

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)

Foreword

I am delighted to introduce the Competency Frameworks for Vaccine Manufacturing and Research and Development Competency Frameworks, which have been prepared through collaborative efforts with key stakeholders in the industry, supported by Africa Centres for Disease Control and Prevention (Africa CDC). The Competency Frameworks are essential tools for ongoing assessment of training needs, the development of curricula and transparency of course offerings.

Established in 2021 by the African Union (AU), the Partnerships for African Vaccine Manufacturing (PAVM) set to deliver a bold goal of enabling the African vaccine manufacturing industry to develop, produce, and supply over 60 percent of the total continental vaccine demand by year 2040, up from the current less than 1 percent. Interim goals have also been set to achieve 10 percent by 2025 and 30 percent by 2030. The Framework for Action (FFA), a guiding document of PAVM, outlines critical strategies and interventions to enable the development and foster the growth of a sustainable vaccine manufacturing industry in Africa.

The African vaccine research, development, and manufacturing sector currently employs approximately 3,000 Full-time Employees (FTEs), which is markedly insufficient compared to the 12,500 FTEs required to realize Africa's 2040 ambitions. This shortfall represents a significant challenge in scaling up vaccine manufacturing and the development of R&D talent across the continent.

The Frameworks delineated in this report are not merely theoretical constructs. They serve as pragmatic tools in our journey towards self-reliance in vaccine manufacturing in pursuit of vaccine self-sufficiency. These Frameworks, among other applications, underpin the development of tools for assessment of vaccine manufacturing and vaccine R&D needs. These assessment tools, to be rolled out by Africa CDC, are designed to map training needs and guide initiatives for talent development. Moreover, they provide consistency in nomenclature and enhance transparency in educational program offerings. As such, we hope they will become invaluable resources for training providers, vaccine manufacturers and research institutions.

I wish to extend my profound gratitude to the Secretariat of the PAVM and to all the dedicated individuals and organizations involved in formulating these frameworks. I am equally indebted to the esteemed experts whose insights and expertise assure these Frameworks' integrity and relevance.

As we embark on this noble endeavour, I call upon all stakeholders to unite. Together, we can bolster talent development and research and development capabilities on the continent. May these competency frameworks be instrumental in achieving the aim of having the African vaccine manufacturing industry develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040.

Looking ahead to the New Deal and the New Public Health Order for Africa, we must strive for a continent that is self-reliant not only in vaccine production but in all aspects of healthcare provision.

H.E. Dr Jean Kaseya

Director General, Africa Centres for Disease Control and Prevention (Africa CDC)



Executive Summary

The African Union and the Africa 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 Africa Centres for Disease Control and Prevention (Africa CDC). The continent 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, with interim targets of 10% by 2025 and 30% by 2030.

A principal challenge in realising AU'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, the PAVM Secretariat working with experts in the field, 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 is part one of two which lays out one of these two frameworks; the vaccine manufacturing competency 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 on the Africa CDC 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.

Africa CDC 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 healthcare sector.

Introduction

The African Union (AU) and Africa Centres for Disease Control and Prevention (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, therapeutics and other health products. 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 across drug substance (DS), drug product (DP) manufacturing and R&D. PAVM has developed a vision to respond to the vaccine manufacturing talent needs that is shown in Figure 1.

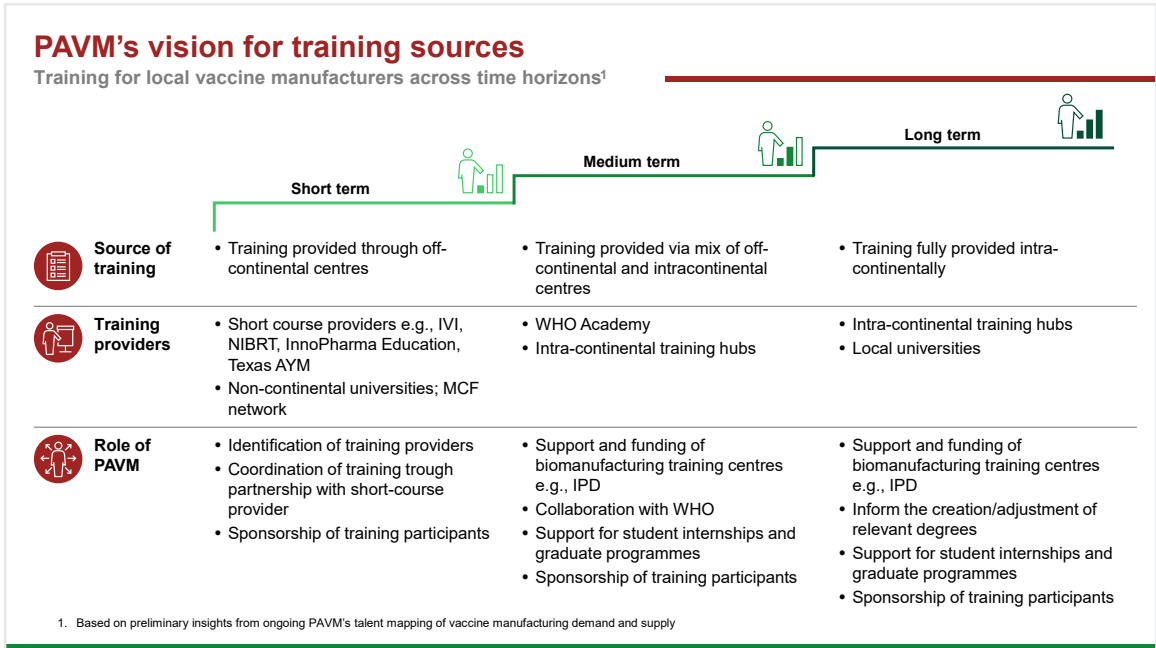


Figure 1. PAVM's vision to respond to Africa's vaccine manufacturing talent needs

The development of vaccine manufacturing talent in Africa currently relies on programmes offered outside the continent to satisfy the short-course 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 Korea in 2021. A similar amount was spent in 2023 for subsequent short course training.

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:

- i. A lack of clarity regarding the most pressing training needs across the continent
- ii. The absence of a comprehensive training needs catalogue
- iii. 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:

- a. 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. R&D and vaccine manufacturing experts reviewed a first draft
- f. Groups of experts conducted final peer reviews and suggested refinements to the competency frameworks.

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

- i. African Vaccine Manufacturing Initiative (AVMI)
- 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

On 10 November 2023 it was further validated and accepted by additional experts of bio-manufacturers, member states, NRAs and global partners.



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 researchers, manufacturers, curricula developers and other stakeholders.

Africa CDC 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 manufacturers and research organisations to reach out to pavm@afriacdc.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.



Appendix

Vaccine Manufacturing Competency Framework

Vaccine Manufacturing Competency Mapping

▀ Drug substance
 ▀ Drug product

		CEO/ GM							
FUNCTIONS	Tech-Operations/ MSAT	Operations	Quality	Automation	Regulatory Affairs	Supply Chain	Maintenance / Engineering	Support	
		DS Tech Ops/ MSAT 6 roles	DS Operations 4 roles	DS Quality Control 5 roles	DS Automation 3 roles	Regulatory Operations 4 roles	Procurement 2 roles	Instrumentation 4 roles	Marketing and Sales 7 roles
	DP Tech Ops/ MSAT 6 roles	DP Operations 4 roles	DS Quality Assurance 3 roles	DP Automation 3 roles	Submission Preparation 2 roles	Materials planning 3 roles	Mechanical 5 roles	Legal 5 roles	
SUB-FUNCTIONS		Operations excellence 2 roles	DP Quality Control 5 roles		Policy and Labelling 2 roles	Logistics 3 roles	HVAC 2 roles	HR 9 roles	
			DP Quality Assurance 3 roles				Capital projects 2 roles	Finance 5 roles	
			Cross-functional QA 2 roles				Utilities 2 roles	IT 3 roles	
							Environmental, Health & Safety 2 roles		

The pages that follow represent the role cards behind each sub-function. The role cards include a description of responsibilities and required competencies for specific roles within each sub-function

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 organisation
- 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 organisational 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 oral communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Thought leadership • Team management • Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Tech-Operations/MSAT

DS Tech Ops/MSAT

Head, Drug Substance MSAT

Roles and responsibilities


- Contribute to strategy development to ensure that processes for 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 drug substance (DS) processes and associated control strategies)
- Lead a team of manufacturing, science and technology (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 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

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts



	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 oral 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 operations during drug substance manufacturing at a client facility
- Lead a team of scientists and engineers responsible for technical floor support of ongoing manufacturing
- Manage 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 current good manufacturing practice (cGMP) environment
- Review and author standard operating procedures (SOPs) and 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 manufacturing, science and technology (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) ● Corrective and preventive actions (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 oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 oral communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Production Technician

Roles and responsibilities

- If required, be able to fulfill typical operations duties, including but not limited to setting up, operating, monitoring and controlling equipment, systems and processes within assigned area
- Perform equipment maintenance, including restoration of lost function, predictive and preventative maintenance
- Perform industrial processes, including fermentation and purification
- Perform corrective maintenance and troubleshooting for vaccine processing and packaging equipment utilising diagnostic equipment and programmable logic controllers (PLCs) 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 (SOPs) and other documents as required
- Train fellow employees in areas of expertise and purposefully learn systems and equipment outside of own area of expertise
- Support manufacturing, science and technologies (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, heating, ventilation and air conditioning (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"> • Enterprise resource planning (ERP) applications • Logbooks • Environmental monitoring 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Manager, Process Validation

Roles and responsibilities

- Provide overall leadership to the drug substance (DS) validation team, including but not limited to prioritisation of workload, troubleshooting validation activities, completion of training requirements and group problem solving
- Define process validation strategies
- Generate and execute validation protocols and write 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
- 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 • Corrective and preventive actions (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 oral 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, 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 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 analyses
- 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 • Corrective and preventive actions (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 oral communication • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

DP Tech Ops/MSAT

Head, DP Tech Ops/MSAT

Roles and responsibilities

- Lead drug product (DP) manufacturing, science and technologies (MSAT) responsible for current good manufacturing practice (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 DP Process Development, Manufacturing and Quality and external contract manufacturing organisations (CMOs) 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
- Contribute to chemistry, manufacturing and controls (CMC) development cycles of individual products
- Provide input into commercial process design, process failure model and effects analysis (FMEA), process characterisation studies, control strategies, dossier and responses to questions from agencies as well driving compliance with medical device combination regulation
- 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

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 practice methodologies, to ensure robust and predictable process operation during drug product manufacturing at a facility
- Lead 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
- Manage a team dedicated to the management and analysis of critical manufacturing data and process modelling
- Review standard operating procedures (SOPs) and 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 transfer and validation specialists responsible for effective transfer of processes and technology from the Process Development group into a current good manufacturing practice 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 ongoing 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
- Ensure top performance management by personnel in the manufacturing, science and technologies (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

Process Engineer

Roles and responsibilities

- Process design for tangential flow filtration (TFF) and chromatography systems
- Provide support for filtration-based purification technologies as needed
- Contribute to initial process validation and process control strategy
- Introduce new products and processes at manufacturing scale
- Monitor processes and conduct root cause investigations
- 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
- Carry out change assessments, de-bottlenecking and continuous improvement
- Support 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 • Corrective and preventive actions (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 	<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 oral 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 setting up, operating, monitoring and controlling equipment, systems and processes within assigned area
- Perform equipment maintenance, including restoration of lost function, predictive and preventative maintenance
- Perform industrial processes, including formulation, filling, lyophilisation, primary packing and inspection
- Perform corrective maintenance and troubleshooting for vaccine processing and packaging equipment utilising diagnostic equipment and programmable logic controllers (PLCs) 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 (SOPs) and other documents, as required
- Train fellow employees in areas of expertise and purposefully learn systems and equipment outside of own area of expertise
- Support manufacturing, science and technologies (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, heating, ventilation and air conditioning (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"> • Enterprise resource planning (ERP) applications • Logbooks • Environmental monitoring 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral 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 drug product (DP) validation team, including but not limited to prioritisation of workload, troubleshooting validation activities, completion of training requirements and group problem solving
- Define process validation strategies
- Generate and execute validation protocols and write final reports
- Conduct sampling
- Support the development and validation of industrial processes including formulation, filling, lyophilisation, 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
- 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, defence 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

Process Validation Engineer

Roles and responsibilities

- Support 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

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 (DS) operational areas (i.e., project management, maintenance, finance, supply chain, manufacturing, science and technologies (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 effectively to 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 significant focus on continuous improvement programmes, development of KPIs, business problem resolution and reviewing key initiative plans
- Conduct financial analyses of certain initiatives including new business opportunities for site as needed
- Develop operating budget
- Identify critical business opportunities and effectiveness needs and 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 that vision
- Support team development and growth, including hiring, coaching and mentoring of team members
- Co-operate with other departments to obtain consensus and achieve site and operational goals
- Ensure 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

Manager, DS Operations


Roles and responsibilities

- Review and approve technical and quality-related documentation (e.g., process and instrumentation diagrams, validations and design documents)
- Provide troubleshooting and problem-solving guidance for daily project and manufacturing issues
- Implement corrective and preventive actions (CAPAs)
- Develop and execute production schedules from project through full scale manufacturing, ensuring project support and production activities are executed in accordance with 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 (i.e., escalation, cascading)
- Ensure compliance with good manufacturing practice (GMP) requirements, develop quality continuous improvement initiatives and develop staff quality culture and GMP knowledge
- Ensure 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 facilities and 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
- Organise 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 ● Corrective and preventive actions (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 oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 current good manufacturing practice (cGMP) compliance and be audit ready at all times
- Coordinate the workload of your team to ensure batch loss and material loss are prevented and 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
- Facilitate and support new product introductions
- Engage and consult with senior leaders, analysing organisational challenges
- Ensure process documentation is completed properly and in accordance with cGMP guidance
- Monitor safety of team members and working conditions and escalate safety issues according to environmental health and safety (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 • Corrective and preventive actions (CAPAs) • Change control • Good manufacturing practices (GMP) • Standard operating procedures • Fermentation • Chromatography • Purification • Tangential flow filtration (TFF) • Packing • Cell cultures • Aseptic technique • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral 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

Technician, DS Operations


Roles and responsibilities

- Maintain a safe working environment and reporting of incidents/accidents to Manufacturing management.
- Effectively demonstrate understanding of good manufacturing practices (GMPs) and how they apply to specific responsibilities
- Follow oral and written procedures in operating production and equipment and performing processing steps; accurately complete appropriate production documentation
- Maintain cleanliness and orderliness in process area
- Ensure production area is stocked with supplies
- Perform electronic work instruction (EWI) revisions and work order generation
- Interact with other support functions such as Quality Assurance, Quality Control, MSAT etc.
- Utilise manufacturing knowledge to improve process operations and effect positive change
- Perform in-process testing of batch samples utilising various physical testing instruments
- Operate material handling equipment such as forklifts, drum lifters and pallet jacks
- Troubleshoot basic mechanical operations
- Collect samples of raw materials, intermediates and finished products utilising appropriate sampling tools and techniques
- Contribute to continuous improvement of all manufacturing documentation (standard operating procedures (SOPs), EWIs, master batch records (MBRs), on-the-job training (OJT)) to ensure they are current, accurate and clear
- Support 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 • Corrective and preventive actions (CAPAs) • Good manufacturing practices (GMP) • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral 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 (DP) operational areas (i.e., Project Management, Site Maintenance, Finance, Supply Chain, MSAT and other stakeholders)
- Build and maintain a comprehensive understanding of all site functions and apply that knowledge effectively to 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 significant focus on continuous improvement programmes, development of KPIs, business problem resolution and reviewing key initiative plans
- Conduct financial analyses of certain initiatives including new business opportunities for site as needed
- Develop operating budget
- Identify critical business opportunities and effectiveness needs and 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 that vision
- Support team development and growth, including hiring, coaching and mentoring of team members
- Co-operate with other departments to obtain consensus and achieve site and operational goals
- Ensure 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 oral 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 in accordance with 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 good manufacturing practice (GMP) requirements, develop quality continuous improvement initiatives and 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 ● Corrective and preventive actions (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 oral 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 current good manufacturing practice (cGMP) compliance and be audit ready at all times
- Coordinate the workload of your team to ensure batch loss and material loss is prevented and 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
- Facilitate and supporting new product introduction.
- Engage and consult with senior leaders, analysing organisational challenges
- Monitor safety of team members and working conditions; escalate safety issues according to environmental health and safety (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 • Corrective and preventive actions (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 oral 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

Technician, DP Operations

Roles and responsibilities

- Maintain a safe working environment and report of incidents/accidents to Manufacturing management
- Demonstrate understanding of good manufacturing practices (GMPs) and how they apply to specific responsibilities
- Follow oral and written procedures in operating production and equipment and performing processing steps; accurately complete appropriate production documentation
- Maintain cleanliness and orderliness in process area
- Ensure production area is stocked with supplies
- Perform electronic work instruction (EWI) revisions and work order generation
- Interact with other support functions such as Quality Assurance, Quality Control, MSAT etc.
- Utilise manufacturing knowledge to improve process operations and effect positive change
- Perform in-process testing of batch samples utilising various physical testing instruments
- Operate material handling equipment such as forklifts, drum lifters and pallet jacks
- Troubleshoot basic mechanical operations
- Collect samples of raw materials, intermediates and finished products utilising appropriate sampling tools and techniques
- Contribute to continuous improvement of all manufacturing documentation (standard operating procedures (SOPs), EWIs, master batch records (MBRs), on-the-job training (OJT)) to ensure they are current, accurate and clear
- Support 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) • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral 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 CI 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
- Utilise digitisation opportunities to reduce waste in the site processes, drive simplification for the customer and deploy 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 accreditation

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 oral 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 CI 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
- Utilise digitisation opportunities to reduce lean waste in site processes; drive simplification for the customer and deploy 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 accreditation

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 oral 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

- Achieve quality and business results through partnerships across site
- Achieve and maintain compliance against national and international standards, as appropriate
- Quality plans: ensure the creation and execution of a site quality master plan and a 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 (DS) and drug product (DP) manufactured at the site
- Lead the design, implementation, maintenance and continuous improvement of the quality requirements of clinical DS and DP 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
- Report key performance indicators (KPIs) and undertake periodic reviews of quality systems
- Establish systems and processes within Quality and a wider analytical platform to ensure that quality assurance (QA) and quality control (QC) procedures, systems, data and documentation comply with current good manufacturing practice (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 DS and DP 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; meet national regulatory authority (NRA) expectations regarding timely notification of events
- Product disposition: ensure independent and timely product disposition using validated processes, batch records data reviews, analytical methods and documented decision-making processes
- Technology and science: hold self and others accountable for making decisions, solving problems, and/or driving improvements through a sound understanding of the technology and science of the products
- Operational excellence (OE): drive innovation and continuous improvement through OE in all quality activities and support 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

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 the Quality Control Team (QC) in support of the manufacturing of drug substance (DS) manufactured at the site
- Lead the design, implementation, maintenance and continuous improvement of the quality control requirements of clinical DS 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
- Monitor key performance indicators (KPIs)
- Establish systems and processes within QC and wider analytical platform to ensure that QC procedures, systems, data and documentation comply with current good manufacturing practice (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 DS platform for project development, manufacture and supply
- Represent QC during internal audits and regulatory inspections
- Issue resolution: ensure there are clear and timely action plans for issue resolution with appropriate escalation, communication and closure
- Stability testing: ensure all marketed product stability testing is completed/reviewed in a timely manner; meet national regulatory authority (NRA) expectations regarding timely notification of events
- 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

QC Manager

Roles and responsibilities

- Accountable for ensuring on-time delivery of completed test certificates and documentation
- Ensure test result accuracy and compliance with current good manufacturing practice (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 approve critical reagent qualification and expiry date extension reports
- Ensure monthly reviews of logbooks completion
- Accurately compile data for tests, products and trends for statistical reports to support regulatory questions and/or submissions as required; perform laboratory information management systems (LIMS) queries as required
- Responsible for organising and managing documents in accordance with department and corporate policies
- Review existing standard operating procedures (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
- Notify Department Head of any laboratory non-conformances
- Lead investigations and provide required support documentation to expedite closure of deviations
- Compile data to support regulatory submissions, audits and root cause analysis as required
- Ensure the timely filing and completion of all good practice (GxP) documents associated with the role
- Support LIMS-related test analysis updates
- Assist with equipment commissioning and decommissioning, qualification and validation
- Ensure appropriate periodic test validation where necessary
- Coordinate 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

QC Supervisor

Roles and responsibilities

- Effectively coordinate the execution of quality control (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 current good manufacturing practice (cGMP) requirements
- Write/revise standard operating procedures (SOPs), technical protocols and reports
- Work with the QC team to continuously improve the quality, compliance and efficiency of QC operations
- Coordinate accurate compiling of data for tests, products and trends for statistical reports; 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
- Train other laboratory staff on method execution and troubleshooting
- Provide 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 (SOPs) • Instrumentation • Good manufacturing practices (GMP) • Good laboratory practices (GLP) 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<ul style="list-style-type: none"> • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion

QC Technician

Roles and responsibilities

- Ensure 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 types of test (e.g., high-performance liquid chromatography (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 (GMP) for products and processes
- Maintain area housekeeping standards and environmental specifications by using a variety of sanitising aids
- Support implementation of new technology for process execution and/or analysis
- Maintain current training status on all applicable standard operating procedures (SOPs)
- Execute SOPs 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 	<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 • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

QC Analyst

Roles and responsibilities

- Test samples utilising a range of chemical, biochemical and biological tests in accordance with regulatory requirements and agreed schedules
- Apply knowledge of physiochemical testing to product testing and stability data
- Test specifications and sampling regimes and the impact they may have on the product
- 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
- Maintain detailed laboratory records in compliance with current good manufacturing practice (cGMP) using controlled proforma/laboratory notebooks
- Ensure all records and test results are accurately prepared and 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 corrective and preventive actions (CAPAs)
- Assist with product investigations and test anomalies
- Be responsible for quality management systems (QMS) records
- Be responsible for routine maintenance of laboratory equipment and ensuring records are adequately maintained
- Ensure the department is kept in a safe, clean and orderly fashion and maintained in an inspection-ready state
- Facilitate the ordering of laboratory consumables to ensure efficient running of the laboratory
- Record incoming samples according to the appropriate standard operating procedures (SOPs)
- Ensure all samples and materials are handled safely following departmental procedures
- Participate in the validation of test methods and equipment used in analysis to meet regulatory requirements
- Implement 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 • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

DS Quality Assurance

QA Department Head


Roles and responsibilities

- Achieve quality and business results through partnerships across site
- Create a high-performance Quality Team culture with goals and values aligned with broader organisation, including creation of a collaborative team environment
- Oversee the conduct of talent management programmes to develop future site leaders, including the creation of robust succession plans for the site
- Direct, oversee and participate in the recruitment, selection, promotion, termination and performance management of site personnel in leadership and critical roles
- Issue resolution: ensure the creation and implementation of clear and timely action plans for issue resolution with appropriate escalation, communication and closure
- Regulatory excellence: ensure sustainable regulatory excellence through systems, science, people and continuous process improvements
- Ensure a favorable site regulatory profile through constant inspection readiness programmes
- Create effective relationships with regulatory agencies to create trust and credibility
- Prepare the site for changes to regulations
- Quality systems: ensure site is compliant with quality systems and marketing authorisations
- Quality plans: ensure the creation and execution of a site quality master plan and a site quality and compliance annual business plan
- Industry standards: drive 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 follow and anticipate impact of emerging regulations on site operations and prepare site for implementation and change as appropriate
- Product disposition: ensure independent and timely product disposition using validated processes, analytical methods and documented decision-making processes
- Technology and science: hold self and others accountable for making decisions, solving problems, and/or driving improvements through a sound understanding of the technology and science of the products
- Operational excellence (OE): drive innovation and continuous improvement through OE in all quality activities and support 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 (SOPs)_ ● 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 oral 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

- Manage the Quality Department team that covers all good manufacturing practice (GMP)/good distribution practice (GDP) quality tasks
- Contribute to compliance and quality gap analysis
- Deliver quality agreement (QA) 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
- Implement a quality management system (QMS) based on company standards and procedures and international and local applicable GMP and GDP regulations
- Implement a quality risk management process on the QMS
- Ensure quality systems, processes, specifications and standard operating procedures (SOPs) are designed to be appropriate for the development, manufacture, testing, timely release and distribution of quality product, consistent with quality strategy and meet all relevant regulatory requirements and guidance
- Ensure products are manufactured in accordance with current good manufacturing practice (cGMP), 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 the company's GMP/GDP vendors
- Interact with regulatory authorities with regard to the company's licences 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

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

QA Analyst

Roles and responsibilities

- Maintain current good manufacturing practice (cGMP) within assigned areas in compliance with company policies and national regulatory authority (NRA) regulations
- Review as needed and approve batch records
- Carry out investigations, process qualifications and validation studies and participate in quality audits of the manufacturing areas to ensure compliance with cGMPs
- Support pre-approval inspection and regulatory filing related activities
- Support sampling requirements and perform material control functions and accountability reviews
- Make 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 track/report 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 	<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) • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<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 (QC) professionals
- Lead the Quality Control Team in support of the manufacturing of drug substance (DS) manufactured at the site
- Lead the design, implementation, maintenance and continuous improvement of the QC requirements of clinical DS 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 current good manufacturing practice (cGMP), data integrity requirements and regulations
- Manage activities related to change control and corrective and preventive actions (CAPAs) as required
- Review or approve data and commentary generated for regulatory submissions as required
- Ensure quality control systems and processes are aligned with the rest of the DS platform for project development, manufacture and supply
- Represent QC 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 all marketed product stability testing is completed/reviewed in a timely manner; meet national regulatory authority (NRA) expectations regarding timely notification of events
- Ensure test methods related to QC are validated and/or verified in accordance with 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 oral 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

- Ensure on-time delivery of completed test documentation
- Ensure accuracy and compliance with current good manufacturing practice (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 approve critical reagent qualification and expiry extension reports
- Ensure monthly reviews of logbooks are completed
- Compile accurate data for tests, products and trends for statistical reports; support regulatory questions and/or submissions as required; perform laboratory information management systems (LIMS) queries as required
- Organise and manage documents in accordance with department and corporate policies
- Review existing standard operating procedures (SOPs) and initiate revisions/approvals of existing or new SOPs, protocols, reports and test summaries as required
- Manage activities related to change control and corrective and preventive actions (CAPAs) as required
- Notify Department Head of any laboratory non-conformances
- Lead investigations and provide required support documentation to expedite closure of deviations
- Compile data to support regulatory submissions, audits and root cause analysis as required
- Ensure the timely filing and completion of all good practice (GxP) documents associated with the role
- Support LIMS-related test analysis updates
- Assist with equipment commissioning and decommissioning, qualification and validation
- Coordinate maintenance and re-certification/recalibration of equipment
- Manage 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 oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Attention to detail ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

QC Supervisor

Roles and responsibilities

- Coordinate the execution of quality control (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 current good manufacturing practice (cGMP) requirements
- Write/revise standard operating procedures (SOPs), technical protocols and reports
- Work with the QC team to continuously improve the quality, compliance and efficiency of QC operations
- Coordinate accurate compilation of data for tests, products and trends for statistical reports and support regulatory questions and/or submissions as required; perform laboratory information management systems (LIMS) queries as required
- Manage activities related to change control and corrective and preventive actions (CAPAs) as required
- Notify QC Manager/QC Department Head of any laboratory non-conformities
- Lead investigations and provide 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
- Train other laboratory staff on method execution and troubleshooting
- Provide 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 oral communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<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 practice (GMP) for products and processes
- Maintain area housekeeping standards and environmental specifications by using a variety of sanitising 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 (SOPs) for unit operations
- Notify QC Manager/QC Department Head of any laboratory non-conformities
- Participate in investigations and provide required support documentation to expedite closure of deviations
- Participate in validation of test methods and equipment used in analysis to meet regulatory requirements
- Implement 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 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 • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

QC Analyst

Roles and responsibilities

- Test samples utilising a range of chemical, biochemical and biological tests in accordance with regulatory requirements and agreed schedules
- Apply knowledge of physiochemical testing to product testing and stability data
- 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., high-performance liquid chromatography (HPLC), viral load tests, sterility tests, etc.)
- 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
- Maintain detailed laboratory records in compliance with current good manufacturing practice (cGMP) using controlled proforma/laboratory notebooks
- Ensure all records and test results are accurately prepared and peer reviewed prior to submission for approval and authorisation according to company, customer and regulatory requirements
- Record deviations from normal practice appropriately, report them to the QC Supervisor/Manager and develop appropriate corrective and preventive actions (CAPAs)
- Assist with product investigations and test anomalies
- Maintain quality management systems (QMS) records
- Undertake routine maintenance of laboratory equipment and ensure records are adequately maintained
- Ensure the department is kept in a safe, clean and orderly fashion and maintained in an inspection-ready state
- Facilitate the ordering of laboratory consumables to ensure efficient running of the laboratory
- Record incoming samples according to the appropriate standard operating procedures (SOPs)
- Ensure all samples and materials are handled safely following departmental procedures
- Participate in the validation of test methods and equipment used in analyses to meet regulatory requirements
- Implement 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 • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

DP Quality Assurance

QA Department Head

Roles and responsibilities

- Oversee the management of training, motivation and development of a team of quality assurance (QA) professionals
- Lead a Quality Control Team in support of the manufacturing of drug substance (DS) manufactured at the site
- Lead the design, implementation, maintenance and continuous improvement of the quality control (QC) requirements of clinical DS manufacture and release
- Ensure change controls, quality deviations, out-of-specification results and quality/business risks associated with this 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 current good manufacturing practice (cGMP), data integrity requirements and regulations
- Manage activities related to change control and corrective and preventive actions (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 DS platform for project development, manufacture and supply
- Represent QC 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 all marketed product stability testing is completed/reviewed in a timely manner and meets national regulatory authority (NRA) expectations regarding timely notification of events
- Ensure that test methods related to QC are validated and/or verified in accordance with 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

			
	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 oral 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

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

QA Manager


Roles and responsibilities

- Managing the Quality Department team that covers all good manufacturing practice (GMP)/good distribution practice (GDP) quality tasks
- Contribute to compliance and quality gap analyses
- Negotiate of quality agreement (QA) plan
- Deliver QA 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
- Implement a quality management system (QMS) based on company standards and procedures, international and local applicable GMP and GDP regulations
- Implement a quality risk management process on the QMS
- Ensure quality systems, processes, specifications and standard operating procedures (SOPs) are designed to be appropriate for the development, manufacture, testing, timely release and distribution of quality product, consistent with quality strategy and meet all relevant regulatory requirements and guidance
- Ensure products are manufactured in accordance with current good manufacturing practice (cGMP), 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 with regard to the company's licences 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 programme 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) ● Enterprise resource planning (ERP) applications
Leadership & functional capabilities			<ul style="list-style-type: none"> ● Written and oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Attention to detail ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

QA Analyst

Roles and responsibilities

- Maintain current good manufacturing practice (cGMP) within assigned areas in compliance with company policies and NRA regulations
- Ensure cGMP is utilised for all batch/facility cleaning documentation, change control and day-to-day operations for a bulk sterile/aseptic process
- Review and approve batch records as needed
- Carry out investigations, process qualifications and validation studies and participate in quality audits of the manufacturing areas/service providers to ensure compliance with cGMP
- Support pre-approval inspection and regulatory filing related activities
- Support sampling requirements and perform material control functions and accountability reviews
- Make 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 track/report metrics
- Review and approve minor deviations, change controls and corrective and preventive actions (CAPAs)
- Perform statistical analyses 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 	<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) • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Cross-functional QA

QA IT Compliance Manager

Roles and responsibilities

- Provide application support and undertake maintenance activities for the quality management system (QMS) including user access, system troubleshooting, end-user process support and change control
- Troubleshoot interface issues with QMS, enterprise resource planning (ERP) and other Quality IT tools/systems
- Participate in ongoing technical training for the development of skills with emphasis on compliance and QMS platform
- Undertake 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, standard operating procedures (SOPs) and training
- Execution support for changes to existing applications
- Creation and delivery of QMS training
- Provide guidance and oversight for global computerised 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 ● Enterprise resource planning (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 oral 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 current good practice (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 quality management system (QMS) platforms.
- Maintain key performance indicators (KPIs) for QMS pertaining to document control
- Work with authors to coach them on the generation of ALCOA-compliant documents
- Maintain audit readiness for document control
- Provide support for corporate and regulatory audits
- Review standard operating procedures (SOPs), determine gaps and provide input 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
- Understand electronic documentation and/or database system processes and communicate 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 • Enterprise resource planning (ERP) applications 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral 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 current good manufacturing practice (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
- Optimise the functionality of networks and systems, including diagnosing and recovering failed systems
- Participate in cybersecurity-related initiatives as directed including backup testing and disaster recovery planning and testing
- Act as a 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 programme for all alarms defined in the system
- Assist in developing a master plan for assigned system
- Direct 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 made to 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 	<ul style="list-style-type: none"> • Change control • Cloud computing 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<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 and 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 stages of strategic projects and partner with product management to build project business cases
- Lead end-to-end robotics process automation and 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 dynamics 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 oral 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 current good manufacturing practices (cGMPs) and safety and environmental regulations
- Undertake system upgrades, troubleshoot issues, identify trends, monitor processes; manage system administration, documentation updates, data querying and operator training and participate 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 be prepared to speak knowledgeably about automation, process and cGMP as it relates to manufacturing operations
- Evaluate automated and information technology systems and develop strategies to optimise and ensure the quality and stability of automation systems through future expansion, replacement or upgrade
- Use technical knowledge to assure the efficient operation of a variety of automated processes, and information technology systems and comply with regulations
- Develop solutions for automation problems
- Participate in and contribute to investigations of automation anomalies to prevent 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 apply computerised 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
- Be 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 oral 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 current good manufacturing practice (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
- Optimise the functionality of networks and systems, including diagnosing and recovering failed systems
- Participate in cybersecurity-related initiatives as directed including backups testing and disaster recovery planning and testing
- Act as a 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 an alarm management programme for all alarms defined in the system
- Assist in developing master plan for assigned system
- Direct 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 made to 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 	<ul style="list-style-type: none"> • Change control • Cloud computing 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<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 and 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 and 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 dynamics 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 oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Attention to detail ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Automation Engineer

Roles and responsibilities

- Understand and support current good manufacturing practice (cGMP), safety and environmental regulations
- Undertake system upgrades, troubleshoot issues, identify trends, monitor processes, manage system administration, documentation updates, data querying, operator training and participate 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 be prepared to speak knowledgeably about automation, process and cGMP details of manufacturing operations
- Evaluate automated and information technology systems and develop strategies to optimise and ensure the quality and stability of automation systems through future expansion, replacement, or upgrade
- Use technical knowledge to assure the efficient operation of a variety of automated processing and information technology systems
- Develop solutions for automation problems
- Participate in and contribute to investigations of automation anomalies to prevent 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 apply computerised 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
- Be 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 oral communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring 	<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 into 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 for national regulatory agencies (NRAs) for all assets)
- Advocate scientifically-sound approaches persuasively to senior leaders at company and to 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 represent Regulatory Affairs function and clearly outline its progress, opportunities for improvement and help needed from broader organisation
- Have complete oversight of the manufacturing and distribution of medicines and scheduled substances in terms of the provisions of relevant 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 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 oral 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

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Manager, Regulatory Operations

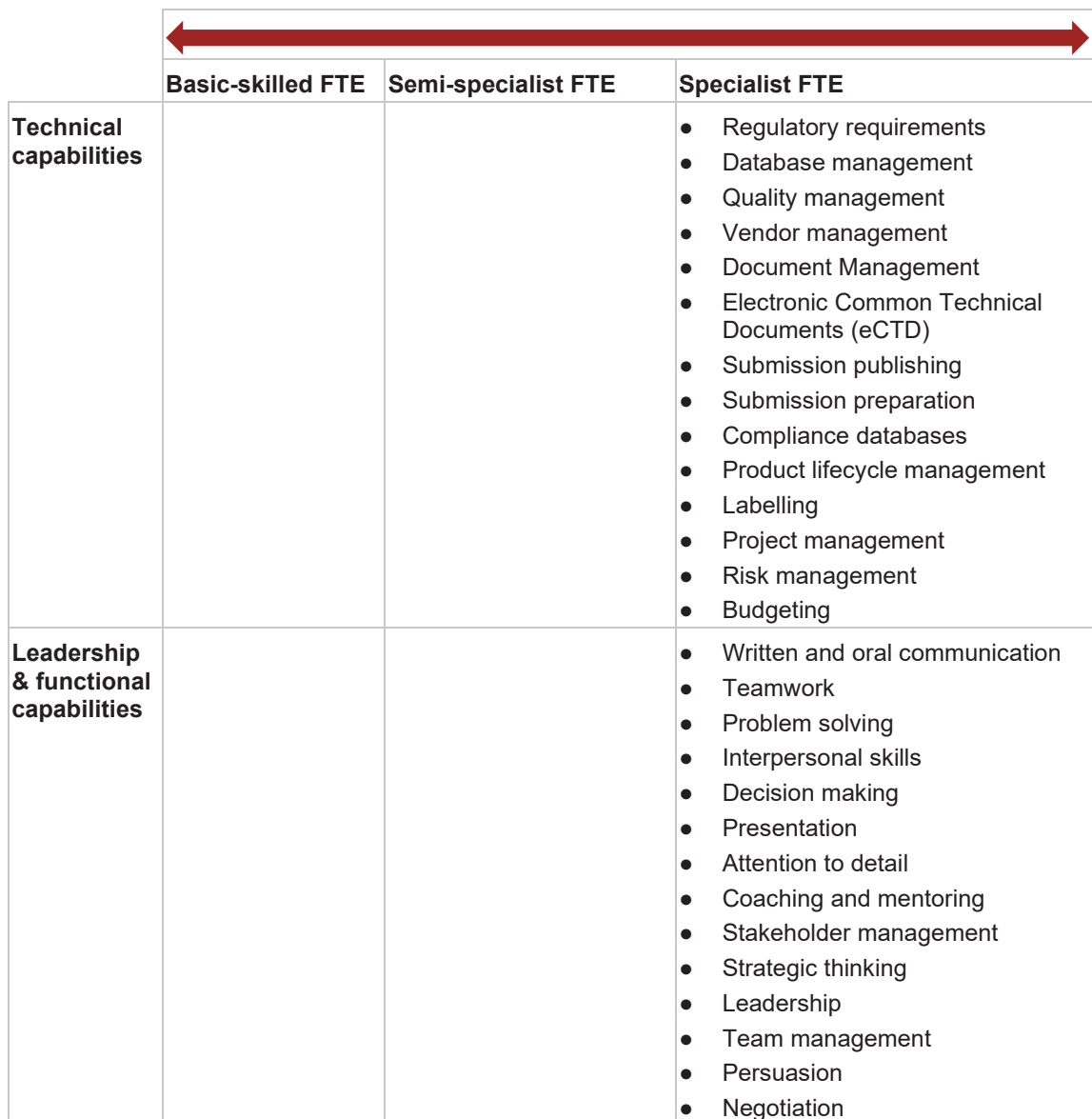
Roles and responsibilities

- 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
- Plan and manage detailed publishing timelines; provide reporting on publishing status to key stakeholders
- Proactively escalate publishing concerns, risks and issues that may delay/impact submissions and present 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 in order to maintain 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
- Keep abreast of regulatory agency submission, publishing and validation standards to ensure compliant and valid dossiers in operating markets
- Oversee performance of regulatory activities in accordance with good regulatory practice (GRP)
- Collaborate with other cross-functional leads (e.g., Clinical Operations, Commercial, CMC) to develop strategies to mitigate risks to timelines and with regard to 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 oral 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 in order to maintain their presence in the market across different geographies
- Ensure regulatory compliance for defined product and project responsibilities
- Ensure 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 	<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 oral communication Attention to detail Teamwork Problem solving Interpersonal skills 	<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 successful outcomes within the required timelines (e.g., contributing 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 standard operating procedures (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 oral 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
- Utilise in-depth knowledge of regulatory submission requirements, processes and procedures, electronic common technical document (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 monitor critical path activities and ensure 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, work closely with the Regulatory Affairs Director to assess the overall programme 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 requirements and guidance associated with electronic submissions, which differs across regions and regulatory authorities
- Lead the Submission Preparation team and provide training, coaching and mentoring including to line and performance management
- Manage and ensure staff competencies are developed and skill gaps are identified and addressed
- Keep abreast of regulatory agency submission, publishing and validation standards to ensure compliant and valid dossiers in operating markets
- Oversee performance of submission preparation activities in accordance with good regulatory practice (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



	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 oral 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, utilising content re-use strategies and applying technical expertise
- Develop submission structure strategies in accordance with health authority and International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regulations, guidelines and specifications
- Prepare and compile regional submission documentation to regulatory health authorities according to ICH/electronic common technical document (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 a timely manner to ensure that resolutions are realised, 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
- Maintain and monitor existing registration dossiers (amendments and updates) and make 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 oral 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
- Manage Regulatory Affairs labelling data in appropriate systems and databases (e.g., Veeva Vault)
- Develop labelling policies, procedures and standard operating procedures (SOPs)
- Evaluate, interpret and communicate global regulations and trends on labelling, including the business impact 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 propose mitigations
- Lead development of Labelling budgets and syndicate with Regulatory Affairs leadership
- Manage adherence to Labelling 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 oral 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) in accordance with 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 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 oral 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-term 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 and 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 work within a matrix organisation
- Evaluate and mitigate risks associated with long standing suppliers and single sourcing
- Ensure that daily procurement needs and transactional activities are executed in line with company policies and standard operating procedures (SOPs)
- Identify opportunities for material cost savings, testing efficiencies and meeting/exceeding inventory reduction goals
- Support sourcing new raw materials required for new projects, products and other departments consistent with the organisation's 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 oral 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 standard operating procedures (SOPs)
- Assist in authoring and review of work instructions and SOPs to deliver a standardised 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 and approval, rejection and coding of invoices)
- Challenge cost savings/cost avoidance from materials planning team and obtain bulk quotes to maximise savings, pricing and stock availability
- Capture cost savings and cost avoidance to align with strategic sourcing and account savings initiatives
- Pursue continuous improvement of purchasing ways of working
- Ensure users are kept informed of progression and status of their orders
- Use agreed procurement systems to process orders
- Be a 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 and safety regulations
- Provide suppliers with rolling 12-18 month forecasts of requirements
- Work through defective material process with supplier (returns, documentation of defect, and credits)
- Maintain enterprise resourcing planning (ERP) system 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 oral 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, quality control (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 and 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 • Enterprise resource planning (ERP) applications • Risk management
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and oral communication • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Attention to detail • Coaching and mentoring • Stakeholder management • Strategic thinking • Leadership • Team management • Persuasion • Negotiation

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Materials Planner

Roles and responsibilities

- Ensure all materials procurement activities carried out comply with relevant site good manufacturing practice (GMP), environmental health and safety (EHS) guidelines and policies and relevant legal requirements
- Undertake continuous improvement initiatives
- 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
- Carry out materials forecasting, including sending annual rolling forecasts to suppliers
- Generate full year order for priority materials, agree on supply dates and monitor delivery dates depending on fluctuating demand
- Facilitate timely and accurate reporting (e.g., deficit reports, materials planning detail reports and local packaging reports)
- Realign supply to the fluctuating demand upon confirmation of deliveries by warehouse technicians
- Review 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 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
- Manage create/change/delete functions in enterprise resource planning (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 ● Enterprise resource planning (ERP) applications ● Risk management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> ● Written and oral 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 stockouts
- 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 • Enterprise resource planning (ERP) applications 	<ul style="list-style-type: none"> • Business process improvement • Materials forecasting 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Negotiation • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Logistics

Manager, Logistics

Roles and responsibilities

- Manage the warehouse team effectively and deliver both internal orders and customer orders coming from the sales department to maintain high customer satisfaction level
- Ensure execution and continuous improvement of standard logistics processes, such as replenishment, data interchange, demand management, electronic data systems administration and related functions
- Manage order processing and on-time-in-full delivery through distributors
- Execute inventory write-offs and physical material dispositioning
- Manage 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/functional stakeholders
- Manage P&L and savings
- Carry out oversight of third-party logistics service providers and be responsible for their performance management
- Undertake risk management
- Manage safety, quality and compliance related to logistics processes
- Work with other company functions and external parties to deliver services
- Foster continuous improvement (i.e., in portfolio/inventory optimisation, cost efficiency and waste reduction)
- Risk management: identify and escalate potential supply risks with potential corrective actions
- Management of safety, quality and compliance: exercise oversight of the team's adherence to all safety, quality and compliance policies
- Work with the Procurement Manager to negotiate shipping lanes
- Present the 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

Supervisor, Logistics

Roles and responsibilities

- Ensure delivery of material and supplies in compliance with regulatory expectations and with consistency for projects
- Manage the day-to-day business of order assembly, fulfillment, picking and packaging operations at the warehouse
- Manage and train a team of warehouse technicians in all associated tasks related to order assembly
- Work with business units/functions 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, analyse 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 enterprise resource planning (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

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	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		<ul style="list-style-type: none"> ● Supply chain management ● Inventory management ● Materials planning ● Enterprise resource 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 oral 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 required good manufacturing practice (GMP) and regulatory standards and making general housekeeping and daily supporting checks
- Move, stage, or receive warehouse materials and products
- Undertake safe loading, unloading, distribution and stowage of materials, including all necessary system transactions
- Undertake safe use of all mechanical handling equipment that individual technicians are licensed to operate
- Complete appropriate documentation associated with work responsibilities using a computerised inventory system
- Collate and pack internal and external orders of material to meet service level agreements
- Respond to visual and audible warning indicators
- Adhere to all standard operating procedures (SOPs), current good manufacturing practice (cGMP), plant safety, quality and documentation system requirements and participate in regulatory and customer audits
- Ensure transaction data entry is completed in a timely manner
- Complete required stockchecks to maintain Inventory control
- Support other warehouse activities as training allows
- Track and resolve problems and deploy warehousing expertise in analysing technical problems
- Identify delivery and process improvements that would be required to 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 and national regulatory authority (NRA) requirements pertaining to facilities and 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 • Enterprise resource planning (ERP) applications • Warehouse management systems • Warehouse equipment • Risk management • Record keeping • Regulatory requirements 	<ul style="list-style-type: none"> • Business process improvement • Vendor management 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Negotiation • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 standard operating procedures (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 and develop, change and/or initiate 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 corrective and preventive action (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 vendor selection
- Manage contracts and act as key contact for electrical equipment and calibration system contractors
- Develop short-term and long-term strategies for supplier selection consistent with site strategy for maintenance and spare parts
- Evaluate and optimise electrical systems spare parts inventory and preventative/predictive maintenance programme
- Develop and maintain electrical safety training programme 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 good manufacturing practice (GMP) regulations, guidelines, policies, SOPs, 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

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	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 ● Enterprise resource planning (ERP) applications ● Regulatory requirements ● Safety principles ● DMAIC techniques ● Pneumatics ● Electronics ● Process automation ● Scheduling
Leadership & functional capabilities			<ul style="list-style-type: none"> ● Written and oral communication ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Attention to detail ● Coaching and mentoring ● Stakeholder management ● Strategic thinking ● Leadership ● Team management ● Persuasion

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Instrumentation Planner

Roles and responsibilities

- Plan and co-ordinate the electrical department maintenance work efficiently in conjunction with operators to minimise production downtime
- Pre-engineer designated maintenance and project activities to meet department requirements efficiently (e.g., spares, materials, site/contract labour and services)
- Liaise with enterprise resource planning (ERP) contracts manager and broader instrumentation function to maximise 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 current good manufacturing practice (cGMP) requirements
- Provide 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 key performance indicators (KPIs) with the Instrumentation/ Electrical Manager for monitoring purposes
- Assist 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 the Instrumentation Manager, coordinating electrical tasks and allocating electrical labour to meet department requirements during their 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 • Enterprise resource planning (ERP) applications • Regulatory requirements • Safety principles • DMAIC techniques • Pneumatics • Electronics • Process automation • Scheduling 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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
- Undertake data entry on calibration test records and assist with calibration scheduling
- Review and approve 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
- Design, order parts and install for machine modification
- Author, review and update work orders and standard operating procedures (SOPs)
- Assist with internal and external plant audits
- Make recommendations on equipment upgrades
- Assist with plant safety programmes and safety awareness
- Provide shutdown and project support
- Ensure adherence to all company and site engineering policies and procedures
- Ensure all work carried out and equipment installed is safe, effective and in compliance with relevant industry standards
- Ensure all work undertaken is reflected accurately in work order documentation and/or up to date engineering/project information files
- Serve as the maintenance management system expert in a current good manufacturing practice (cGMP) environment as it relates to instrumentation
- Review and approve work carried out to systems and equipment by OEM suppliers, partners, service and construction contractors
- 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 a continuous improvement philosophy
- Analyse trends in deviations, non-conformances and any downtime issues
- Facilitate analysis of latest technologies for equipment
- Review the performance and operation of equipment
- Analyse 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 ● Enterprise resource planning (ERP) applications ● Regulatory requirements ● Safety principles ● DMAIC techniques ● Pneumatics ● Electronics ● Process automation ● Scheduling 	
Leadership & functional capabilities		<ul style="list-style-type: none"> ● Written and oral communication ● Attention to detail ● Teamwork ● Problem solving ● Interpersonal skills ● Decision making ● Presentation ● Coaching and mentoring 	<ul style="list-style-type: none"> ● Leadership ● Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 corrective and preventive actions (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 optimising machinery and components
- Assist in feasibility assessments for new product introductions
- Manage and deliver on budget
- Undertake 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 programmes, strategies, plans and tools at 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
- Provide support, coaching and guidance to Maintenance staff in planning and executing shutdown activities
- Take a tactical role on investigations and improvements partnering with operations, quality, supply chain and other functions
- Establish short-term performance goals, monitor results and make timely adjustments to achieve delivery objectives. Make his/her team accountable for the overall Mechanical function performance and behaviours
- Assure staff compliance with all procedures, current good manufacturing practice (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 in external audits by answering questions regarding equipment under the Mechanical function's responsibility, including resolving audit actions
- Maintain good maintenance practices by authoring and updating standard operating procedures (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

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 and services)
- Liaise with enterprise resource planning (ERP) contracts manager and broader Mechanical function to maximise 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.
- Provide 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 key performance indicators (KPIs) on a monthly basis for Mechanical Manager for monitoring purposes
- Assist 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 their 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 • Blueprinting • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance management systems • Engineering business systems • Control systems • Enterprise resource planning (ERP) applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Mechanical Coordinator

Roles and responsibilities

- Support manufacturing operations related to mechanical equipment and 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
- Design, order parts and install machine modifications
- Author and review standard operating procedures (SOPs)
- Assist with plant audits
- Make recommendations on equipment upgrades
- Assist with plant safety programmes and safety awareness
- Provide shutdown and project support
- Ensure adherence to all company and site engineering policies and procedures
- Ensure all work carried out and equipment installed is safe, effective and in compliance with appropriate industry standards
- Ensure all work undertaken is reflected accurately in work order documentation and/or up to date engineering/project information files
- Be the maintenance management system expert in a current good manufacturing practice (cGMP) environment as related to instrumentation
- Review and approve work carried out to systems and equipment by OEM suppliers, partners, service and construction contractors
- 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 a continuous improvement philosophy
- Analyse trends in downtime
- Facilitate analysis of latest technologies for equipment
- Review the performance and operation of equipment
- Analyse preventative maintenance routines and ensure appropriateness and value

Minimum years of experience required	6
Minimum educational level required	Ordinary National Diploma (OND) or equivalent (i.e., high school) (Bachelors preferred); artisan (with 10 years' experience); diploma (with 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 • Blueprinting • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance management systems • Engineering business systems • Control systems • Enterprise resource planning (ERP) applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Reliability Engineer

Roles and responsibilities

- Maintain, test, inspect and perform field calibration of process, utility and analytical instrumentation
- Maintain inventory and compile records
- Document all work order activities in maintenance management systems and relevant equipment logs
- Troubleshoot and resolve calibration/instrumentation issues in a timely manner utilising DMAIC (Define, Measure, Analyse, 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 standard operating procedure (SOP) and current good practice (cGxP) requirements
- Lead and/or participate in continuous improvement activities
- Use predictive techniques to minimise 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 • Blueprinting • Packing • Safety principles • Regulatory requirements • Equipment reliability • Business process improvement • Maintenance management systems • Engineering business systems • Control systems • Enterprise resource planning (ERP) applications • Root cause analysis • Failure modes and effects analysis • Scheduling • Vendor management 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Mechanical Technician

Roles and responsibilities

- Assess mechanical equipment to determine issues and ensure that appropriate engineering standard operating procedures (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 minimise 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 of biohazardous 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 synchrony 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 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 procedures
- Report equipment services or events which are out of regulatory compliance using relevant procedures
- 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 i.e., high school (Bachelors preferred); artisan (with 5 years' experience); diploma (with 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 • Enterprise resource planning (ERP) applications 	<ul style="list-style-type: none"> • Maintenance planning • Blueprinting • 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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

HVAC

HVAC Manager


Roles and responsibilities

- Provide technical, quality and compliance-focused leadership to the HVAC team within the Maintenance and Engineering function
- Optimise operations through continuous improvement and best practices for heating, ventilation and air conditioning (HVAC), refrigeration and associated equipment
- Work cross-functionally across the site to ensure the HVAC programme consistently meets the needs of the business in a fully compliant manner
- Schedule and manage sitewide 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 environmental health and safety (EHS) and good manufacturing practice (GMP) regulations, company policies, engineering standards, operating procedures and industry practice
- Provide subject matter expertise for HVAC equipment deviations and corrective and preventive actions (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 programmes 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
- Utilise building management systems, computerized maintenance management systems (CMMS) and reliability maintenance techniques for HVAC, refrigeration and associated systems to deliver a highly efficient, reliable and cost-effective maintenance programme
- Optimise the work order process (corrective maintenance, preventative maintenance, calibrations and spare parts) to ensure compliance (GMP, EHS, cost, schedule, etc.) for all maintenance work and documentation
- Develop justifications, 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 ● Enterprise resource planning (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 oral 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

- Ensure regulatory compliance while minimising losses and maximising recovery via effective leak detection, maintenance procedures and use of reclaiming, recycling and recovery equipment
- Troubleshoot and adjust HVAC systems and air volume control equipment to maintain proper temperature, humidity and airflow conditions
- Monitor and measure pressure drops in HVAC filters and replace them as necessary, observing all system integrity and safety requirements
- Clean HVAC coils, evaporators and condensers with chemicals, air, special cleaning agents, high pressure wash units etc. to maintain equipment in good operating condition
- Repair and adjust 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
- Answer alarms associated with monitoring systems and make routine decisions concerning priority of response
- Review unusual problems and situations with the HVAC Manager
- Execute against work orders and predictive maintenance (PM) checklists while maintaining necessary work records and logs in a current good manufacturing practice (cGMP) compliant manner and documenting activities via daily labour records
- Provide routine rigging and alignment work, as required by refrigeration system maintenance
- Communicate effectively in a professional manner with management to provide equipment and system status, parts and other work requirements
- Operate recovery, recycling and reclaiming devices to minimise refrigerant impact on environment and obtain appropriate certification as necessary to comply with applicable regulations
- Complete department training directives (e.g., orientation, standard operating procedures (SOPs), safety, etc.) as directed by management
- Prepare and assist technicians, supervisors and planners across other functions in preparing labour and materials estimates
- Assist management with the assigning, scheduling and prioritisation of work order requests using maintenance management systems
- Make recommendations and prepare orders for spare parts, additional stock room items, tools, etc.
- Consult 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 (i.e., high school; artisan (with 5 years' experience); diploma (with 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 • Enterprise resource planning (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 oral 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

- Lead 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
- Ensure 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 satisfy all project controls elements (i.e., programme, cost, risk and reporting)
- Develop and maintain positive relationships with customers and other site functions
- Provide co-ordination to balance site priorities, resources and potential clashes
- Work with site-preferred suppliers and other support services through existing and new contracts
- Ensure stagegate, governance papers and project investment proposal (PIP) submissions align with 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 with all environmental health and safety (EHS), quality and finance aspects of the company
- Present the team's performance using 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 oral 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
- Ensure 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 and dispute resolution and dealing with any legal issues.
- Work closely with procurement, direct bid evaluation and contract award processes and coordinate the negotiation of contracts with general contractors and oversee 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 permits 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 oral 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 recognising 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 current good manufacturing practice (cGMP) standards
- Coordinate and directly supervise utility outages and the performance of emergency and routine maintenance on utilities and facilities
- Identify opportunities to utilise the site-critical systems in a more efficient manner to improve reliability and reduce operating costs
- Manage respective corrective and preventive actions and work with Quality to ensure timely completion of investigations and corrective and preventive actions (CAPAs) implementation
- 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 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 to 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

Utilities Technician

Roles and responsibilities

- Repair and maintain plant utilities equipment in accordance with manufacturing specifications, standard operating procedures (SOPs), current good manufacturing practice (cGMP) and relevant regulations
- Troubleshoot problems with utilities equipment as necessary and as directed by Utilities Manager
- Ensure engineering areas, facilities and equipment are kept in a clean, safe and serviceable condition and the highest standards of general housekeeping are maintained
- Complete site documentation before and after work tasks, as appropriate
- Ensure all issues over shift are communicated via passdown to the next shift on shift changeover in a smooth and efficient manner
- Assist with investigations relating to utilities equipment
- Carry out risk assessments 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 (i.e., high school; artisan (with 5 years' experience); diploma (with 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 • Enterprise resource planning (ERP) applications • Water treatment • Safety principles • Regulatory requirements 	<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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Environmental, Health & Safety

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 and safety (EHS) 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 standard operating procedures (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 good manufacturing practice (GMP) regulations, guidelines, policies, SOPs, industry practice 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 and Safety, Mechanical Engineering, Systems

EHS Specialist


Roles and responsibilities

- Ensure compliance with environmental, health and safety (EHS) regulations, guidelines and industry practices within the vaccine manufacturing organisation
- 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 EHS training programmes for employees, emphasising 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 organisation is prepared to handle environmental and safety-related emergencies
- Stay informed about changes in EHS regulations and update organisational policies and procedures accordingly
- Assist in the preparation for and response to EHS inspections and audits
- Conduct risk assessments related to EHS, 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 and 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 programme development ● Emergency preparedness planning ● Risk assessment ● Stakeholder communication 		
Leadership & functional capabilities	<ul style="list-style-type: none"> ● Written and oral communication ● Attention to detail ● Teamwork ● Problem solving ● Interpersonal skills 		

Support

Marketing and Sales

Marketing Manager

Roles and responsibilities

- Develop a strategy and plan 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 use
- 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
- Analyse 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

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 optimisation (SEO) ● Search engine marketing (SEM) ● Customer service ● Customer relationship management ● Innovation ● Vendor management
Leadership & functional capabilities			<ul style="list-style-type: none"> ● Written and oral 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 (return on investment (ROI) and key performance indicators (KPIs))
- Conduct market research and analyse 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 optimise 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 optimisation (SEO) • 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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 programmes
- 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 	<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 oral communication Attention to detail Teamwork Problem solving Interpersonal skills 	<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 including both qualitative and quantitative research; analyse data/insights and draw out implications
- Design, analyse 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 analysing 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 from 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"> • 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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Sales Manager

Roles and responsibilities

- Develop and execute sales strategy
- Oversee daily operations of sales function
- Meet planned sales goals
- Set individual sales targets with the sales team
- Track sales goals and report results as necessary
- Oversee the activities and performance of the sales team
- Coordinate with marketing on lead generation
- Undertake ongoing training of salespeople
- Develop sales team through motivation, counseling and product knowledge education
- Promote the organisation and its products
- Understand customers and how they relate to the company's products

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

Sales Representative

Roles and responsibilities

- Generate leads
- Meet or exceed sales goals
- Negotiate contracts with prospective clients
- Support determination of pricing schedules for quotes, promotions and negotiations
- Prepare weekly and monthly reports
- Give sales presentations to a range of prospective clients
- Coordinate sales efforts with marketing programmes
- Understand and promote company programmes
- Obtain deposits and balance of payment from customers
- Prepare and submit sales contracts for orders
- Visit customers and potential customers to evaluate needs or promote products and services
- Maintaining customer records
- Answering customer 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 oral 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

- Advise executive members on new laws, existing laws and legal rights that would impact functionality of the business
- Oversee the legal matters of the business as a whole, including acting as the business's legal representative
- Oversee the legal strategy in response to any litigation. Work with litigation counsel (including any external litigation counsel) to ensure litigation proceeds effectively and efficiently. Exercise ultimate authority and responsibility for litigation outcomes
- Be responsible for all corporate recordkeeping. Also exercise responsibility for all corporate financial and other regulatory filings (but not those related to drug filings)
- Maintain knowledge of the company's legal documents and operations
- Craft and review legal strategy in response to any litigation
- Keep records of all legal documents and proceedings for the company
- Facilitate filings of licensing forms and other statutory requirements
- Communicate with outside counsel
- Legally file for copyright of intellectual property
- Act as the primary point of communication with all outside counsel; delegate as appropriate
- Manage all corporate intellectual property (trade secrets, copyrights and trademarks)
- Serve as a member of the Board of Directors as secretary; be responsible for the duties typically associated with such role
- Oversee the entire Legal department for the company. Establish and maintain clear goals and directions for the department and work 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 oral 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, product 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
- Work closely with the General Counsel and, if used, outside counsel, to reach swift and efficient outcomes for all litigation matters
- Represent the 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 the consumer health and pharmaceutical environment

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

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
- Select, evaluate and manage 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 oral 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

- Participate in and counsel multiple internal client teams within the organisation such as Clinical, CMC, Regulatory, etc.
- Negotiate/draft and/or review a wide range of commercial agreements that are typical for a pharmaceutical company
- Advise on legal aspects of sales and promotion including review of product claims and challenges
- Advise and manage commercial dispute resolution and litigation
- Provide legal support on industry issues, crisis management and product incidents
- Oversee and manage legal risks within Risk Management and Compliance
- Deliver/coordinate legal training to other function.
- Liaise with other groups within Legal (such as Patents, Trademarks, Business Development) and other departments (such as Corporate Tax, Finance etc.)
- Advise 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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Negotiation 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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 crosschecks 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-licence/out-licence 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 	<ul style="list-style-type: none"> • Pharmaceuticals law • Competition law • Contracts 	
Leadership & functional capabilities	<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<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 strategise 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 ensure that relevant professional standards are met
- Ensure the company complies with current regulations, accepted professional standards, policies and procedures and legislation (including legislation on data protection, equality 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 and reward and recognition) as well as maintaining and improving HR systems and management of the HR budget
- Drive a continuous improvement agenda with focus on engagement and welfare activities, maximising 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 programmes • 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 programmes • Impact measurement and evaluation • Recruiting • Competency assessments • Diversity management
Leadership & functional capabilities			<ul style="list-style-type: none"> • Written and oral 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

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Manager, Compensation and Benefits

Roles and responsibilities

- Align compensation and benefits strategy and policies with company's overall HR strategy
- Provide expertise and advise on all reward-related programmes, 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 analysed 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 programmes and recommend future initiatives
- Act as a consultant and expert for labour negotiations related to all reward matters
- Develop and oversee 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, analyse trends and produce management reports

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 programmes ● Legal frameworks for compensation ● Business acumen ● Financial acumen ● Diversity management
Leadership & functional capabilities			<ul style="list-style-type: none"> ● Written and oral 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 programmes including life, disability and health insurance plans
- Administers employee savings plans that may include personal savings plans and deferred compensation programmes
- 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 organisation's 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 organisation's 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 human resource information (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 programmes • Legal frameworks for compensation • Business acumen • Financial acumen 	
Leadership & functional capabilities		<ul style="list-style-type: none"> • Written and oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills • Decision making • Presentation • Coaching and mentoring • Negotiation 	<ul style="list-style-type: none"> • Leadership • Team management

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

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, programme 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 utilising 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 and 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

People Analytics Specialist/ Analyst

Roles and responsibilities

- Partner with HR leadership to support deliverables for special projects related to the company's people strategy (e.g., diversity, retention, etc.) including framing of key issues, designing analytic approaches, executing analyses and communicating 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 company programmes and initiatives (e.g., analyse exit survey results; analyse key drivers of performance through analysing 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 company's HR leadership 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 oral 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 maximise 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 programme 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, analyse and proactively respond to trends and issues related to learning, development and knowledge management
- Align development of training content and programmes 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

Learning and Development Specialist

Roles and responsibilities

- Carry out capability assessments across the organisation
- Design blended learning solutions
- Use digital tools to create flexible and innovative learning programmes
- Apply adult learning theories to ensure employees get the best out of their development
- Design a range of learning interventions, including technical, behavioural and leadership programmes
- Drive a culture of continuous professional development
- Facilitate learning interventions
- Create a coaching culture in the organisation
- Monitor 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 	<ul style="list-style-type: none"> Training programmes Talent retention Diversity management 	
Leadership & functional capabilities	<ul style="list-style-type: none"> Written and oral communication Attention to detail Teamwork Problem solving Interpersonal skills 	<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
- Undertake 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 a candidate persona 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
- Ensure candidates meet the specification and are identified within deadline and are within 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

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 a 'best place to work'
- Conduct background checks prior to making an offer of employment
- Conduct remuneration negotiation
- Conduct talent identification and align with the company's 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 oral 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 the enterprise's 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 and the quality of finance service as well as drive profitability and the financial solvency of the 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 oral 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

- Manage the accounting staff who are responsible for financial reporting, billing, collections, payroll and budget preparation
- Recruit and hire accounting and financial staff and conduct performance evaluations
- Coordinate training programmes for new staff and identify training needs for current staff
- Establish internal controls and guidelines for accounting transactions and budget preparation
- Oversee preparation of business activity reports, financial forecasts and annual budgets
- Oversee the production of periodic financial reports; ensure reported results comply with generally accepted accounting principles and/or financial reporting standards
- Exercise responsibility for tax planning throughout the fiscal year; file annual corporate tax return
- Review accounts to ensure compliance with government regulations; coordinate with external auditors and provide information required for the annual external audit
- Present recommendations to management on short-term and long-term financial objectives and policies
- Provide financial analyses with an emphasis on capital investments, pricing decisions and contract negotiations
- Ensure 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

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 utilised properly and protect reserves
- Review financial information for inconsistencies
- Provide tax planning strategies in accordance with existing legislation
- Create financial forecasts and analyse 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 oral communication • Attention to detail • Teamwork • Problem solving • Interpersonal skills 	<ul style="list-style-type: none"> • Decision making • Presentation • Coaching and mentoring 	

Note: Based on insights from analysis of global multinational companies and expert reviews - potential tailoring may be needed to continental and company specific contexts

Financial Planning and Analysis Manager

Roles and responsibilities

- Manage the budgeting, forecasting and long-term planning processes
- Analyse actuals against budget/forecast and prior year
- Lead analysis of key performance indicators (KPIs), especially those relating to financial metrics such as sales, expenditure 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 into business performance
- Present the monthly and quarterly financial reports of various units and departments
- Develop financial models and analyse them to support strategic initiatives
- Support management team and heads of department with data-driven analyses
- Perform ad-hoc analysis where required to assist in management decision-making
- Monitor and analyse 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 utilised 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, return on investment (ROI) analyses and risk assessments to secure funding for strategic initiatives
- Analyse 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

Financial Planning and Analysis Analyst


Roles and responsibilities

- Analyse trends in key performance indicators (KPIs), especially those relating to financial metrics such as sales, expenditures and profit margin
- Assist in monitoring KPIs and identify the cause of any unexpected variances
- Develop and continually improve budgeting, financial projections and operating forecasts
- Prepare ad-hoc business performance reporting
- Present monthly and quarterly financial reports of various units and departments
- Develop financial models and analyse them to support strategic initiatives
- Support management team and the heads of department/function with data-driven analyses
- 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 oral 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 (IT) and computer systems
- Plan, organise, 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 around IT systems, applications and tools, ensuring employees have the necessary skills and knowledge to use technology effectively 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 oral 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 	

