project information files.
- To be the Maintenance Management System expert in a cGMP environment as related to instrumentation.
- To review and approve work carried out to systems and equipment by OEM suppliers, partners, service and construction contractors.
- To implement all planned maintenance activities in accordance with cGMP and excellence in engineering practices.
- When necessary, review all maintenance task lists, SOPs and other relevant documentation and instigate the necessary changes post review.
- Deliver training to colleagues in line with site training procedures, when required.
- Pursue solutions consistent with continuous improvement philosophy.
- Analysis and trending of deviations, non-conformances, and any downtime issues
- Facilitating analysis of latest technologies for equipment
- Review the performance and operation of equipment
- Analyze Preventative Maintenance routines and ensure appropriateness and value

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Electrical Engineering, Systems Engineering, Mechanical Engineering, Computer Science, IT/ Technology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Instrumentation • Instrument reliability • Calibration • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Business process improvement • Failure modes and effects analysis • Engineering Business Systems • Maintenance Management Systems • Control systems • ERP applications • Regulatory requirements • Safety principles • DMAIC techniques • Pneumatics • Electronics • Process automation • Scheduling 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Mechanical

Mechanical Manager

Roles and responsibilities

- Responsible for ensuring equipment availability is maintained through real time problem solving, management of maintenance staff, and identification/ implementation of improvement projects.
- Ensure preventive, curative and modificative maintenance of site's equipment and buildings to ensure their maximum availability.
- Provide technical support on various technical problems for site equipment under the Mechanical function's responsibility.
- Facilitate and participate in equipment-based Root Cause Failure Analysis (RCFA) investigations, including selection of corresponding CAPAs
- Lead and provide technical maintenance oversight to develop execution plans, and associated engineering studies for equipment component installation etc.
- Provide daily trouble shooting and maintenance support.
- Improve equipment efficiency by optimizing machinery and components.
- Assist in feasibility assessments for new product introduction.
- Ability to manage and deliver on budget.
- Responsible for the direct supervision, performance, training, counseling and development of maintenance and engineering staff (e.g., coordinators, planners, and technicians)
- Support Maintenance Coordinators and technicians to develop and implement reliability programs, strategies, plans and tools at the site level.
- Work with other function leaders in the execution of new business, or any potential technical transfers or related projects. This will include providing technical oversight for these initiatives, supporting the site strategy, and ensuring the entire Mechanical function is fully aligned with company and site goals.
- Provides support, coaching and guidance to Maintenance staff in planning and executing shutdown activities.
- Takes a tactical role on investigations and improvements partnering with operations, quality, supply chain and other functions.
- Establishes short-term performance goals, monitors results, and makes timely adjustments to achieve delivery objectives. Make his/ her team accountable for the overall Mechanical function performance and behaviors.
- Assures staff compliance with all procedures, cGMP regulations, and safety rules, while ensuring that appropriate corrective actions are taken to eliminate hazardous conditions.
- Manage and document deviations by integrating changes to maintenance operations
- Actively participate to external audits by answering questions regarding equipment's under the Mechanical function's responsibility, including resolving audit actions
- Maintain good maintenance practices by authoring and updating SOPs and the checklists associated with them.

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Industrial Engineering, Mechatronics Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Hydraulics • Pneumatics • Blue printing • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance Management Systems • Engineering Business Systems • Control systems • ERP applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Mechanical Planner

Roles and responsibilities

- Plan and co-ordinate the Mechanical function's maintenance work efficiently in conjunction with operators to minimize production downtime.
- Pre-engineer designated maintenance and project activities to meet department requirements efficiently, i.e., spares, materials, site/ contract labour, services.
- Liaise with ERP contracts manager and broader Mechanical function to maximize the use of resources ensuring effective use of labour, facilities, equipment, and services
- Ensure that all legislative and regulatory work is carried out to schedule and recorded to comply with current and future regulations.
- Providing ERP system support and training in respect of end user requirements and queries.
- Source, select and procure spares/ equipment, etc. as required to fulfil future maintenance workload.
- Generate Engineering KPI's monthly for Mechanical Manager for monitoring purposes.
- Assisting with continuous improvement.
- Review the monthly maintenance backlog for all trades to ensure effective use of resources
- Co-ordinate and manage weekly maintenance planning meetings for operations, mechanical, electrical and instrument groups to establish the overall maintenance plan.
- Provide cover for mechanical manager, coordinating mechanical tasks and allocating electrical labour to meet department requirements during manager's absence from site.

Minimum years of experience required	6
Minimum educational level required	Bachelors/ B-Tech
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Industrial Engineering, Mechatronics Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities		<ul style="list-style-type: none"> • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Hydraulics • Pneumatics • Blue printing • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance Management Systems • Engineering Business Systems • Control systems • ERP applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 		
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	→ <ul style="list-style-type: none"> • Leadership • Team management 	

Mechanical Coordinator

Roles and responsibilities

- Support manufacturing operations related to mechanical equipment, maintain plant mechanical equipment
- Promote teamwork, a positive work environment and an atmosphere that enhances continuous improvement.
- Order parts as required to repair equipment.
- Communicate work order status with all shifts.
- Troubleshoot and repair production and plant mechanical equipment.
- Train peers and mechanics on equipment supported by the Mechanical function.
- Designs, orders parts, and installs machine modification.
- Author and review SOPs.
- Assist with plant audits.
- Make recommendations on equipment upgrades.
- Assist with plant safety programs and safety awareness.
- Provision of shutdown and project support.
- Ensure all company and site engineering policies and procedures are adhered to.
- Ensure all work carried out and equipment installed is safe, effective and in compliance with the appropriate industry standards.
- Ensure all work undertaken is reflected accurately in work order documentation and/ or up to date engineering / project information files.
- To be the Maintenance Management System expert in a cGMP environment as related to instrumentation.
- To review and approve work carried out to systems and equipment by OEM suppliers, partners, service and construction contractors.
- To implement all planned maintenance activities in accordance with cGMP and excellence in engineering practices.
- When necessary, review all maintenance task lists, SOPs and other relevant documentation to instigate the necessary changes post review.
- Deliver training in line with site training procedures, when required.
- Pursue solutions consistent with continuous improvement philosophy.
- Analysis and trending of downtime issues
- Facilitating analysis of latest technologies for equipment
- Review the performance and operation of equipment
- Analyze Preventative Maintenance routines and ensure appropriateness and value

Minimum years of experience required	6
Minimum educational level required	Ordinary National Diploma (OND) or equivalent e.g., High School (Bachelors preferred); Artisan(w/ 10 years experience); Diploma (w/ 6 years experience)
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Industrial Engineering, Mechatronics Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Hydraulics • Pneumatics • Blue printing • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance Management Systems • Engineering Business Systems • Control systems • ERP applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Reliability Engineer

Roles and responsibilities

- Maintain, test, inspect and perform field calibration of process, utility and analytical instrumentation
- Maintenance of inventory and compilation of records
- Document all work order activities in Maintenance Management Systems and relevant equipment logs
- Troubleshoot and resolve calibration/ instrumentation issues in a timely manner utilizing DMAIC (Define, Measure, Analyze, Improve and Control) techniques
- Read and follow equipment schematics, logic diagrams and engineering drawings
- Support engineering projects to select and install appropriate instrumentation
- Perform duties in a safe manner with a focus on zero Injuries
- Follow all SOP and cGxP requirements
- Lead and/ or participate in continuous improvement activities
- Use predictive techniques to minimize maintenance costs and equipment downtime.

Minimum years of experience required	6
Minimum educational level required	Bachelors/ B-Tech
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Industrial Engineering, Mechatronics Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Hydraulics • Pneumatics • Blue printing • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance Management Systems • Engineering Business Systems • Control systems • ERP applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Mechanical Technician

Roles and responsibilities

- Assess mechanical equipment to determine issues and ensure that appropriate engineering SOPs and manufacturing manuals are followed to manage problems.
- Repair mechanical systems by first isolating complex problems and then determining ways to troubleshoot them.
- Perform both preventative and regular maintenance work on assigned mechanical systems to ensure that they work efficiently and to minimize chances of breakdown and downtime
- Install and repair components required to run mechanical systems properly to ensure minimum downtime
- Assist machine operators in understanding machine functions and procedures to ensure that they can perform their work efficiently
- Create reports on machine malfunctions and ensure timely submission to coordinators/ supervisors
- Work with and dispose bio-hazardous waste
- Oversee inventory of required components, parts, and supplies for repairing and maintaining mechanical systems
- Ascertain work compliance to standards, tolerance, and fits, and ensure that all practices are in sync with sound engineering standards and SOPs.
- Test equipment for proper operations and install new or reconditioned parts to mechanical systems
- Test and recheck all repairs to ensure that they are in accordance with factory specifications and SOPs.
- Complete electronic notification and/ or paper documents to confirm completion of tasks
- Document equipment/ system modifications using relevant procedure
- Report equipment services or events which are out of regulatory compliance using relevant procedure
- Communicate equipment status to operators
- Support Third Party resources to complete contracted tasks

Minimum years of experience required	2
Minimum educational level required	Ordinary National Diploma (OND) or equivalent e.g., High School (Bachelors preferred); Artisan (w/ 5 years experience); Diploma (w/ 3 years experience)
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Industrial Engineering, Mechatronics Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Maintenance • Predictive maintenance • Preventive maintenance • Hydraulics • Pneumatics • Packing • Safety principles • Regulatory requirements • ERP applications 	<div>→</div> <ul style="list-style-type: none"> • Maintenance planning • Blue printing • Equipment reliability • Business process improvement • Maintenance Management Systems • Engineering Business Systems • Control systems • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

HVAC

HVAC Manager

Roles and responsibilities

- Provides technical, quality and compliance focused leadership to the HVAC team within the Maintenance and Engineering function.
- Optimize operations through continuous improvement and best practices for HVAC, refrigeration, and associated equipment.
- Work cross functionally across the site to ensure the HVAC program consistently meets the needs of the business in a fully compliant manner.
- Schedule and manage site wide maintenance, troubleshooting, and repair activities for HVAC, chillers, cooling towers, and refrigeration systems.
- Serve as the primary technical contact for HVAC-related daily operations, process improvements and infrastructure projects.
- Perform all job responsibilities in compliance with applicable EHS and GMP regulations, company policies, engineering standards, operating procedures, and industry practice.
- Provide subject matter expertise for HVAC equipment deviations and CAPAs.
- Ensure assets and areas of ownership are maintained in an audit-ready manner, including provision of subject matter support as required for internal and external audits.
- Manage department operating expenses to planned budget.
- Identify and implement programs aligned to value creation.
- Manage minor capital projects as assigned to HVAC function within approved budget and deliver on time and in full.
- Supervise activities of direct staff including hiring, training, and performance management.
- Oversee activities of supporting contractors, ensuring that safety, quality behaviors and compliance are routinely demonstrated by all staff and aligned with contractors.
- Utilize Building Management Systems, CMMS and reliability maintenance techniques for HVAC, refrigeration and associated systems to deliver a highly efficient, reliable and cost-effective maintenance program.
- Optimize the work order process (corrective maintenance, preventative maintenance, calibrations, and spare parts) to ensure compliance (GMP, OSHA, Cost, Schedule, etc.) for all maintenance work and documentation.
- Develop justification, specifications and costs for new equipment.
- Serve as HVAC owner in related project teams to ensure commissioning, validation, maintenance plans, operating procedures, training and turnover are executed in a satisfactory manner.
- Act as primary HVAC equipment interface for site projects to ensure end users' needs are delivered.

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Mechanical Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • HVAC • Maintenance • Maintenance planning • Preventive maintenance • Predictive maintenance • Safety principles • Root cause analysis • Failure modes and effects analysis • Maintenance Management Systems • Engineering Business Systems • ERP applications • Control systems • Equipment reliability • Business process improvement • Regulatory requirements • Vendor management • Scheduling 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

HVAC Technician

Roles and responsibilities

- Ensures regulatory compliance while minimizing losses and maximizing recovery via effective leak detection, maintenance procedures, and use of reclaiming, recycling, recovery equipment.
- Troubleshoots and adjusts HVAC systems and air volume control equipment to maintain proper temperature, humidity, and air flow conditions.
- Monitors and measures pressure drop of HVAC filters and replaces them as necessary, observing all system integrity and safety requirements.
- Cleans HVAC coils, evaporators, and condensers via chemicals, air, special cleaning agents, high pressure wash units etc. to maintain equipment in good operating condition.
- Repairs and adjusts refrigeration systems to maintain design parameters e.g., temperature pressure, level, etc.
- Monitor, troubleshoot, and maintain applicable system performance consistent with required unit and/or area conditions, following all change control procedures.
- Answers alarms associated with monitoring systems and makes routine decisions concerning priority of response.
- Reviews unusual problems and situations with the manager.
- Executes against work orders and Predictive Maintenance (PM) checklists while maintaining necessary work records and logs in a cGMP compliant manner and documenting activities via daily labour records.
- Provides routine rigging and alignment work, as required by refrigeration system maintenance.
- Communicates effectively in a professional manner with management to provide equipment and system status, parts and other work requirements.
- Operates recovery, recycling and reclaiming devices to minimize refrigerant impact on environment and obtains appropriate certification as necessary to comply with applicable regulations.
- Completes department training directives, e.g., orientation, SOP, safety, etc. as directed by management.
- Prepares and assists technicians, supervisors, and planners across other functions in preparing labor and material estimates.
- Assists management with the assigning, scheduling and prioritisation of work order requests using maintenance management systems.
- Makes recommendations and prepares orders for spare parts, additional stock room items, tools, etc.
- Consults with management and other technicians on problem resolution/ troubleshooting

Minimum years of experience required	5
Minimum educational level required	Ordinary National Diploma (OND) or equivalent e.g., High School; Artisan (w/ 5 years experience); Diploma (w/ 3 years experience)
Degree majors typically studied	Mechanical Engineering, Electrical Engineering, Systems Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • HVAC • Maintenance • Preventive maintenance • Predictive maintenance • Safety principles • ERP applications • Regulatory requirements 	<ul style="list-style-type: none"> • Maintenance planning • Root cause analysis • Failure modes and effects analysis • Maintenance Management Systems • Engineering Business Systems • Control systems • Equipment reliability • Business process improvement • Vendor management • Scheduling 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Capital Projects

Engineering Manager

Roles and responsibilities

- Leading the capital portfolio aligned to the site strategy and be responsible for delivery of all projects within cost and schedule targets.
- Lead a team consisting of site staff and contractors to deliver the successful outcome of project scopes.
- Ensuring team skills are maintained and developed to maintain and improve capacity and capability.
- Act as a role model for capital project delivery (following the site Project Management Framework), and satisfying all projects controls elements (i.e., programme, cost, risk and reporting)
- Develop and maintain positive relationships with the customers and other site functions
- Provide co-ordination to balance site priorities, resources and potential clashes.
- Working with site preferred suppliers and other support services through existing and new contracts
- Ensure stage gate, governance papers and Project Investment Proposal (PIP) submissions align to the site Capital Plan - review and provide feedback on charters, project plans and PIPs prior to submission to ensure Front End Engineering Design (FEED) criteria have been met along with defining a robust business case for investment.
- Ensure effective implementation and compliance to all EHS, Quality and Finance aspects of the company
- Presentation of Team's performance to established goals and metrics

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Electrical Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Project Investment Proposals • Project Planning • Project Management • Construction management • Construction drawings • Procurement management • Risk management • Project costing • Progress reporting • Engineering design process • Feasibility studies • Design management • Vendor management • Regulatory requirements 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Engineering Project Manager

Roles and responsibilities

- Provide input into project plans and successfully execute them according to established schedule, cost, and performance standards
- Oversee design, construction, commissioning, qualification, and readiness for each assigned project.
- Ensures that projects are safe, of high quality, are completed on schedule and remain within budget.
- Direct design and construction management activities, including capital planning, budgeting, designer selection, design review, project management, dispute resolution and any legal issues.
- Working closely with procurement, direct the bid evaluation and contract award processes and coordinate the negotiation of contracts with general contractors, and oversight of construction management activities.
- Manage all external design team professionals from project inception through completion and ensure they produce thorough and accurate drawings which comply with all established standards.
- Review all construction drawing documents and specifications, coordinating necessary reviews with business unit representatives and regulatory authorities
- Ensure efficient and timely turnover of space for effective operations, including a maintenance and calibration package.
- Oversee relationship with regulatory authorities for project permitting and other business related to site improvements.
- Track and report progress as required against project deliverables, highlight risks and mitigation plans and provide regular updates to project sponsors

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Electrical Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Project Investment Proposals • Project Planning • Project Management • Construction management • Construction drawings • Procurement management • Risk management • Project costing • Progress reporting • Engineering design process • Feasibility studies • Design management • Vendor management • Regulatory requirements 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Utilities

Utilities Manager

Roles and responsibilities

- Lead all assigned maintenance personnel and contractors in assuring all requirements of their assignments and responsibilities are clearly communicated and understood.
- Guide project and utility teams to resolve basic equipment issues
- Manage daily, weekly, and monthly process for overseeing the operation of the services being delivered.
- Foster a culture of teamwork, compliance, quality, safety, and productivity.
- Take prompt action to remediate employee performance issues while recognizing and rewarding positive results and performance.
- Coordinate with operations to complete necessary work with minimal disruption.
- Work with Instrumentation and Mechanical functions to improve reliability and performance of production process equipment and utility equipment.
- Ensure continuous reliable uninterrupted service for all critical systems that support manufacturing operation.
- Improve standard plant operating procedures, emergency control procedures and control room practices to cGMP standards.
- Coordinate and directly supervise utility outages and the performance of emergency and routine maintenance on utilities and facilities.
- Identify opportunities to utilize the site critical systems in a more efficient manner to improve reliability and reduce operating costs.
- Manages respective corrective and preventive actions and works with Quality to ensure timely completion of investigations and CAPA implementations.
- Support Internal and external audits as required.
- Actively contribute to the improvement of policy, practices, and procedures.
- Manage staff training and ensure they are fully qualified to perform their duties.
- Work with planning and scheduling for timely completion of daily corrective and preventative maintenance work.
- Efficiently coordinate the workflow and documentation of work orders.
- Assist Maintenance and Engineering function Leader with annual maintenance budgets, approve expenditures, create and issue purchase orders, and forecast expenses.
- Submit capital requests as needed to support equipment replacement, upgrades, and other improvements.
- Partner with Instrumentation and Mechanical functionsto ensure successful commissioning and qualification activities.
- Oversee the smooth transition of projects into day-to-day operations.
- Ensure a safe work environment is maintained through adherence to safety guidelines and policies.
- Help establish departmental goals and expectations of direct reports.

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Electrical Engineering

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Maintenance • Maintenance planning • Predictive maintenance • Preventive maintenance • Equipment reliability • Maintenance Management Systems • Engineering Business Systems • Control systems • ERP applications • Water treatment • Safety principles • Regulatory requirements • Project management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

Utilities Technician

Roles and responsibilities

- Repair and maintain plant utilities equipment as per manufacturing specifications, SOPs, cGMPs, and other relevant regulations.
- Troubleshoot problems with utilities equipment as necessary and as directed by Utilities Manager
- Ensuring engineering areas, facilities, and equipment are kept in a clean, safe and serviceable condition, and general housekeeping highest standards are maintained.
- Complete site documentation before and after work tasks, as appropriate
- Ensures all issues over shift are communicated via pass down to the next shift on shift change-over in a smooth and efficient manner
- Assist with investigations on utilities equipment.
- Carry out risk assessment of equipment maintenance task list steps and ensure these are always kept valid.
- Carry out periodic reviews of SOPs to ensure documents are always current and valid.
- Participate in appropriate training as assigned

Minimum years of experience required	3
Minimum educational level required	Ordinary National Diploma (OND) or equivalent e.g., High School; Artisan (w/ 5 years experience); Diploma (w/ 3 years experience)
Degree majors typically studied	Mechanical Engineering, Chemical Engineering, Chemistry

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Maintenance • Predictive maintenance • Preventive maintenance • ERP applications • Water treatment • Safety principles • Regulatory requirements 	<div>→</div> <ul style="list-style-type: none"> • Maintenance planning • Equipment reliability • Maintenance Management Systems • Engineering Business Systems • Control systems • Project management 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

EHS Manager

Roles and responsibilities

- Foster a safety and quality mindset among team members with the goal of zero accidents, incidents, injuries, illnesses, or defects
- Select initial maintenance strategies for new environmental, health & safety instruments and equipment.
- Lead the performance of root cause failure analysis of EHS deficiencies, initiating maintenance activities such as preventive maintenance, Condition Based Monitoring (CBM), calibration, and training
- Provide training and skill development opportunities to EHS staff, ensuring a well-qualified team
- Author, review, revise, and approve operational and maintenance SOPs for all relevant EHS systems
- Provide technical and commercial input in procedures for the procurement of contractors and vendors
- Provide support during inspections or third-party audits and manage the Corrective Action and Preventive Action (CAPA) process
- Perform all job responsibilities in compliance with applicable EHS and GMP regulations, guidelines, policies, standard operating procedures, industry practices, and industrial excellence initiatives

Minimum years of experience required	5
Minimum educational level required	Bachelor's Degree
Degree majors typically studied	Occupational safety, Environmental Health & Safety, Mechanical Engineering, Systems

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> Regulatory compliance Incident investigation and analysis Safety training program development Emergency preparedness planning Risk assessment Stakeholder communication 	<ul style="list-style-type: none"> Business process improvement Engineering Business Systems Maintenance Management Systems Control systems 		
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Attention to detail Teamwork Problem solving Interpersonal skills 	<ul style="list-style-type: none"> Decision making Presentation Coaching and mentoring 		

EHS Specialist


Roles and responsibilities

- Ensure compliance with environmental, health, and safety (EHS) regulations, guidelines, and industry practices within the vaccine manufacturing organization
- Monitor and assess safety practices, identifying areas for improvement and implementing corrective actions
- Conduct investigations into safety incidents, accidents, and near misses, identifying root causes and recommending preventive measures.
- Manage the documentation and reporting of safety incidents, ensuring adherence to regulatory reporting requirements
- Develop and implement environmental, health, and safety training programs for employees, emphasizing a safety culture and best practices
- Collaborate with relevant departments to ensure employees receive adequate training on safety protocols
- Develop and maintain emergency response plans, ensuring the organization is prepared to handle environmental and safety-related emergencies
- Stay informed about changes in EHS regulations and update organizational policies and procedures accordingly.
- Assist in the preparation for and response to EHS inspections and audits
- Conduct risk assessments related to environmental, health, and safety, providing recommendations for risk mitigation strategies

Minimum years of experience required	3
Minimum educational level required	Bachelor's degree
Degree majors typically studied	Occupational safety, Environmental Health & Safety, Mechanical Engineering, Systems

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none">• Regulatory compliance• Incident investigation and analysis• Safety training program development• Emergency preparedness planning• Risk assessment• Stakeholder communication		
Leadership & functional capabilities	<ul style="list-style-type: none">• Written and verbal communication• Attention to detail• Teamwork• Problem solving• Interpersonal skills		

Support

Marketing and Sales

Marketing Manager

Roles and responsibilities

- Strategy development and planning of campaigns that can promote the business and generate customer/ consumer traffic
- Deploy successful marketing campaigns and own their implementation from ideation to execution
- Experiment with a variety of organic and paid acquisition channels like content creation, content curation, pay per click campaigns, event management, publicity, social media, lead generation campaigns, copywriting, and performance analysis
- Create engaging and informative content for the website, blog, social media, and any other content marketing channels that the business might leverage
- Build strategic relationships and partner with key industry players, agencies and vendors
- Prepare and monitor the marketing budget on a quarterly and annual basis and allocate funds wisely
- Oversee and approve marketing material, from website banners to hard copy brochures and case studies
- Measure and report on the performance of marketing campaigns, gain insight and assess against goals
- Analyze customer/ consumer behavior and adjust email and advertising campaigns accordingly

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Marketing strategy • Marketing campaigns • Marketing channels • Online marketing • Offline marketing • Field marketing • Marketing analytics • Marketing research • Brand strategy • Brand communication • Analytics tools • Business acumen • Budgeting • Search Engine Optimisations (SEOs) • Search Engine Marketing (SEM) • Customer service • Customer relationship management • Vendor management • Innovation 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Brand Manager

Roles and responsibilities

- Conduct consumer and market research
- Identify how a given brand is currently positioned in the market
- Develop a research-based brand strategy
- Develop and execute marketing campaigns aimed at communicating brand message
- Communicate brand personality internally and align company around foundational ideas
- Lead marketing team members through campaigns
- Measure and report on success of marketing campaigns
- Anticipate customer/ consumer trends and keep brand up to date
- Establish and manage the corporate brand management budget effectively
- Scope, shape, plan and co-create company communications and events and project manage internal branding initiatives

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Marketing strategy • Marketing campaigns • Marketing channels • Online marketing • Offline marketing • Marketing analytics • Marketing research • Brand strategy • Brand communication • Analytics tools • Business acumen • Budgeting • Search Engine Optimisations (SEOs) • Search Engine Marketing (SEM) • Customer service • Customer relationship management • Innovation • Vendor management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Digital Marketer

Roles and responsibilities

- Develop digital marketing strategies that align with the organisation's business goals
- Manage and execute campaigns across various digital channels, including email, social media, search engines, and display advertising
- Measure and report on the performance of digital marketing campaigns, and assess against goals (ROI and KPIs)
- Conduct market research and analyze trends to identify new opportunities and improve campaign performance
- Collaborate with cross-functional teams, including creative, content, and web development, to produce engaging content and optimize user experience
- Keep up with emerging digital marketing trends and technologies

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Marketing campaigns • Marketing channels • Online marketing • Marketing analytics • Marketing research • Analytics tools • Business acumen • Customer service • Search Engine Optimisations (SEOs) • Search Engine Marketing (SEM) 	<ul style="list-style-type: none"> • Marketing strategy • Brand strategy • Brand communication • Vendor management • Innovation 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Field Marketer

Roles and responsibilities

- Plan and complete field marketing campaigns after conducting preliminary research
- Develop robust knowledge of relevant products
- Produce various literature, signage, merchandise, and other materials to be used at field marketing events
- Maintain relationships with third-party vendors and venues
- Negotiate with retailers and other third-party partners on promotional display and merchandise placement
- Promote business expansion opportunities to retailers and other merchants through successful field marketing programs
- Attend relevant trade shows and events
- Monitor industry trends and competitor activities
- Manage social media activity surrounding field marketing campaigns
- Track field marketing expenses
- Report weekly/monthly on the status of field marketing activities
- Document and share customer intelligence with sales team.

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> Marketing campaigns Field marketing Offline marketing Marketing analytics Marketing research Customer service Business acumen 	<div>→</div> <ul style="list-style-type: none"> Marketing strategy Brand strategy Brand communication Vendor management Customer relationship management Innovation 	
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Attention to detail Teamwork Problem solving Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> Decision making Presentation Coaching and mentoring Negotiation 	

Marketing Analyst

Roles and responsibilities

- Contribute to the understanding of market, doctors and patients, development of brand strategy and planning of Sales detail by conducting primary market research incl. both qualitative and quantitative research, analyze the data/ insights and propose the implications.
- Design, analyze and report primary market research for all company products.
- Ensure all market research activities are conducted in an ethical way and according to relevant Codes of Conduct and regulatory requirements.
- Answer business questions of company brands by analyzing and interpreting data/ insights of doctors and patients through primary market research
- Actively share new learnings from primary market research with team members, across the therapeutic area/ vaccine expertise area and worldwide market research members.
- Leverage best practices and learnings across the vaccine expertise area to own research.

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • M Marketing campaigns • Marketing channels • Marketing analytics • Marketing research • Analytics tools • Business acumen 	<ul style="list-style-type: none"> • Marketing strategy • Brand strategy • Brand communication • Innovation 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Sales Manager

Roles and responsibilities

- Development and execution of sales strategy
- Overseeing daily operations of sales function
- Meeting planned sales goals.
- Setting individual sales targets with the sales team.
- Tracking sales goals and reporting results as necessary.
- Overseeing the activities and performance of the sales team.
- Coordinating with marketing on lead generation.
- Ongoing training of salespeople.
- Developing sales team through motivation, counseling, and product knowledge education.
- Promoting the organisation and products.
- Understand customers and how they relate to our products.

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Sales strategy • Sales • Customer relationship management • Customer service • Business acumen • Innovation 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Sales Representative




Roles and responsibilities

- Generating leads.
- Meeting or exceeding sales goals.
- Negotiating contracts with prospective clients.
- Support determination of pricing schedules for quotes, promotions, and negotiations.
- Preparing weekly and monthly reports.
- Giving sales presentations to a range of prospective clients.
- Coordinating sales efforts with marketing programs.
- Understanding and promoting company programs.
- Obtaining deposits and balance of payment from clients.
- Preparing and submitting sales contracts for orders.
- Visiting clients and potential clients to evaluate needs or promote products and services.
- Maintaining client records.
- Answering client questions about credit terms, products, prices, and availability.

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Marketing, Communications

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none">• Sales• Customer relationship management• Customer service• Business acumen	 <ul style="list-style-type: none">• Sales strategy• Innovation	
Leadership & functional capabilities	<ul style="list-style-type: none">• Written and verbal communication• Attention to detail• Teamwork• Problem solving• Interpersonal skills	 <ul style="list-style-type: none">• Decision making• Presentation• Coaching and mentoring• Negotiation	

Legal

General Counsel

Roles and responsibilities

- Advising executive members on new laws, existing laws and legal rights that would impact functionality of the business
- Overseeing the legal matters of the business as a whole, including acting as the business' legal representative
- Overseeing the legal strategy in response to any litigation. Working with the litigation counsel (including any external litigation counsel) to ensure litigation proceeds effectively and efficiently. Has ultimate authority and responsibility for litigation outcomes.
- Responsible for all corporate record keeping. Also responsible for all corporate financial and other regulatory (but not those related to drug filings) filings.
- Maintaining knowledge of the company's legal documents and operations
- Crafting and reviewing legal strategy in response to any litigation
- Keeping a record of all legal documents and proceedings for the company
- Facilitating filings of licensing forms and other statutory requirements
- Communicating with outside counsel
- Legally filing for copyright of intellectual property
- Primary point of communication with all outside counsel; delegated as appropriate
- Responsible for the management of all corporate intellectual property (trade secrets, copyrights, and trademarks)
- Member of the Board of Directors as Board Secretary; responsible for the duties typically associated with such role
- Oversees the entire Legal department for the company. Establishes and maintains clear goals and directions for the department and works regularly with her/his staff to ensure goals are being met, and that problems are being avoided
- Develop and manage budget for the Legal department

Minimum years of experience required	15
Minimum educational level required	Bachelors
Degree majors typically studied	Law, Masters of Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Pharmaceuticals litigation • Pharmaceuticals law • Competition law • Contracts • Government contracts and tenders • Business transactions (e.g., acquisitions, joint ventures etc.) • Patents • Legal research • Regulatory requirements • Anti-Bribery and Corruption • First chair trials • Patent database management systems 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Senior Counsel, Litigation

Roles and responsibilities

- Develop and execute litigation strategy in all areas of operation of the company, including, but not limited to, products liability, healthcare fraud and abuse, government investigations, contract and commercial matters, and other areas. This includes active participation in and oversight of internal fact investigation, discovery process, selection of experts, motion practice, preparation of witnesses, trial strategy, settlement strategy and negotiations.
- Works closely with the General Counsel and, if used, outside counsel, to reach swift and efficient outcomes for all litigation matters
- Represent Company at meetings, mediations, and arbitrations.
- Lead and conduct attorney-client privileged internal investigations involving allegations of fraud, corruption, or breach of laws that could result in liability for the company and/or its employees acting on behalf of the company, and/or that could result in significant reputational harm to the company.
- Juggle numerous competing priorities and perform in a continually changing legal, regulatory, and scientific environment.
- Interface with company employees at all levels, including senior management and business employees and lawyers. Communicate effectively and build teamwork in managing litigation and investigations.
- Work closely with external counsel on appropriate matters to develop and drive overall litigation strategy, ensure compliance with company policies, manage litigation budget and drive cost savings. In consultation with outside counsel, recommend and monitor financial reserves for lawsuits and investigations.
- Conduct early case assessments and provide preventive legal advice to business clients and business sector attorneys to avoid potential litigation and/or by resolving disputes.
- Develop, improve, and implement best litigation processes for team. Demonstrate capacity for innovation in providing unique and creative solutions to complex legal and business issues.
- Provide additional leadership within the department/company, including driving litigation/legal department initiatives and process improvement projects.
- Keep abreast of legal developments and continue legal education in substantive areas and litigation practices as they relate to Consumer Health environment

Minimum years of experience required	10
Minimum educational level required	Bachelors
Degree majors typically studied	Law, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Pharmaceuticals litigation • Pharmaceuticals law • Competition law • Contracts • Business transactions (e.g., acquisitions, joint ventures etc.) • Patents • Legal research • Regulatory requirements • Anti-Bribery and Corruption • First chair trials 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Senior Counsel, Corporate

Roles and responsibilities

- Deliver high quality legal services to enable corporate functions to deliver their objectives.
- Advise on, draft, and negotiate licensing, collaborations, commercial and corporate agreements, and other business transactions.
- Support related due diligence for transactions.
- Provide legal support for ongoing alliance management matters.
- Be the principal point of contact to certain corporate functions.
- Anticipate and proactively support the prevention and management of legal risks facing the company arising under third-party transactions and alliances including actively advising corporate functions on transactional risks, such as intellectual property ownership, compliance, and other policy matters.
- Build trusted relationships with key stakeholders by providing well informed, and practical legal advice.
- Selecting, evaluating, and managing effective, timely and cost-efficient outside legal counsel services as needed.
- Provide training to other company functions and legal colleagues.
- Support knowledge sharing and business process improvement activities and provide assistance to less experienced attorneys and paralegals and contribute to their development.
- Engage with other company functions and stakeholders to ensure appropriate communication and consideration of relevant issues.

Minimum years of experience required	7
Minimum educational level required	Bachelors
Degree majors typically studied	Law, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Pharmaceuticals litigation • Pharmaceuticals law • Business transactions (e.g., acquisitions, joint ventures etc.) • Competition law • Contracts • Patents • Government contracts and tenders • Regulatory requirements • Anti-Bribery and Corruption • Legal research • First chair trials • Patent database management systems 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Counsel, Corporate

Roles and responsibilities

- Participation and counsel to multiple client teams within the organization such as Clinical, CMC, Regulatory, etc.
- Negotiating/ drafting and/ or reviewing a wide range of commercial agreements that are typical for a pharmaceutical company
- Advising on legal aspects of sales and promotion including review of product claims and challenges
- Advising and managing commercial dispute resolution and litigation
- Providing legal support on industry issues, crisis management and product incidents
- Oversight and management of legal risks within Risk Management and Compliance framework
- Delivering/ coordinating legal training to other functions.
- Liaising with other groups within Legal (such as Patents, Trademarks, Business Development) and other departments (such as Corporate Tax, Finance etc.)
- Advising on anti-corruption issues.
- Appropriately manage legal budget.

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Law, Business Administration

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Pharmaceuticals litigation • Pharmaceuticals law • Business transactions (e.g., acquisitions, joint ventures etc.) • Competition law • Contracts • Patents • Government contracts and tenders • Regulatory requirements • Anti-Bribery and Corruption • Legal research • First chair trials • Patent database management systems 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Negotiation 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Paralegal

Roles and responsibilities

- Provide full patent paralegal support to attorneys covering all aspects of patent preparation and prosecution including, but not limited to preparing patent specification, figures, sequence listings, filing patent applications, routine drafts of responses to official communications and office actions, and any other activity related to patent preparation and prosecution.
- Provide full paralegal support to attorneys covering all aspects of departmental operations
- Work with docketing systems, actively managing attorney dockets, ensuring attorneys have full visibility of future, upcoming and urgent matters, where appropriate performing cross checks and closing out office actions.
- Maintain electronic files relating to attorney case dockets, incorporating internal and official correspondence from patent offices around the world.
- Initiate and compose routine correspondence, ensuring timely and accurate drafting.
- Communicate with relevant patent offices and external counsel as required.
- Act independently, anticipating upcoming activities, determining priorities and during attorney's absence, delegate matters to appropriate staff persons.
- Support specific work projects/assignments associated with developing and/ or improving patent paralegal ways of working.
- Assist attorneys with the tasks involved in-license/ out-license of cases and be part of any patent prosecution team

Minimum years of experience required	5
Minimum educational level required	High School
Degree majors typically studied	Law, Paralegal certificate, Business Administration,

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Legal research • Patents • Patent database management systems 	<div>→</div> <ul style="list-style-type: none"> • Pharmaceuticals law • Competition law • Contracts 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring • Negotiation 		

HR

Head of HR

Roles and responsibilities

- Develop organisational HR strategy in line with overall business strategy and ensure its execution
- Provide reports on all areas of HR, Payroll and Learning and Development, including the application of Employment Law, HR policy, best practice, and workforce development.
- Advise and strategize on the development of effective employment policies across the company.
- Provide professional leadership, support, and development to HR staff, to increase knowledge, share best practices and to ensure that relevant professional standards are met.
- Ensure that the company complies with current regulations, accepted professional standards, policies and procedures and legislation (including legislation on data protection, the Equality Act and health and safety).
- Manage the execution of the HR Strategy and core areas of the HR department including Recruitment, Employee Relations, Workforce Administration, Employee Engagement, Payroll, Reward and Recognition, as well as maintaining and improving HR systems and management of the HR budget.
- Drive the continuous improvement agenda with focus on engagement & welfare activities, maximizing productivity, devolving HR responsibilities to cross-functional managers and building leadership capability.
- Take a lead role in transforming and strengthening the organisational culture, ensuring that the company values and approach are displayed.
- Execute a plan for diversity, equality, and inclusion that aligns with company values, business strategy and commitments.
- Regularly coach, mentor and support senior and high potential colleagues to identify individual strengths and development needs, develop and maintain effective relationships and encourage retention.
- Ensure managers are sufficiently skilled and enabled to access appropriate guidance and information to manage workforce issues.
- Oversee the development of employee metrics and data trends for interpretation and translation into HR strategies that meets business objectives and employee needs.
- Develop and oversee a robust talent identification and retention strategy

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Organisational Science, Human Resources

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Position evaluation • Pay administration policies and practices • Pay increase budget development and administration • Recognition and rewards programs • Legal frameworks for compensation • HR-related policies (e.g., Equality, Health and Safety) • Business acumen • Financial acumen • People analytics • Workforce planning • Workforce behaviours • Project management • Human Resource Information Systems • Professional development • Training programs • Impact measurement and evaluation • Recruiting • Competency assessments • Diversity management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Manager, Compensation and benefits

Roles and responsibilities

- Align Compensation & Benefits strategy and policies with company's overall HR strategy
- Provide expertise and advise on all reward-related programs, policies and legislation to other company functions
- Oversee the development and refinement of pay administration policies and procedures
- Ensure that market survey data on rewards are collected and analyzed on a periodic basis, including developing proposals based on research analysis and align on policy changes with head of HR
- Review national, regional, and local compensation surveys and propose adjustments to compensation accordingly
- Maintain an equitable job evaluation review and reports on the company's position with respect to pay equity as legislated under the relevant local/ regional law
- Ensure proper integration of salaries and benefits as part of the company's compensation package.
- Advise on best-practice compensation and reward systems
- Be aware of emerging trends and changes to legislations and requirements across different regions
- Monitor the effectiveness of new and current programs and recommend future initiatives.
- Act as a consultant and expert for labour negotiations related to all reward matters
- Develops and oversees implementation of performance evaluation systems and policies
- Review overall performance evaluation results and take necessary actions accordingly
- Ensure company benefits management team is in place
- Manage employee benefits data generation, trending, and management reporting

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Organisational Science, Human Resources

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Position evaluation • Compensation surveys • Pay administration policies and practices • Pay increase budget development and administration • Recognition and rewards programs • Legal frameworks for compensation • Business acumen • Financial acumen • Diversity management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Compensation and benefits administrator

Roles and responsibilities

- Administers employee insurance programs including life, disability, and health insurance plans.
- Administers employee savings plans that may include personal savings plans and deferred compensation programs.
- Advises and informs employees of changes and developments related to benefits including eligibility, coverage, and provisions.
- Researches and compares incentive compensation plans offered by demographically comparable organisations; assesses competitors plans and makes recommendations for enhancements or improvements required to keep the organisations plans competitive and effective.
- Facilitates accurate and timely delivery of employer contributions and employee payroll deductions to carriers, plan administrators, or other appropriate service providers.
- Completes records, reporting, and other documentation required by regulatory authorities and company policies.
- Conducts employee surveys, census, and other research and demographic efforts required to collect accurate quotes from benefit providers.
- Identifies and selects carriers and plans based on quotes, available benefits, and prior experience.
- Monitors administrators and insurance carriers reports to ensure the organisations compliance with plan requirements.
- Maintains knowledge of economic conditions, labour market, and other factors related to ensuring the organisation provides competitive and reasonable benefits and compensation scales and structures.
- Maintains knowledge of trends, developments, and best practices in compensation and benefits administration.
- Ensure accurate calculations for benefit deductions in the HRIS system

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Organisational Science, Human Resources

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

		←	
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> • Position evaluation • Compensation surveys • Pay administration policies and practices • Pay increase budget development and administration • Recognition and rewards programs • Legal frameworks for compensation • Business acumen • Financial acumen 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Negotiation 	<p>→</p> <ul style="list-style-type: none"> • Leadership • Team management

Manager, People Analytics

Roles and responsibilities

- Lead the evolution of people planning and analytics strategies and set the vision roadmap for the company
- Lead the strategic workforce planning approach based on external and internal benchmarking of business practices, predictive capabilities, competitive intelligence, and continuous alignment to global labour trends
- Develop employee predictive analytics to identify significant differences, relationships, and trends in data, as well as factors that could affect the results of research, and translate data and trends into strategies and stories to achieve client, program, and business objectives for resource optimisation
- Manage and implement surveys including designing questions and reports, delivering executive presentations, creating complex data models, and performing analysis to identify trends used for actionable insights and workforce decision-making
- Educate the broader HR function in utilizing the workforce insights to drive higher workforce performance and deploy self-service dashboard capabilities to identify workforce patterns and trends
- Work closely with cross-functional teams to proactively create business rules, deploy analytics, and manage decisions
- Evaluate effectiveness of all workforce strategies (e.g., training/ development, compensation, inclusion & diversity, performance, etc.) and clearly communicate and influence leaders on findings and recommendations
- Partner with the broader HR functions to understand and deliver on their data needs from standard reporting, workforce planning support, to organisational analysis and recommendations

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Organisational Science, Human Resources, Computer Science, Statistics, Data Science

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • People analytics • People surveys • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) • Statistics • Data science • Workforce planning • Workforce behaviours • Research • Project management • Human Resource Information Systems • Business acumen • Financial acumen • Diversity management 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

People Analytics Specialist/ Analyst

Roles and responsibilities

- Partner with HR leadership to support deliverables for special projects related to firm People Strategy (e.g., diversity, retention, etc.) i.e., framing of key issues, designing analytic approach to address, execution of analysis and communication of insights
- Lead dataset development for near-term needs (e.g., create and maintain a dataset that can be leveraged across various use cases) and help build out a more robust long-term system
- Spearhead innovative analyses to drive business decisions and measure success of firm programs and initiatives (e.g., analyze exit survey results; analyze key drivers of performance through analyzing the correlation between performance trends and potential drivers etc.)
- Point of contact and subject matter expert for ad hoc people data and analytics requests
- Partner with firm's People Functions to support ongoing operational analytics efforts (e.g., recruiting funnel analysis; performance trends analysis; hours and staff utilisation analysis; developing a model to identify employees eligible for bonus time off etc.)
- Lead systems assessment and implementation as needs arise (e.g., applicant tracking system, Human Resource Information Systems (HRIS), learning management system, etc.)
- Support the broader goals of the HR team
- Identify risks and investigate recommendations to mitigate such risks

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Organisational Science, Human Resources, Computer Science, Statistics, Data Science

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • People surveys • People analytics • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) • Statistics • Data science • Research • Business acumen • Financial acumen • People surveys 	<ul style="list-style-type: none"> • Human Resource Information Systems • Project management • Workforce planning • Workforce behaviors 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

Manager, Learning and Talent Management

Roles and responsibilities

- Ensure effective achievement of functional objectives through leadership of corporate-level learning and development department, setting departmental and individual objectives, managing performance, developing, and motivating staff, providing formal and informal feedback and appraisal to maximize subordinate and departmental performance
- Provide expert advice on matters related to learning, development and knowledge management to executives, managers, and HR colleagues
- Work closely with the head of HR and different internal stakeholders to establish company's overall learning, development and knowledge management philosophies and strategies
- Research, recommend, implement, and manage global and local learning, development, knowledge management processes and program to support delivery of business strategy, plans and objectives
- Provide input to the workforce planning process
- Work with functional leaders to establish and implement skills frameworks and learning, development and knowledge management processes
- Establish processes for competence assurance and accreditation and monitor their effective implementation and on-going operation
- Develop appropriate learning channels and partnerships to support learning, development and knowledge management and develop metrics to measure progress and assess results
- Manage the learning and development team and ensure their continuing professional development
- Manage the global learning and development budget
- Monitor, analyze and proactively respond to trends and issues related to learning, development, and knowledge management.
- Align development of training content and programs with the different needs of various company functions.

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Organisational Science, Human Resources, Psychology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Professional development • Talent retention • Diversity management • Competency assessments • Training programs • Impact measurement and evaluation • Business acumen • Financial acumen • Research 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Learning and Development Specialist

Roles and responsibilities

- Carrying out capability assessments across the organization
- Designing blended learning solutions
- Using digital tools to create flexible and innovative learning programmes
- Applying adult learning theories to ensure employees get the best out of their development
- Designing a range of learning interventions, including technical, behavioural, and leadership programmes
- Driving a culture of continuous professional development
- Facilitating learning interventions
- Creating a coaching culture in the organisation
- Monitoring how effectively learning has been transferred to employees.
- Develop training templates and material by partnering with internal and external stakeholders and subject matter experts
- Identify risks and investigate recommendations to mitigate such risks

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Organisational Science, Human Resources, Psychology

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←		
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> Professional development Competency assessments Impact measurement and evaluation Business acumen Financial acumen Research 	<div>→</div> <ul style="list-style-type: none"> Training programs Talent retention Diversity management 	
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and verbal communication Attention to detail Teamwork Problem solving Interpersonal skills 	<div>→</div> <ul style="list-style-type: none"> Decision making Presentation Coaching and mentoring Negotiation 	

Manager, Recruiting

Roles and responsibilities

- Develop a sustainable recruiting strategy
- Communicate with organisational functions to get a clear view on their hiring needs and organisational goals
- Research into competitors and marketplace to identify competitor recruiting practices, including supporting people analytics
- Lead team of recruiters in performance of recruiting function responsibilities
- Define job description and document specifications
- Identify prospective candidates using a variety of channels
- Create candidate personas for each open position
- Conduct confidential interviews
- Follow-up references and check credits
- Present shortlisted candidates
- Present detailed candidate profile summaries
- Research and develop recruiting leads
- Keep up with best recruiting practices
- Facilitate workforce planning with managers, co-develop the workforce plans, consolidate across all departments for approval
- Candidates meet the spec and are within deadline and budget
- Ensure retention of top talent through robust recruitment strategies

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Organisational Science, Human Resources

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Recruiting • Candidate selection • Candidate enticement • Interviewing • Competency assessment • Applicant Tracking Systems • Human Resource Information Systems • Business acumen 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Recruiter

Roles and responsibilities

- Design and implement overall recruiting strategy
- Develop and update job descriptions and job specifications
- Perform job and task analysis to document job requirements and objectives
- Prepare recruitment materials and post jobs to appropriate job board/ newspapers/ universities/ colleges etc.
- Source and recruit candidates by using databases, social media etc.
- Conduct campus recruiting initiatives to hire entry-level talent
- Screen candidates resumes and job applications
- Conduct interviews using various reliable recruiting and selection tools/methods to filter candidates within schedule
- Assess applicants' relevant knowledge, skills, soft skills, experience and aptitudes
- Onboard new employees to become fully integrated
- Monitor and apply HR recruiting best practices
- Provide analytical and well documented recruiting reports to the rest of the team
- Act as a point of contact and build influential candidate relationships during the selection process
- Promote company's reputation as "best place to work"
- Conduct background checks prior to making an offer of employment
- Conduct remuneration negotiation
- Conduct talent identification and alignment with company needs

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Organisational Science, Human Resources

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Recruiting • Candidate selection • Candidate enticement • Interviewing • Business acumen 	<ul style="list-style-type: none"> • Competency assessment • Applicant Tracking Systems • Human Resource Information Systems 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring • Negotiation 		

Finance

Finance Director

Roles and responsibilities

- Support CEO, Board of Directors, and Senior Management Team in making strategic finance-related decisions to support the Company's overall goals and objectives.
- Lead the development of annual financial and operating budgets and manage the budgeting/forecasting process.
- Evaluate the financial feasibility and return on investment for potential expansions, new product introductions, and technology upgrades within the vaccine manufacturing process.
- Implement robust cost management practices and controls specific to vaccine manufacturing in Africa, considering factors such as local currency fluctuations, supply chain disruptions, and fluctuating commodity prices.
- Develop measurement tools to evaluate performance and make strategic operating and investment decisions
- Steer and oversee development and approve finance-related guidelines, policies, and procedures
- Oversee and ensure integrity of quarterly review/ performance management process for company functions
- Oversee all periodic and year-end closings, the year-end audit, and the preparation of consolidated financial statements. Manage the external accounting firm and audit relations. Communicate quarterly financial results to investors
- Set enterprise risk framework and monitor risk factors and trends
- Oversee and ensure effective tax planning and compliance with local tax regulations
- Continuously assess Finance structure and processes with focus toward implementing operational improvements that will facilitate and increase efficiency, quality of finance service, drive profitability and financial solvency of company
- Exercise authority and approve decisions on major finance and corporate matters
- Effectively lead a team of finance professionals by developing talent and cultivating a high-performance culture

Minimum years of experience required	15
Minimum educational level required	Masters and CPA/CFA
Degree majors typically studied	Business Administration, Finance, Economics, Accounting, Auditing, Taxation, Healthcare Management, Regulatory Affairs, Project Management, Communications, Leadership

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Business acumen • Financial acumen • Accounting • Financial statements • Financial reporting • Budgeting • Auditing • Audit management • Internal controls • Financial analysis • Financial forecasting • Tax planning • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion • Negotiation 	

Manager, Accounting

Roles and responsibilities

- Manages the accounting staff who are responsible for financial reporting, billing, collections, payroll, and budget preparation.
- Recruits and hires accounting and financial staff and conducts performance evaluations.
- Coordinates training programs for new staff and identifies training needs for current staff.
- Establishes internal controls and guidelines for accounting transactions and budget preparation.
- Oversees preparation of business activity reports, financial forecasts, and annual budgets.
- Oversees the production of periodic financial reports; ensures that the reported results comply with generally accepted accounting principles or financial reporting standards.
- Responsible for tax planning throughout the fiscal year; files annual corporate tax return.
- Audits accounts to ensure compliance with government regulations; coordinates with external auditors and provides needed information for the annual external audit.
- Presents recommendations to management on short- and long-term financial objectives and policies.
- Provides financial analysis with an emphasis on capital investments, pricing decisions, and contract negotiations.
- Ensures compliance with government requirements.

Minimum years of experience required	8
Minimum educational level required	Bachelors and CPA/CFA
Degree majors typically studied	Business Administration, Finance, Economics, Accounting, Auditing, Taxation, Communications, Leadership

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Business acumen • Financial acumen • Accounting • Financial statements • Financial reporting • Budgeting • Auditing • Audit management • Internal controls • Financial analysis • Financial forecasting • Tax planning • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Accountant




Roles and responsibilities

- Oversee the ongoing day-to-day maintenance of accounts.
- Ensure payroll is accurate and records are maintained.
- Support management in the accurate production of budgets.
- Reconcile accounts including receivable and payable.
- Ensure cashflow is utilized properly and protect reserves.
- Audit financial information for inconsistencies.
- Provide tax planning strategies in accordance with existing legislation.
- Create financial forecasts and analyze risk.

Minimum years of experience required	2
Minimum educational level required	Bachelors and CPA/CFA
Degree majors typically studied	Business Administration, Finance, Economics, Accounting, Auditing, Taxation

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

			
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	<ul style="list-style-type: none"> • Business acumen • Financial acumen • Accounting • Financial statements • Auditing • Financial analysis • Financial forecasting • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) 	 <ul style="list-style-type: none"> • Financial reporting • Budgeting • Internal controls • Tax planning 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	 <ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Financial Planning and Analysis Manager

Roles and responsibilities

- Managing the budgeting, forecasting and long-term planning process
- Analyzing actuals against budget/ forecast and prior year
- Lead analysis of Key Performance Indicators (KPIs), especially relating to financial metrics such as sales, expenditures, and profit margin.
- Monitor KPIs and identify the cause of any unexpected variances
- Support decision-making by providing stakeholders with timely, detailed, and meaningful insights and visibility on business performance
- Present the monthly and quarterly financial reports of various units and departments
- Develop financial models and analyze them to support strategic initiatives
- Support management team and the Heads of Department with data-driven analysis
- Perform ad-hoc analysis where required to assist in management decision making
- Monitor and analyze cost drivers across various departments, identifying opportunities for cost optimisation and efficiency improvements.
- Develop and implement cost control measures and initiatives to ensure the company's financial resources are utilized effectively and in line with budgetary targets.
- Identify and assess financial risks, including currency fluctuations, inflation, regulatory changes, and market uncertainties specific to Africa.
- Develop risk mitigation strategies and recommend actions to safeguard the company's financial stability and profitability.
- Evaluate potential investments and business opportunities, conducting financial analysis and feasibility studies to assess their viability and potential returns.
- Collaborate with cross-functional teams to prepare business cases and investment proposals, including financial projections, ROI analysis, and risk assessments, to secure funding for strategic initiatives.
- Analyze and report on financial impacts related to sustainability initiatives, including environmental stewardship, social responsibility, and corporate governance practices.
- Continuously evaluate and enhance financial planning and analysis processes, systems, and tools to improve efficiency, accuracy, and data integrity.

Minimum years of experience required	8
Minimum educational level required	Bachelors and CFP/CFA/CMA
Degree majors typically studied	Business Administration, Finance, Economics, Accounting, Financial Analysis, Financial Modelling, Communications, Leadership

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Business acumen • Financial acumen • Accounting • Financial statements • Financial reporting • Budgeting • Financial analysis • Financial forecasting • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation 	

Financial Planning and Analysis Analyst

Roles and responsibilities

- Analyze the trends of Key Performance Indicators (KPIs), especially relating to financial metrics such as sales, expenditures, and profit margin.
- Assists in monitoring KPIs and identify the cause of any unexpected variances
- Develop and continually improve budgeting, financial projections, and operating forecast
- Ad-hoc business performance reporting
- Present the monthly and quarterly financial reports of various units and departments
- Develop financial models and analyze them to support strategic initiatives
- Support management team and the Heads of Department with data-driven analysis
- Ensure accuracy, completeness, and integrity of financial data and reports.
- Collaborate with IT and Finance teams to enhance data collection, consolidation, and reporting processes.
- Continually enhance financial planning and analysis processes, tools, and methodologies to improve efficiency, accuracy, and effectiveness.
- Act as a resource for financial inquiries, providing guidance, insights, and recommendations based on analysis and financial expertise.

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Business Administration, Finance, Economics, Accounting, Financial Analysis, Financial Modelling

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Business acumen • Financial acumen • Accounting • Financial statements • Financial analysis • Financial forecasting • Analytics tools (e.g., Excel, Power BI, Tableau, Alteryx) 	<ul style="list-style-type: none"> • Financial reporting • Budgeting 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

IT

IT Manager

Roles and responsibilities

- Manage information technology and computer systems
- Plan, organize, control, and evaluate IT and electronic data operations
- Manage IT staff by recruiting, training, and coaching employees, communicating job expectations, and appraising their performance
- Design, develop, implement, and coordinate systems, policies, and procedures
- Ensure security of data, network access and backup systems
- Act in alignment with user needs and system functionality to contribute to organisational policy
- Identify problematic areas and implement strategic solutions in time
- Audit systems and assess their outcomes
- Preserve assets, information security and control structures
- Handle annual budget and ensure cost effectiveness
- Evaluate, select, and manage relationships with IT vendors and service providers, negotiating contracts and service level agreements to ensure optimal performance and cost-effectiveness.
- Coordinate with vendors for system upgrades, maintenance, and technical support, ensuring timely resolution of IT-related issues.
- Establish and enforce IT policies, procedures, and controls to mitigate risks, maintain compliance, and promote efficient and secure IT operations.
- Conduct periodic IT audits to assess compliance with internal policies and external regulations, addressing any identified gaps or vulnerabilities.
- Provide training and support to end-users on IT systems, applications, and tools, ensuring employees have the necessary skills and knowledge to effectively use technology in their roles.
- Foster a culture of IT awareness and security consciousness among employees, promoting best practices for data handling, password management, and cybersecurity.

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, Information Technology, Computer Engineering, Management Information Systems, Business Information Systems, Project Management, Cybersecurity, Data Science, Communications, Leadership, Regulatory Compliance

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			<ul style="list-style-type: none"> • Technical management • Information analysis • Computer hardware and software systems • Data centre management • Data governance • Data security • Database management • Computer networks • Network administration • Network installation • Programming • Program architecture • Software development • Agile development methodologies 	
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and verbal communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion 	

IT Analyst

Roles and responsibilities

- Analyzing current IT systems, architectures, and processes.
- Identifying risks, opportunities, faults, and areas for development within the company's IT framework.
- Designing IT solutions and solving issues effectively.
- Executing well-thought-out solutions and plans to improve company efficiencies.
- Maintaining robust systems processes and ensuring compliance with relevant regulatory bodies.
- Developing new IT methods and solutions for the business.
- Reporting issues, advances made, and other important information to stakeholders.
- Advising management on weak points, avenues for improvement, and risks in the company's IT infrastructure.
- Strategizing with other key stakeholders on how to best align IT systems with company objectives.
- Facilitate the implementation of new IT systems and technologies, ensuring smooth transitions, user acceptance, and minimal disruption to business operations.
- Develop and deliver user training programs, workshops, and documentation to educate employees on the effective use of IT systems and promote IT literacy within the organization.
- Assist in the development and enforcement of IT policies, procedures, and controls to ensure regulatory compliance, data privacy, and information security.
- Participate in IT audits and assessments to verify compliance with industry standards, regulatory requirements, and internal policies.

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, Information Technology, Computer Engineering, Business Information Systems

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Information analysis • Computer hardware and software systems • Data security • Database management • Computer networks • Network administration • Network installation • Programming • Software development 	<ul style="list-style-type: none"> • Data centre management • Data governance • Program architecture • Agile development methodologies 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

IT System Administrator

Roles and responsibilities

- Install and configure software and hardware
- Manage network servers and technology tools
- Set up accounts and workstations
- Provide user support and troubleshooting assistance for account-related issues, password resets, and access requests.
- Monitor performance and maintain systems according to requirements
- Troubleshoot issues and outages
- Ensure security through access controls, backups, and firewalls
- Upgrade systems with new releases and models
- Train staff on new technologies
- Build technical documentation, manuals, and IT policies for various systems
- Respond to and resolve IT-related incidents and service requests, adhering to established service level agreements (SLAs) and maintaining a high level of customer satisfaction.
- Perform root cause analysis to identify the underlying causes of incidents, implement corrective actions, and prevent recurrence.
- Assist in conducting IT audits and assessments, implementing corrective actions, and maintaining audit trails and documentation for regulatory compliance purposes.

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Computer Science, Information Technology, Computer Engineering, Business Information Systems, Management Information Systems, Cybersecurity, Regulatory Compliance

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	←			→
	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities	<ul style="list-style-type: none"> • Computer hardware and software systems • Computer networks • Network administration • Network installation • Troubleshooting • System maintenance • Database management • Programming • Software development 	<ul style="list-style-type: none"> • Data center management • Data governance • Program architecture • Agile development methodologies 		
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and verbal communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 		

