African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

PART I I:

Vaccine R&D Competency Framework

PAVM TALENT DEVELOPMENT WORKSTREAM

November 2023

Contents

Abbreviations

AU	African Union
BARDA	Biomedical Advanced Research and Development Authority
BLA	Biologics licence applications
CDC	Centres for Disease Control and Prevention
CDISC	Clinical Data Interchange Standards Consortium
CMC	Chemistry, manufacturing and controls
CMOs	Contract manufacturing organisations
CRFs	Case report forms
CROs	Contract research organisations
CTMS	Clinical trial management systems
DNA	Deoxyribonucleic acid
eCTD	Electronic common technical documents
EDC	Electronic data capture
FIH	First in human
FTE	Full-time equivalent
FTIR	Fourier-transform infrared spectroscopy
GCLP	Good clinical laboratory practice
GCP	Good clinical practice
GLP	Good laboratory practices
GMP	Good manufacturing practices
GRP	Good regulatory practices
GVP	Good pharmacovigilance practices
GxPs	Good practices
HPLC	High-performance liquid chromatography
HR	Human resources
IB	Investigator brochures
ICF	Informed consent form

ICH	The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IND	Investigational new drug
IT	Information technology
MAA	Marketing authorisation application
MLR	Mixed lymphocyte reaction
NMR	Nuclear magnetic resonance
NRAs	National regulatory agencies
PAT	Process analytical technologies
PFS	Progression-free survival
POCs	Proof of concept
PV	Pharmacovigilance
QA	Quality assurance
QA/QC	Quality assurance/quality control
QbD	Quality by design
QMS	Quality management system
R&D	Research and development
RFPs	Requests for proposal
RFQs	Requests for quotation
RN	Registered nurse
SAP	Statistical analysis plan
SOPs	Standard operating procedures
TNA	Training needs analysis
TPP	Target product profile
UAT	User acceptance testing

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 African 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 development and manufacturing capabilities. At present, talent development in Africa relies heavily on programmes offered outside the continent, incurring significant cost.

To address this, PAVM has defined a set of talent development initiatives. As part of 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 two of two which lays out one of these two frameworks: the vaccine R&D competency framework. This framework was created based on data analysis and expert reviews. It defines the roles of staff in vaccine R&D. 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 R&D 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 and 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.

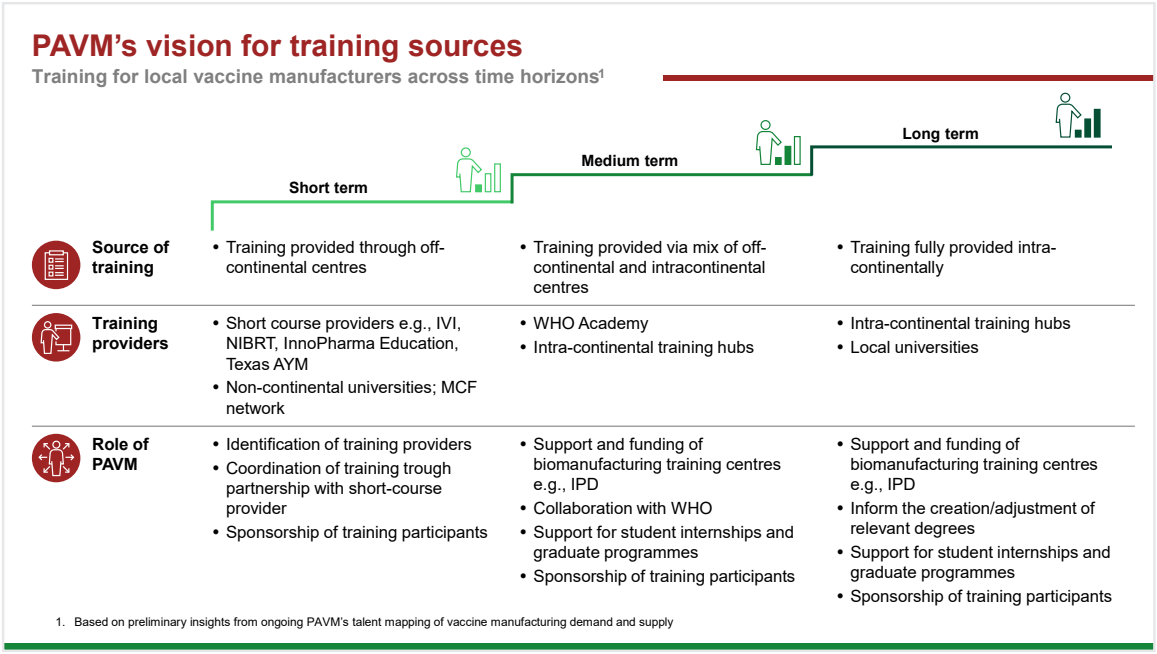


Figure 1. **PAVM's vision to respond to Africa's vaccine manufacturing talent needs**

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 research and 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 vaccine research and development. 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 R&D 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 programmes

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 R&D Competency Framework

The R&D vaccine 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 R&D organisation, we have defined seven 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. Knowledge-based understanding (e.g., genomics, pathogenesis, infectious diseases, etc.)

v. Roles and responsibilities

vi. Technical capabilities (e.g., business process improvement, tangential flow filtration, etc.) including variations in required proficiency between basic-skilled, semi-specialised and specialist employees)

vii. 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 R&D Competency Framework

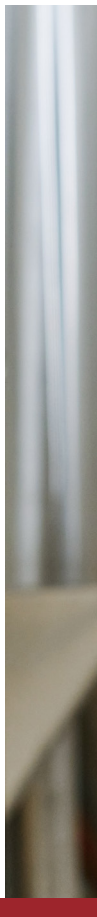
We followed a six-step approach in building the vaccine R&D competency framework:

a. We designed an end-to-end vaccine R&D 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 R&D Competency Framework was peer reviewed by 14 experts from 13 organisations:

i. CEPI

ii. Bill & Melinda Gates Foundation

iii. University of Cape Town

iv. KEMRI Wellcome Trust

v. African Leadership in Vaccinology Expertise

vi. Rwanda Zambia Health Research Group

vii. Biomedical Advanced Research and Development Authority

viii. Innopharma Technology

ix. Department of Health & Human Services, USA

x. International AIDS Vaccine Initiative

xi. Innovative Biotech

xii. KAVI Institute of Clinical Research - University of Nairobi

xiii. African Research Universities Alliance

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 development and 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 by research institutes and manufacturers 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

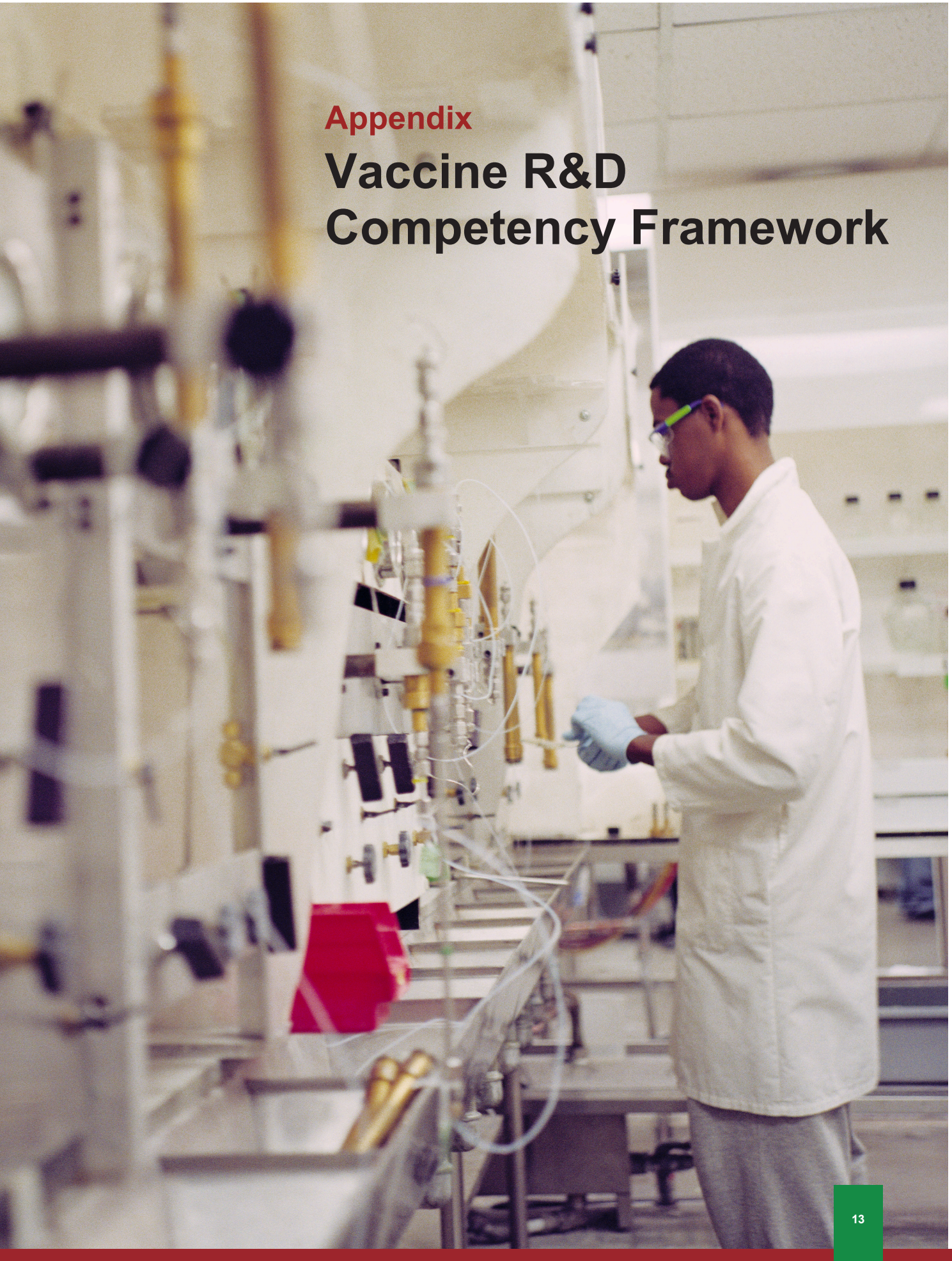
The framework is accessible via the AfricaCDC website to ensure access across the continent as reference for researchers, manufacturers, curricula developers and other stakeholders.

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

Appendix

Vaccine R&D Competency Framework



R&D Competency Framework: Vaccine R&D (sub-) functions

Role can also be covered outside of R&D, at corporate level

HEAD OF R&D

DIVISION	Discovery/ Pre-Clinical Research		Clinical Development					Other			
FUNCTIONS	**Vaccines Discovery Research**	**Pre-Clinical Research**	**Clinical Development**	**Clinical Operations**	**Data Sciences**	**Regulatory**	**Pharmacovigilance and Drug Safety**	**R&D Quality**	**CMC/ Process development**	**Medical Affairs**	**Support Functions**
SUB-FUNCTIONS	Virology and Molecular biology	Pre-Clinical/ Translational Medicine	Epidemiology	Site Management	Biostatistics	Regulatory Operations	Pharmacovigilance Strategy & Operations	Quality Control	Upstream Process Development	Medical Affairs	Program management
	1 roles	1 roles	1 roles	2 roles	1 roles	2 roles	1 roles	2 roles	1 roles	1 roles	1 roles
	Microbiology	Animal Studies	Clinical Development Strategy	Site Training	Data Management	Regulatory CMC		Quality Assurance	Downstream Process Development		Human Resource
	1 roles	2 roles	1 roles	1 roles	1 roles	1 roles		5 roles	1 roles		1 roles
	Immunology	Vaccine formulation		Vendor Management		Regulatory Clinical		Clinical Trials Laboratory	Analytical Development		Purchasing
	1 roles	1 roles		1 roles		1 roles		2 roles	1 roles		1 roles
	Biochemistry			Clinical IT Support		Policy and Labelling			Formulation / Drug Product Development		Health, Safety & Environment
	1 roles			1 roles		1 roles			5 roles		1 roles
	Vaccine design and construction								Drug Substance Pilot Plant incl. GMP		Finance and Accounting
	1 roles								4 roles		1 roles
									Toxicology		
									2 roles		

Specific core competencies such as GLP, GCP, report writing, etc. will be assessed across functions and are not indicated here by a separate sub-function

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

Head of R&D

Roles and responsibilities

Core responsibilities

- Develop and drive execution of R&D strategy to meet identified goals
- Drive early and late-stage product development from Discovery research up until manufacturing processes
- Oversee and manage external funding or scientific opportunities to support and accelerate vaccine R&D
- Oversee and manage risks that could affect achievement of R&D targets
- Oversee development and/or compilation of the Target Product Profile (TPP)

Leadership and team management

- Oversee, lead and guide the R&D organisation, across both Discovery and Development functions
- Motivate, develop and coach staff to reach desired production and quality goals

Compliance

- Oversee and ensure quality and compliance for all activities within the organisation adhere to SOPs and regulations

Stakeholder management and communication

- Communicate with function leads with regard to decision-making, programme management and initiative implementation
- Liaise with manufacturing division to ensure seamless transition of and scaling of assets from CMC into large-scale manufacturing operations

Finance and resource planning

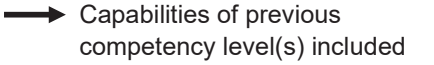
- Oversee development of R&D budgets and ensure clinical activities are within budget

Indicative summary

Minimum years of experience required	15
Minimum educational level required	MD/PhD
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, clinical development, infectious diseases, molecular biology, immunology, pharmaceuticals

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Good clinical practice (GCP) • Fundraising • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Discovery/Pre-clinical Research

Head of Discovery/Pre-clinical Research

Roles and responsibilities

Core responsibilities

- Define the strategy and vision of the Discovery/Pre-clinical function
- Oversee the incorporation of new technologies and support integration of new technical innovations across discovery sub-functions to support long-term research plans
- Oversee and manage external funding or scientific opportunities to support and accelerate pre-clinical discovery and development of innovative drugs
- Oversee continuous research to understand targeted diseases, viruses and their serotypes
- Oversee the preparation of the product dossier for further vaccine candidate development, ensuring its accuracy, scientific validity and compliance with regulatory requirements

Leadership and team management

- Manage and lead multiple teams across Discovery/Pre-clinical function
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Oversee collaboration with Regulatory Affairs, R&D quality and process development groups to drive projects
- Oversee the integrity of the data collected and ensure the documentation of results is according to quality standards and in accordance with regulatory requirements, working towards First In Human (FIH) trials
- Oversee the drafting and submission of patent claims as appropriate

Stakeholder management and communication

- Oversee preparation for governance meetings, adequately representing Discovery/Pre-clinical function and clearly outlining its progress, opportunities for improvement and help needed from broader organisation
- Build positive external reputation for the Discovery/Pre-clinical function by overseeing research publications in journals and overseeing proper representation at scientific events and to external parties, such as regulatory authorities

Finance and resource planning

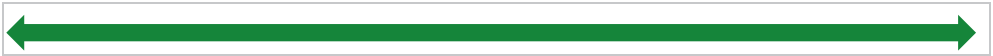
- Oversee the development of R&D preparation budgets
- Oversee adherence to R&D budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	MD/PhD
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, Clinical development, Infectious diseases, Molecular biology, Immunology, Pharmaceuticals, Genomics, Pathogenesis, Microenvironments

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Biochemical assays • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Antibody cloning • Sequencing • Epitope mapping • Single cell sorting	• Flow cytometry • Scientific writing • Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Budgeting
Leadership & functional capabilities			• Written & verbal communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring	• Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Vaccines Discovery Research

Director, Vaccines Discovery Research

Roles and responsibilities

Core responsibilities

- Develop and drive the Discovery Research strategy, as well as communicate it with the team
- Oversee the design and execution of bioscience experiments integrating both disease and pathway approaches in support of portfolio programs
- Accountable for medium-to-long-term development of the Discovery Research function
- Drive innovation and scientific excellence in Vaccine Discovery through internal scientific development, external collaborations, publications and competitive awareness

Leadership and team management

- Lead the Discovery Research team and provide training and guidance
- Oversee that staff competencies are developed, and skill gaps are identified and addressed

Compliance

- Oversee collaboration with Regulatory Affairs, R&D quality and process development groups to drive projects
- Oversee the integrity of the data collected and documentation of results is according to quality standards and as per regulatory requirements, working towards pre-clinical and clinical studies
- Draft and submit patent claims as appropriate

Stakeholder management and communication

- Drive preparation for governance meetings, adequately representing Discovery Research function and clearly outlining its progress, opportunities for improvement and help needed from the broader organisation
- Build a positive external reputation for the Discovery function by overseeing research publications in journals and overseeing proper representation at scientific events and to external parties, such as regulatory authorities

Finance and resource planning

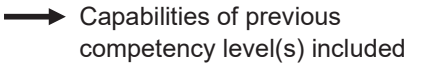
- Lead development of Discovery Research budgets and syndicate with R&D leadership
- Manage adherence to Discovery Research budgets

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, molecular biology, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Biochemical assays • Immunoprecipitation • Cell cultures • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Antibody cloning • Sequencing	• Epitope mapping • Single cell sorting • Flow cytometry • Regulatory requirements • Risk management • Project management • Business process improvement • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Virology and Microbiology

Virologist/Molecular Biologist

Roles and responsibilities

Core responsibilities

- Identify potential targets for vaccine development (antigens), such as viral proteins that can trigger protective immune responses
- Conduct experiments to analyse and manipulate viruses, which might involve growing viruses in cell cultures, performing molecular assays, and evaluating vaccine candidates' efficacy
- Study the structure and activity of macromolecules to identify and validate antigen targets, target pathways, and biomarkers
- Perform characterization, isolation, and manipulation of molecular components of cells, such as DNA, RNA, and various proteins, to aid in vaccine discovery
- Handle expression-profiling experiments from the acquisition of appropriate experimental samples to generation of completed data sets
- Perform biological techniques such as: stock preparation, cloning, isolation, and inactivation
- Operate and maintain lab equipment including plate readers, spectrophotometers, and tissue-culture environment
- Perform routine equipment calibration, cleaning, assembly, and maintenance
- Collect, process and analyse internal laboratory swipes/swabs for quality assurance/quality control (QA/QC) and contamination monitoring located
- Construct candidate vaccines for in vitro and in vivo studies
- Provide computational analysis of scientific data (e.g., genetics, genomics)
- Develop and apply computational tools to help with vaccine research
- Communicate with scientists and other stakeholders to ensure that the results of their work are understood and used effectively

Compliance

- Ensure integrity of data collected and documentations adhere to organizational SOPs, defined research policies (e.g., CDISC) and regulatory requirements
- Assist with drafting and submitting of patent claims as appropriate

Stakeholder management and communication

- Present results and findings of the Discovery function to multidisciplinary team environment across organizational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation as per SOP and regulations

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

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, molecular biology, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	**Semi-specialist FTE**	**Specialist FTE**
Technical capabilities	• Cell cultures • Data analysis • Regulatory requirements • Risk management	• Antibodies • Cell biology • Cytotoxicity • Elisa • Flow cytometry • Functional immunoassays • Culture viruses • Neutralisation assays • Skilled in various tech platforms e.g. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	• Molecular assays • Serologic and virologic assays • Molecular sequencing • Wet lab techniques • Bioinformatics • Vaccine design
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Microbiologist

Roles and responsibilities

Core responsibilities

- Investigate underlying microbial pathways related to vaccine development
- Execute experiments to characterise pathogens and understand their interaction with potential vaccine candidates
- Collaborate with epidemiologists to contribute microbiological insights to surveillance methodologies
- Assist in the design and implementation of surveillance systems to monitor microbial threats
- Propose and design microbiology-focused research projects to support vaccine development
- Utilise laboratory research and environmental studies to enhance understanding of microbial behavior
- Support constructing of candidate vaccines for in vitro and in vivo studies
- Perform culturing and engineering of primary cells and cell lines using transfection and viral transduction

Compliance

- Ensure adherence to good laboratory practices (GLP) in all microbiological experiments
- Maintain documentation in compliance with organisational standard operating procedures (SOPs) and regulatory requirements

Stakeholder management and communication

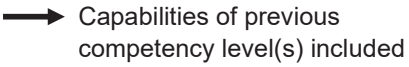
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation in accordance with SOPs and regulations
- Contribute to scientific publications
- Collaborate with project team scientists to ensure data quality and interpret experimental results
- Collaborate with vendors and contract staff in matters of lab support

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or Masters (PhD preferred)
Degree majors typically studied	Microbiology, Biological Sciences, Biochemistry, Biotechnology
Knowledge-based understanding	Molecular biology and genetics, immunology, pharmaceutical microbiology, public health

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Data analysis • Regulatory requirements • Risk management	• Molecular assays • Serologic and virologic assays • Molecular sequencing • Wet lab techniques	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Immunology

Immunologist

Roles and responsibilities

Core responsibilities

- Design and conduct experiments to study the immune response to vaccines
- Support animal models in vivo studies, including performing injections, routinely bleeding mice, harvesting tissues and isolating cells for downstream functional assays
- Execute and analyse immunoassays
- Conduct cell co-culture experiments such as cytotoxicity assays and mixed lymphocyte reaction (MLR)
- Create and optimise laboratory assays to measure immune responses against viruses and vaccine candidates
- Design and execute experiments to assess safety and efficacy of novel vaccines
- Evaluate vaccine adjuvants and novel delivery systems

Compliance

- Maintain accurate and up-to-date records of all work performed, including data analysis and interpretation, tool development, and communication with stakeholders
- Ensure integrity of data collected and documentation adhere to organisational standard operating procedures (SOPs), defined research policies (e.g., CDISC) and regulatory requirements
- Assist with drafting and submitting of patent claims as appropriate

Stakeholder management and communication

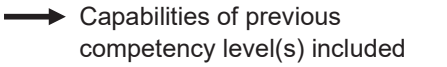
- Maintain an organised lab notebook, analysing (FlowJo, Excel, GraphPad Prism, etc.) and presenting data at various internal meetings
- Manage relationships with key stakeholders

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, molecular biology, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Data analysis • Regulatory requirements • Risk management	→	• Antibodies • Cell biology • Cytotoxicity • Immunoassays • In vivo animal work • Flow cytometry • Skilled in various tech platforms e.g. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→	• Presentation • Coaching and mentoring • Decision making • Innovation

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

Biochemistry

Biochemist

Roles and responsibilities

Core responsibilities

- Identify the chemical and physical properties of vaccine substance
- Characterise various biological pathways; build and test hypotheses about disease intervention
- Investigate correlates of protection; build and test hypotheses about disease intervention

Compliance

- Maintain accurate and up-to-date records of all work performed, including data analysis and interpretation, tool development, and communication with stakeholders
- Ensure integrity of data collected and documentation adhere to organisational standard operating procedures (SOPs), defined research policies (e.g., CDISC) and regulatory requirements
- Assist with drafting and submitting of patent claims as appropriate

Stakeholder management and communication

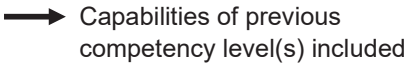
- Maintain detailed documentation of working protocols, vialing records and substrate inventory
- Present results and findings to multidisciplinary team environment across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation in accordance with SOPs and regulations

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or Masters (PhD preferred)
Degree majors typically studied	Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Data analysis • Regulatory requirements • Risk management	• Protein expression • Biochemical assays	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Vaccine Design and Construction

Scientist, Vaccine Design and Construction

Roles and responsibilities

Core responsibilities

- Analyse experimental data to inform vaccine design strategies
- Conduct molecular biology experiments and analyses to understand the genetic and biochemical aspects of targeted pathogens and disease pathways
- Develop and execute assays to characterize the antigenic and structural properties of vaccine candidates
- Analyse and interpret data from assays, providing insights into vaccine efficacy and potential modifications for optimisation
- Collaborate with cross-functional teams to integrate bioinformatics and molecular biology data for vaccine design

Compliance

- Ensure the integrity of experimental data, documentation, and research processes in adherence to organizational SOPs and regulatory requirements
- Contribute to the drafting and submission of patent claims for novel vaccine constructs and technologies
- Uphold safety standards in the design and execution of experiments, ensuring compliance with medical and human safety aspects

Stakeholder management and communication

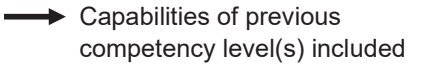
- Present results and findings of vaccine-related research to multidisciplinary teams across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain documentation in compliance with SOPs and regulations
- Contribute to scientific publications and present research plans and results to internal and external stakeholders

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, public health

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Data analysis • Regulatory requirements • Risk management	• Molecular biology techniques • Immunological assays • Bioinformatics tools and analyses • Skilled in various tech platforms e.g. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Skilled in adjuvant research and vaccine delivery	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Pre-Clinical Research

Pre-Clinical/Translational Medicine

Scientist, Translational Medicine

Roles and responsibilities

Core responsibilities

- Investigate the immunological responses elicited by vaccine candidates to understand their mechanisms of action and potential efficacy
- Apply statistical and computational techniques to identify patterns, correlations, and potential biomarkers relevant to disease progression or treatment response
- Identify and validate biomarkers that can serve as indicators of vaccine safety, immunogenicity and effectiveness
- Utilise biomarker data to inform decision-making during vaccine development
- Collaborate with other scientists and integrate their insights to advance translational research
- Design and conduct experiments and collect and analyse data to draw conclusions to guide antigen selection based on correlates of protection
- Contribute to building the data infrastructure for analysis, knowledge and hypothesis generation
- Identify, champion and develop new ideas
- Apply knowledge to relevant research projects and constantly acquire and maintain in-depth knowledge of translational medicine

Compliance

- Ensure integrity of data collected and documentations adhere to organisational standard operating procedures (SOPs), defined research policies (e.g., CDISC) and regulatory requirements
- Assist with drafting and submitting of patent claims as appropriate

Stakeholder management and communication

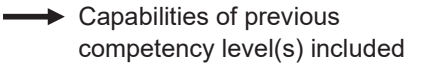
- Present results and findings to multidisciplinary team environment across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation in accordance with SOPs and regulations
- Contribute to scientific publications

Indicative summary

Minimum years of experience required	5
Minimum educational level required	PhD
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, molecular biology, microbiology, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Sequencing • Cell/molecular biology or virology lab and immunoassays (e.g., ELISA) experience • Adherence to international laboratory standards of practice • Data analysis • Regulatory requirements • Risk management	• Biochemical assays • Immunoprecipitation • Antibody cloning • Epitope mapping • Single cell sorting • Flow cytometry • In vivo animal work • Correlates of protection • Project management • Business process improvement • Skilled in various tech platforms e.g. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Animal Studies

Scientist, Animal Studies

Roles and responsibilities

Core responsibilities

- Design and conduct experiments using animal models to understand disease pathways, evaluate the safety and efficacy of vaccine candidates, and gain insights into immune responses
- Plan and execute high-quality animal testing to assess the effectiveness of vaccine candidates in preventing or mitigating infectious diseases, ensuring that studies adhere to ethical and regulatory standards
- Keep up to date with relevant scientific literature, and review studies on animal models, vaccine development and immunology to inform research activities
- Develop experimental protocols and methodologies, implement animal testing studies and oversee data collection to obtain meaningful results
- Analyse data obtained from animal testing, interpret results and draw conclusions regarding the safety and efficacy of vaccine candidates
- Oversee quality control testing to ensure that vaccine formulations meet safety and efficacy standards. Ensure the accurate quantification of antigens and adjuvants in vaccine formulations
- Collaborate with clinical trial teams to provide optimised vaccine candidates for testing in human subjects. Contribute to monitoring and analysing clinical trial data. Apply knowledge to relevant research projects and continuously acquire and maintain in-depth knowledge

Compliance

- Ensure that all animal testing and research activities are conducted in compliance with ethical guidelines, good laboratory practices (GLP) and regulatory requirements

Stakeholder management and communication

- Present results and findings to multidisciplinary team environment across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation in accordance with SOPs and regulations
- Contribute to scientific publications

Indicative summary

Minimum years of experience required	2-3
Minimum educational level required	Bachelors or Masters
Degree majors typically studied	Pharmaceutical Sciences, Biochemistry, Biotechnology
Knowledge-based understanding	Animal models, regulatory compliance, infectious diseases, molecular biology, immunology, pharmaceuticals, pathogenesis

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Ability to lead a small in vivo sciences project • Understanding of the basic science of infectious diseases • Problem-solving skills related to in vivo research and data analysis • Understanding of the basic principles and concepts in a broad range of technology, or substantial experience in a narrower field of technology • Understanding of compliance systems • Adherence to international laboratory standards of practice • Understanding of local animal welfare policies and regulations • Understanding of ELISA and other toxicology and immunogenicity assays • Ability to operate sanitisation and sterilisation equipment • Animal handling skills	→ • Various laboratory and immune assays • Animal models • Animal handling • Project management • Business process improvement	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving		

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

Animal Caregiver

Roles and responsibilities

Core responsibilities

- Inspect and maintain the health of animals, dispose of carcasses, track and record data and keep detailed records
- Monitor animal husbandry activities
- Ensure that daily activities are conducted according to biosafety procedures
- When required, administer vaccine candidates to animals

Compliance

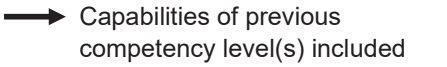
- Ensure all animal testing and research activities are conducted in compliance with ethical guidelines, good laboratory practices (GLP) and regulatory requirements

Indicative summary

Minimum years of experience required	1
Minimum educational level required	High school
Degree majors typically studied	Pharmaceutical Sciences, Biochemistry, Biotechnology
Knowledge-based understanding	Zootechnics, regulatory compliance, infectious diseases, pathogenesis, surgical techniques

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Understanding of local animal handling and welfare policies and regulation • Adherence to international laboratory standards of practice • Animal handling skills	→	• Laboratory experience • Animal handling experience • Surgical technics
Leadership & functional capabilities	• Strong attention to detail • Verbal and written communication skills	→	

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

Vaccine Formulation

Scientist, Vaccine Formulation

Roles and responsibilities

Core responsibilities

- Lead the design, development, and optimisation of vaccine delivery systems to ensure the stability, efficacy and safety of vaccines. This includes selecting the appropriate adjuvants, carriers and dosing strategies
- Investigate and innovate adjuvant technologies to enhance the immune response and improve vaccine performance. Evaluate novel adjuvants for their compatibility with vaccine antigens
- Research and develop various dosage forms for vaccines, including injectable solutions, oral vaccines and alternative delivery systems such as nasal or mucosal routes
- Oversee quality control testing to ensure vaccine formulations meet safety and efficacy standards
- Ensure the accurate quantification of antigens and adjuvants in vaccine formulations
- Plan and execute pre-clinical studies to assess the safety, immunogenicity, and efficacy of vaccine delivery systems in animal models. Interpret data and make recommendations for further development
- Collaborate with clinical trial teams to provide optimised vaccine delivery systems for testing in human subjects. Contribute to monitoring and analysing clinical trial data. Apply knowledge to relevant research projects and continuously acquire and maintain in-depth knowledge

Compliance

- Ensure that vaccine delivery methods and formulations comply with regulatory requirements and standards. Participate in regulatory submissions and approvals
- Contribute to the drafting and submission of patent claims for novel vaccine constructs and technologies

Stakeholder management and communication

- Present results and findings to multidisciplinary team environment across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses and maintain appropriate documentation in accordance with standard operating procedures (SOPs) and regulations
- Contribute to scientific publications and presentations to internal and external stakeholders

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors or masters
Degree majors typically studied	Pharmaceutical Sciences, Biochemistry, Biotechnology
Knowledge-based understanding	Vaccine discovery, infectious diseases, molecular biology, microbiology, immunology, pharmaceuticals, genomics, pathogenesis, microenvironments

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Understanding of infectious diseases, virology, biochemistry and immunology • Cell/molecular biology or virology lab and immunoassays (e.g., ELISA) experience • Adherence to international laboratory standards of practice • Computer software and data analysis • Regulatory requirements • Risk management	• Biochemical assays • Immunoprecipitation • Antibody cloning • Epitope mapping • mucosal immunology • Single cell sorting • Flow cytometry • Animal models • Animal handling • Adjuvants • Skilled in various tech platforms e.g. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Project management • Business process improvement	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Clinical Development

Head of Clinical Development

Roles and responsibilities

Core responsibilities

- Develop and define the clinical sciences strategy (e.g., the antigens/immunogens for which trials will be conducted, target populations, clinical operations etc.) for the department and ensure its successful execution
- Sign off on the clinical development plan and overall protocol synopsis
- Oversee the clinical development process and ensure the generation of evidence from the clinical development data that will support the licensing and commercialisation of the new products (e.g., define evidence generation plan, lead interpretation of clinical data, provide decision-making pathways based on study outcomes, provide risk management analyses and mitigation plans etc.)
- Lead implementation of new business processes and strategies and proactively identify issues and propose strategies to manage implications and risks on study timelines, budgets and goals
- Drive innovative approaches to clinical study delivery
- Make decisions which balance risks and benefits with clear understanding of impact on studies and projects; including action to mitigate risk where appropriate
- Oversee the preparation of key clinical documents to be prepared for clinical trials (protocols, reports), interactions with governance bodies, external experts and committees
- Build and maintain a strong network across internal organisational functions (e.g., Discovery and Development functions), opinion leaders and national regulatory authorities (NRAs)

Leadership and team management

- Lead multiple clinical development subfunctions in design and delivery of clinical studies, including provision of guidance where needed
- Support technical and leadership development of study delivery staff via mentoring and coaching

Compliance

- Oversee collaboration with Regulatory Affairs, R&D quality and process development groups to drive projects
- Oversee the integrity of the data collected and that the documentation of results meets quality standards and in accordance with regulatory requirements, working towards first-in-human (FIH) trials

Stakeholder management and communication

- Oversee preparation for governance meetings, adequately representing Clinical Development function and clearly outlining its progress, opportunities for improvement and help needed from broader organisation
- Build a positive external reputation for the Clinical Development function by overseeing research published in high-tier journals and representing the function at scientific events

Finance and resource planning

- Oversee the development of Clinical Development budgets
- Oversee adherence to Clinical Development budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	MD/PhD
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Clinical Development

Epidemiology

Scientist, Epidemiology

Roles and responsibilities

Core responsibilities

- Collect epidemiology data or conduct surveys to determine the burden of disease
- Conduct high-quality epidemiological analyses to evaluate effectiveness of current interventions, understand disease patterns and inform strategic planning related to diseases within the region
- Assist with scientific literature review on relevant topics as needed (e.g., surveillance methods, drivers of transmission and intervention effectiveness)
- Monitor, evaluate and improve the performance of surveillance processes and platforms and contribute to the formulation of surveillance guidelines, standard operating procedures (SOPs) and training materials
- Design, implement, analyse and disseminate operational research projects evaluating programme or intervention effectiveness
- Build strong internal and external partnerships by providing expert consultations on all aspects of real-world data (RWD) studies and analyses, including feasibility assessment, data source identification, protocol development and statistical analyses

Compliance

- Ensure integrity of data collected and documentations adhere to organisational SOPs, defined research policies (e.g., CDISC) and regulatory requirements
- Assist with drafting and submitting of patent claims as appropriate
- Ensure the medical and human safety aspects of the clinical and epidemiology programs are upheld

Stakeholder management and communication

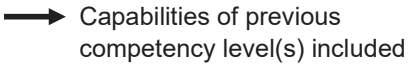
- Present results to multidisciplinary team environment across organisational functions
- Prepare precise technical reports, protocols, quantitative analyses, and maintain appropriate documentation in accordance with SOPs and regulations
- Contribute to scientific publications
- Present research plans and results to internal and external stakeholders

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, public health

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Good laboratory practices (GLP) • Data analysis • Regulatory requirements • Risk management	→ • Project management • Business process improvement • Database management“ • Epi modelling	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Clinical Development Strategy

Head, Clinical Development Strategy

Roles and responsibilities

Core responsibilities

- Develop and define the Clinical Sciences strategy (e.g., antigens/ immunogens for which trials will be conducted, target populations, Clinical Operations etc.) for the department and ensure successful execution
- Sign off on the clinical development plan and overall protocol synopsis
- Oversee the clinical development process from early-stage development until licensure and ensure the generation of evidence from the clinical development data that will support the licensure and commercialization of the new products (e.g., define evidence generation plan, lead interpretation of clinical data, provide decision-making pathways based on study outcomes, provide Risk Management analyses and mitigation plans etc.)
- Lead implementation of new business processes and strategies and proactively identify issues and propose strategies to manage implications and risks on study timelines, budgets, and goals
- Drive innovative approaches to clinical study delivery through external facing advances in technology and sciences
- Make decisions which balance risks and benefit with clear understanding of impact on studies and projects; including action to mitigate risk where appropriate
- Oversee the preparation of key clinical documents to be prepared for clinical trials (protocols, reports), interactions with governance bodies, external experts and committees
- Build and maintain a strong network across internal organizational functions (e.g., Discovery and Development functions), opinion leaders and regulatory authorities (NRAs)

Leadership and team management

- Lead multiple clinical development subfunctions in design and delivery of clinical studies, including provision of guidance where needed
- Support technical and leadership development of study delivery staff via mentoring and coaching

Compliance

- Oversee collaboration with Regulatory Affairs, R&D quality and process development groups to drive projects through licensure pathway
- Oversee the integrity of the data collected and documentation of results is according to quality standards and as per regulatory requirements, working towards First In Human (FIH) trials

Stakeholder management and communication

- Oversee preparation for governance meetings, adequately representing Clinical Development function and clearly outlining its progress, opportunities for improvement and help needed from broader organization
- Build a positive external reputation for the Clinical Development function by overseeing research published in high-tier journals and representing the function at scientific events

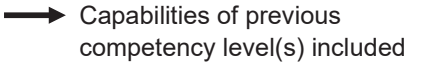
Indicative summary

Minimum years of experience required	10
Minimum educational level required	MD/PhD

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

Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Clinical development, infectious diseases, molecular biology, immunology, pharmaceuticals, public health

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Good laboratory practices (GLP) • Data analysis • Regulatory requirements • Risk management
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Teamwork • Interpersonal skills • Problem solving

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

Clinical Operations

Director, Clinical Operations

Roles and responsibilities

Core responsibilities

- Responsible for compliance of all clinical operational activities with applicable local/global regulations, guidelines and standard operating procedures (SOPs)
- Develop the clinical operations strategy for the department and ensure its successful execution
- Oversee the activities within Clinical Operations (i.e., scientific, technical and operational aspects of the clinical trials) and ensure they are conducted in accordance with regulations and SOPs
- Oversee the content and completion of clinical trial documentation (e.g., protocol and amendments, investigator brochures (IB), informed consent forms (ICFs) and case report forms (CRFs))
- Oversee continual optimisation of the organisational design and resources, ownership and optimisation of key processes, talent and succession management, overall operating budget management and oversight of all high-priority programmes and studies
- Oversee feasibility, study placement and scheduling, volunteer and patient recruiting, project management, clinical operations staffing and resource management and data management
- Address safety issues/concerns and create protocols to improve safety and prevent incidents
- Oversee the quality of the clinical trials to ensure they are up to regulatory and business standards and address any issues that may arise
- Oversee and develop innovative and advanced new concepts to improve processes across Clinical Operations
- Oversee the creation and implementation of local/global SOPs within Clinical Operations, ensuring staff are trained accordingly
- Monitor industry best practices and regulatory requirements and ensure knowledge is up to date

Leadership and team management

- Lead all the teams within Clinical Operations and coach direct and indirect reports
- Oversee the development and maintenance of capabilities (staff, facilities and equipment) to conduct a broad range of clinical trials

Compliance

- Be a key representative for audits and inspections for quality and compliance
- Oversee compliance of all clinical operational activities with applicable local/global regulations, guidelines and SOPs

Stakeholder management and communication

- Educate the organisation on critical developments and regulatory changes related to Clinical Operations and ensure standards are upheld within the organisation

Finance and resource planning

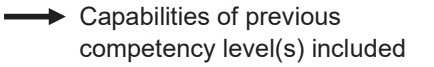
- Oversee the development of Clinical Operations budgets
- Oversee adherence to Clinical Operations budgets

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

Indicative summary

Minimum years of experience required	12
Minimum educational level required	MD/Masters
Degree majors typically studied	Medicine, Nursing, Biological Sciences, Pharmacy, Clinical Science, Toxicology
Knowledge-based understanding	Pharmaceuticals, clinical trials, clinical operations

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Clinical trial design • Regulatory requirements • Standard operating procedures (SOPs) • Good clinical practice (GCP) • Clinical trial management systems (CTMS) • Electronic data capture (EDC) • Risk management • Project management • Business process improvement • Quality management • Document management • Vendor management • Feasibility assessment • Budgeting • Data analysis • Strategic planning	
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills	• Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Site Management

Site Management Specialist

Roles and responsibilities

Core responsibilities

- Conduct operational and administrative support services to site staff, including handling regulatory and compliance activities, assisting with patient recruitment, ensuring the team has the latest training, etc.
- Assist with patient recruitment by collaborating with the team to identify potential study participants, assist with screen eligible candidates and coordinate enrolment procedures
- Ensure site staff have the latest training so that they have the necessary skills and knowledge to perform their duties effectively and safely
- Support the management of investigative sites and ensure that all sites adhere to the requirements and regulations
- Conduct site visits to understand if activities are going according to plan and assist with issues that may arise
- Monitor industry best practices, regulatory requirements and appropriate tools and resources (e.g., metrics, site health, risk-based monitoring signals, etc.) and ensure knowledge is up to date
- Assist with sharing best practices across all sites
- Contribute to the development of innovative, advanced new concepts to improve and standardise processes across Site Management

Compliance

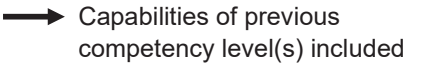
- Understand and ensure all studies adhere to SOPs and regulations
- Prepare and handle regulatory submissions and filings

Indicative summary

Minimum years of experience required	3
Minimum educational level required	MD/Masters
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, clinical operations

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical trial design • Regulatory requirements • Standard operating procedures (SOPs) • Clinical trial management systems (CTMS) • Electronic data capture (EDC) • Risk management • Document management • Good clinical practice (GCP) • Data analysis	• Project management • Business process improvement • Quality management • Feasibility assessment • Site selection • Performance monitoring	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Medical Writer

Roles and responsibilities

Core responsibilities

- Prepare and write clinical start-up study reports
- Generate Investigator Brochures (IBs) and other documents related to the conduct of clinical trials and non-interventional studies
- Generate patient-facing material (e.g. patient information)
- Support the project team in preparation and compilation of narrative safety reports
- Provide scientific knowledge, analytical skills and support to Clinical Operations and other related functions to deliver submission documents
- 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., contributions to documents and activities included in registration files and authoring clinical documents supporting studies following defined templates etc.)
- Ensure the consistency and quality level of all documents that are issued

Compliance

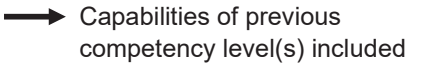
- Ensure compliance of clinical/regulatory documents with SOPs, company policies and local and global regulatory requirements

Indicative summary

Minimum years of experience required	3
Minimum educational level required	MD/Masters
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Biochemistry, Biotechnology, Business Administration
Knowledge-based understanding	Infectious diseases, immunology, pharmaceutical, clinical trials, clinical operations

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Medical writing • Editing • Regulatory requirements • Risk management • Document management • Electronic common technical documents (eCTD) • Clinical trial management systems (CTMS)	→ • Project management • Business process improvement	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Site Training

Site Training Coordinator

Roles and responsibilities

Core responsibilities

- Create and manage a training schedule that ensures all training is delivered in a timely manner and that all users have attained sufficient competence to perform their roles post the go-live date
- Assist with any training-related risks, issues and dependencies and escalate to leadership as appropriate
- Ensure all areas on site have the tools and knowledge available to complete all training requirements
- Research training materials from a variety of vendors and select appropriate materials based on business need and share with team
- Contribute to developing programmes and training/retraining courses which meet employees' learning objectives by delivering core training during onboarding, support employees in obtaining proficiency and help them explore future growth opportunities
- Contribute to the improvement of existing training curricula and the development of new ones
- Tailor the core training toolkit to reflect local requirements

Compliance

- Ensure a standardised system is utilised across the site for all training documentation and storage of training records to ensure targets are achieved and that training is in accordance with regulatory requirements
- Ensure local training complies with regulatory requirements and quality standards

Stakeholder management and communication

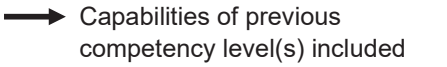
- Coordinate with teams across the organisation to conduct needs analysis, develop learning objectives and assist with defining competency requirements that in each case help define the training necessary for one or more given employees and/or departments on business-specific initiatives, regulations, systems and projects
- Collaborate with individual department trainers or designers to ensure common training is carried out in a standardised manner and set schedule

Indicative summary

Minimum years of experience required	6
Minimum educational level required	RN, Bachelors
Degree majors typically studied	Medicine, Nursing, Biological Sciences, Pharmacy
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, clinical operations

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Clinical trial design • Regulatory requirements • Standard operating procedures (SOPs) • Good clinical practice (GCP) • Clinical trial management systems (CTMS) • Electronic data capture (EDC) • Risk management • Project management • Business process improvement • Quality management • Document management • Data analysis • Site training • Curriculum building • Coordinating • Learning management systems • Training needs analysis (TNA) • Study metrics • Performance monitoring
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Vendor Management

Vendor Management Lead

Roles and responsibilities

Core responsibilities

- Contribute to the development of a clinical operations strategy and drive execution
- Develop and drive the vendor management strategy, as well as communicate it to the team
- Manage the strategic identification and specification of scope and drive the selection process of clinical vendors, including Clinical Research Organisations (CROs)
- Lead negotiations with vendors to meet study specifications within timeline and budget
- Oversee change order process and forecasting with CROs and other external partners for clinical operations
- Manage a pool of vendors and maintain partnerships, including overseeing quality risk assessments for vendor qualification and planning audit/vendor review after delivery
- Oversee vendor performance against agreed-upon metrics, track deliverables and carry out performance evaluations while identifying and addressing any issues that may arise
- Lead the process of improving the vendor management process and associated frameworks
- Oversee and attend vendor governance meetings and provide guidance on resolving issues
- Oversee the completion and quality of vendor documents, including contract agreements, communications, performance evaluations, etc.
- Monitor industry best practices and regulatory requirements and ensure knowledge is up to date
- Oversee best practice sharing and uphold quality across functions within the organisation

Leadership and team management

- Lead a team of vendor management experts 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

Compliance

- Oversee vendors and CROs to ensure they comply with local regulations, company guidelines and quality standards

Stakeholder management and communication

- Manage RFP development, selection and management of project CROs and other clinical trial vendors in the delivery of contracted services in close cooperation with cross-functional team leads

Finance and resource planning

- Lead development and preparation of Vendor management budgets and syndicate with Clinical Operations leadership
- Manage adherence to Vendor management budgets
- Strategically review and compare budgets and quotes and provide recommendations as to preferred vendors

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

Indicative summary

Minimum years of experience required	9
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Biochemistry, Biotechnology, Finance, Business Administration
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, finance

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Clinical trial design • Regulatory requirements • Standard operating procedures (SOPs) • Good clinical practice (GCP) • Risk management • Project management • Business process improvement • Quality management • Document management • Vendor management • Feasibility assessment • Budgeting • Data analysis • Procurement
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Clinical IT Support

IRT Lead/Manager

Roles and responsibilities

Core responsibilities

- Assess the usability of study medication that has been affected by a temperature excursion at the site, in co-operation with QA, to ensure that where a drug's pharmaceutical quality has been compromised it cannot be administered to patients
- Understand protocol requirements from the clinical team, then partner with the interactive response technology (IRT) vendor to ensure the IRT system is programmed according to the protocol, test scripts are complete and accurate, and execute user acceptance testing (UAT) in order to put the system into production successfully
- Collaborate with the IRT vendor in producing and documenting system requirements for new and amended studies
- Write and execute UAT test plans where UAT is employed
- Collaborate with the IRT vendor to create IRT-supportive documents and investigator meeting slides for clinical teams and investigator site personnel
- Provide and manage input into SOPs and process development to aid quality management

Leadership and team management

- Provide guidance and training to study teams, clinical research associates (CRAs) and site personnel on the handling of study medication and the IRT system

Compliance

- Lead the setup and testing of the system, ensuring it meets the requirements of the clinical study protocol and that all associated processes are fully compliant with regulations
- Serve as subject matter expert during regulatory inspections for assigned studies

Stakeholder management and communication

- Train partnering lines on the system functionality applicable to their study
- Provide technical expertise and knowledge sharing across engagement and system design teams to ensure consistency in standards, design and strategic decision making

Finance and resource planning

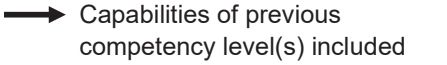
- Lead development of automation budgets and syndicate with Clinical Operations leadership
- Manage adherence to automation budgets

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Medicine, Biochemistry, Biological Sciences, Computer Science, Data/Mathematics, Pharmacy, Biochemistry, Biotechnology, Business Administration
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, clinical operations

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Electronic data capture (EDC) • Regulatory requirements • Risk management • Project management • Business process improvement • Quality management • Document management • Vendor management • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Data Sciences

Director, Data Sciences

Roles and responsibilities

Core responsibilities

- Develop and drive the data science strategy, as well as communicate it with the team
- Oversee and guide the implementation of technology advancements including AI (including external benchmarking against pharmaceutical and other companies using advanced technology)
- Make sure that models to predict risk, etc. can be explained well (both internally and to regulators), avoid bias, are readily supported, proofs of concept (POCs) can be scaled and are continuously calibrated (to ensure inputs/outputs remain true/relevant) and ensure controls are in place to manage data model risk
- Oversee the creation of prototypes, predictive models and demonstrations to help articulate the value of insights for advancing science and discovery

Leadership and team management

- Manage and lead multiple teams across Data Sciences
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Oversee compliance of all data science activities with applicable local/global regulations, guidelines and standard operating procedures (SOPs)
- Stakeholder management and communication
- Educate the organisation about critical developments and regulatory changes related to data science and ensure data quality and integrity are upheld within the organisation in accordance with SOPs and regulations
- Partner cross-functionally to develop and execute a hypothesis-driven analytics strategy across quality business lines to ensure a strategic, optimised and consistent approach (data standards) with metrics and thresholds that meet stakeholder needs

Finance and resource planning

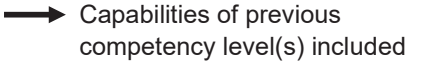
- Oversee the development of budgets for Data Sciences
- Oversee adherence to Data Sciences' budgets

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters
Degree majors typically studied	Statistics, Biostatistics, Data Science, Information Technology, Applied Mathematics, Computer Science, Engineering
Knowledge-based understanding	Statistics, clinical trial

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Programming • Data analysis • Statistical computer databases • Electronic data capture (EDC) • Regulatory requirements • Standard operating procedures (SOPs) • CDISC standards • ICH guidelines • Business process improvement • Risk management • Project management • Quality management • Document management • Vendor management • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Biostatistics

Biostatistician

Roles and responsibilities

Core responsibilities

- Assist with developing a statistical analysis plan (SAP) that outlines the statistical methods and procedures to be used for analysing study data
- Assist in determining the appropriate statistical tests, models and methodologies to analyse efficacy, safety and other study outcomes
- Provide statistical input to the design, analysis, reporting and interpretation of data from clinical studies
- Assist with end-to-end project support across the entire range of drug development, from early clinical development to registration and marketed product support
- Perform statistical analyses of study results and write summary reports and present results
- Prepare statistical analysis plans including the definition of derived data, and the design of statistical tables, figures, and data listings for clinical summary reports
- Contribute to clinical development plans, regulatory and commercial strategies
- Identify, develop and implement novel statistical methodologies in support of vaccine development
- Provide statistical programming support for multiple clinical projects, including effective management of contract research organisations (CROs)
- Review study database structures, edit checks and data management coding conventions

Compliance

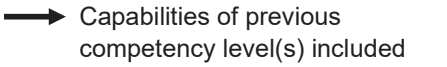
- Liaise with other organisational functions to enhance integrity of data and ensure they adhere to standard operating procedures (SOPs) and regulatory requirements

Indicative summary

Minimum years of experience required	3
Minimum educational level required	Masters
Degree majors typically studied	Statistics, Biostatistics, Data Science, Information Technology, Applied Mathematics, Computer Science, Engineering
Knowledge-based understanding	Statistics, clinical trial

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Programming • Data analysis • Statistical methodologies • Electronic data capture (EDC) • Regulatory requirements • Standard operating procedures (SOPs) • Risk management • Document management	→ • Linear/non-linear models • Model selection and validation • Interpret research requirements • Statistical computer databases • Business process improvement • Project management • Quality management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Data Management

Specialist, Clinical Data Management

Roles and responsibilities

Core responsibilities

- Assist with designing and developing the structure and architecture of clinical databases and/or data management systems
- Monitor and ensure accurate and timely entry of clinical trial data into designated databases, performing data validation checks and ensuring data integrity
- Assist with implementing standardised coding systems and dictionaries for consistent data collection and reporting
- Maintain and update databases, including regular backups and implementation of security measures
- Assist with providing user support and training for individuals accessing the database or data management system
- Assist with ensuring data security and confidentiality by implementing access controls, encryption measures and data protection protocols
- Collaborate with cross-functional teams throughout the clinical trial lifecycle, actively participating in data management meetings and contributing to overall study planning and execution

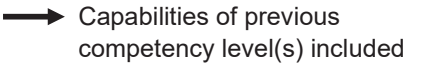
Compliance

- Conduct quality control checks to ensure adherence to data management processes, standard operating procedures (SOPs) and regulatory guidelines

Indicative summary

Minimum years of experience required	4
Minimum educational level required	Bachelors
Degree majors typically studied	Statistics, Biostatistics, Data Science, Information Technology, Applied Mathematics, Computer Science, Engineering
Knowledge-based understanding	Statistics, clinical trial

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Programming • Data analysis • Interpret research requirements • Statistical computer databases • Electronic data capture (EDC) • Regulatory requirements • Standard operating procedures (SOPs) • CDISC standards • ICH guidelines • Risk management • Document management	• Business process improvement • Project management • Quality management • Statistical software	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Regulatory

Regulatory Operations

Director, Regulatory Affairs

Roles and responsibilities

Core responsibilities

- Develop the strategy for the Regulatory Affairs department and ensure its successful execution
- Lead the coordination of the compilation of the target product profile (TPP)
- 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 and 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 the company is present (i.e., be the point of contact with the relevant national regulatory agencies (NRAs) for all assets)
- Oversee and advocate scientifically sound approaches persuasively to senior leaders at company and to NRAs
- Ensure appropriate interaction with commercial teams

Leadership and team management

- Manage and lead multiple teams across Regulatory Affairs
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Oversee compliance with relevant regulatory requirements at every stage of the product life cycle

Stakeholder management and communication

- Oversee preparation for governance meetings, adequately representing Regulatory Affairs and clearly outlining its progress, opportunities for improvement and help needed from broader organisation
- Build a positive external reputation for Regulatory Affairs by overseeing research published in high-tier journals and representing the function at scientific events

Finance and resource planning

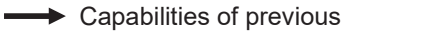
- Oversee the development of Regulatory Affairs budgets
- Oversee adherence to Regulatory Affairs budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Submission publishing • Submission preparation • Database management • Quality management • Document management • Electronic common technical documents (eCTD) • Compliance databases • Product lifecycle management • Labelling • Project management • Risk management • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Regulatory Affairs Specialist

Roles and responsibilities

Core responsibilities

- Ensure timely submission and approval of all licensing applications in compliance with local and global regulatory requirements
- Ensure timely delivery of clinical trial approvals and maintenance of high regulatory compliance standards achieved through provision of local regulatory expertise
- Prepare high quality regulatory applications and regulatory responses
- Provide regulatory input to stock and supply issues
- Conduct revisions and updates of regulatory work for ongoing products to meet evolving regulatory requirements, such as changes in labelling, safety information, manufacturing processes or post-marketing surveillance to maintain their presence in the market across different geographies

Compliance

- Ensure regulatory compliance for defined product and project responsibilities
- Assure appropriate standards and policies are maintained for all technical aspects of the company's regulatory activities

Stakeholder management and communication

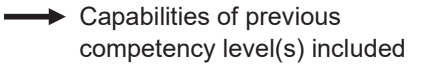
- Liaise with labelling function to manage pack changes and ensure labelling compliance
- Manage the regulatory process and effectively negotiate with regulatory agencies to provide rapid regulatory approvals with competitive labelling
- Develop professional working relationships with assessors and administrative staff within the regulatory agencies
- Support the delivery of commercial objectives, including representing Regulatory Affairs within appropriate cross-functional teams

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Submission publishing • Submission preparation • Regulatory requirements • Document management • Document management systems • Electronic common technical documents (eCTD) • Product lifecycle management • Labelling • Risk management	• Project management • Database management • Quality management • Compliance databases	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Negotiation • Coaching and mentoring • Decision making • Innovation	

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

Medical Writer

Roles and responsibilities

Core responsibilities

- Contribute to the planning, authoring, review and approval of clinical/regulatory documents for medical writing projects to achieve a successful outcome within the required timelines (e.g., contributing to documents and activities included in registration files and authoring clinical documents supporting studies that follow defined templates)
- Ensure the consistency and quality level of all documents that are issued
- Advise on methods for achieving accelerated timelines, including review tools and automation
- Contribute to all aspects of document development planning, coordination and review meetings to integrate and address stakeholder comments
- Contribute to process improvement activities in the Regulatory Operations subfunction

Leadership

- Contribute to development of training materials for clinical document preparation; provide mentoring and/or training in clinical documentation and submission planning to individuals or teams

Compliance

- Ensure compliance of clinical/regulatory documents with standard operating procedures (SOPs), company policies and local and global regulatory requirements

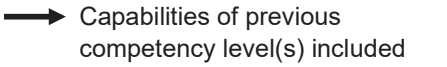
Stakeholder management and communication

- Collaborate closely with the submission team to provide input to submission plan, timelines, document content and dependencies

Indicative summary

Minimum years of experience required	2
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Medical writing • Editing • Regulatory requirements • Risk management • Document management • Electronic common technical documents (eCTD)	• Project management • Quality management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Negotiation • Coaching and mentoring • Decision making • Innovation	

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

Regulatory CMC

Specialist/Associate, Regulatory Affairs CMC

Roles and responsibilities

Core responsibilities

- Support effective chemistry, manufacturing and controls (CMC) regulatory strategies for submissions (e.g., investigational new drug (IND)/clinical trial applications (CTA)/biologics licence applications (BLA)/marketing authorisation applications (MAA)) and identify regulatory risks
- Support the creation and maintenance of CMC submission templates
- Provide guidance for regulatory CMC aspects of product development projects
- Review documents for their readiness for submission to ensure that all submissions conform to health authority guidelines

Compliance

- Manage regulatory agency submission, publishing and validation standards to ensure compliant and valid dossiers in operating markets
- Perform CMC regulatory activities in accordance with good regulatory practices (GRP)

Stakeholder management and communication

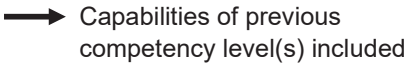
- Contribute to CMC Regulatory discussions and interactions with health authorities to facilitate review and approval of submissions
- Provide CMC regulatory guidance to manufacturing and quality teams, including evaluation of CMC change controls

Indicative summary

Minimum years of experience required	3
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Submission preparation • Submission publishing • Regulatory requirements • Document management • Document management systems • Electronic common technical documents (eCTD) • Risk management	→ • Project management • Database management • Quality management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Negotiation • Coaching and mentoring • Decision making • Innovation	

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

Regulatory Clinical

Clinical Regulatory Specialist

Roles and responsibilities

Core responsibilities

- Provide expert regulatory guidance and interpretation to clinical research teams, ensuring compliance with local and international regulatory requirements
- Prepare and review regulatory documents, including clinical trial applications, investigational new drug (IND) submissions and other regulatory submissions in order to secure necessary approvals
- Ensure the consistency and quality level of all documents issued
- Advise on methods for achieving accelerated timelines, including review tools and automation
- Contribute to all aspects of document development planning, coordination and review meetings to integrate and address stakeholder comments
- Contribute to process improvement activities in the Regulatory Operations subfunction

Leadership

- Contribute to development of training materials for clinical document preparation; provide mentoring and/or training in clinical documentation and submission planning to individuals or teams

Compliance

- Perform regular reviews of clinical trial documentation and data to maintain high-quality and audit-ready records
- Ensure compliance of clinical regulatory documents with standard operating procedures (SOPs), company policies and local and global regulatory requirements

Stakeholder management and communication

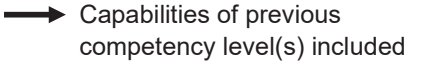
- Collaborate closely with cross-functional teams to ensure that clinical trials are conducted in accordance with regulatory guidelines, good clinical practice (GCP), and institutional SOPs

Indicative summary

Minimum years of experience required	6
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration
Knowledge-based understanding	Clinical development, infectious diseases, immunology, pharmaceuticals, genomics, pathogenesis

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Submission preparation • Submission publishing • Regulatory requirements • Database management • Quality management • Document management • Document management systems • Project management • Risk management
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Policy and Labelling

Specialist, Regulatory Affairs Labelling

Roles and responsibilities

Core 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 that the labelling documents submitted to regulatory authorities are of the highest quality
- 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

Compliance

- Perform work in accordance with established procedures, regulatory requirements and good practices (GxPs)

Stakeholder management and communication

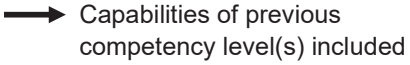
- Communicate with regulatory agencies and third parties on behalf of Regulatory Affairs Labelling staff
- Provide advice regarding regulatory authority labelling requirements company labelling processes and standards to the rest of the Regulatory Affairs function

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Business Administration
Knowledge-based understanding	Vaccine discovery and development

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities		• Labelling • Product Information • Regulatory requirements • Database management • Quality management • Document management • Document management systems • Submission preparation • Project management • Risk management	
Leadership & functional capabilities		• Written and oral communication • Teamwork • Interpersonal skills • Problem solving • Presentation • Negotiation • Coaching and mentoring • Decision making • Innovation	

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

Pharmacovigilance and Safety

Director, Pharmacovigilance and Safety

Roles and responsibilities

Core responsibilities

- Develop the pharmacovigilance (PV) and drug safety strategy for the department and ensure successful execution
- Oversee and manage clinical development plans, protocol development (inclusion/exclusion criteria, collection, and monitoring of safety data), statistical analysis and reporting of study data
- Oversee and manage the successful implementation, execution and maintenance of safety processes and systems that conform to the company's strategy and industry standards and comply with local and global regulations
- Oversee PV and drug safety management activities including monthly meetings, action item tracking and ensuring adequate documentation
- Manage routine signalling activities assessment and investigation and ensure they are completed in accordance with standard operating procedures (SOPs)
- Lead quality checking of cases to ensure quality and monitoring of all cases moving through the workflow steps are compliant with local regulations and SOPs
- Manage complex timelines to achieve on-time completion with cross-functional collaboration and delivery of key documents
- Monitor industry best practices and regulatory requirements and ensure knowledge is up to date
- Lead continuous process improvement related to PV and drug safety activities

Leadership and team management

- Manage and lead multiple teams across Pharmacovigilance and Drug Safety function
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Lead and author safety reports in accordance with SOPs and local/global regulatory requirements
- Be a key representative for audits and inspections for quality and compliance
- Manage preventative and corrective action plans arising from audits and inspections
- Oversee safety reports received and ensure they are processed in a consistent and fully compliant manner

Stakeholder management and communication

- Oversee responses to safety related requests from health authorities
- Educate the organisation about critical developments and regulatory changes related to PV and drug safety

Finance and resource planning

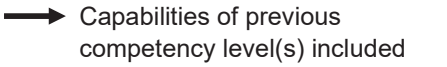
- Lead development of Pharmacovigilance and Safety budgets
- Manage adherence to Pharmacovigilance and Safety budgets

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

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Biological Sciences, Medicine, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, pharmacovigilance

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Signal detection • Review and synthesis • Data analysis • Training • Report writing • Drug safety regulations • Risk management • Project management • Business process improvement • Quality management • Document management
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Pharmacovigilance Strategy and Operations

Drug Safety/Pharmacovigilance Specialist/Associate

Roles and responsibilities

Core responsibilities

- Contribute to the successful implementation, execution and maintenance of safety processes and systems that conform to the company's strategy and industry standards and comply with local and global regulations
- Design and perform analyses of safety information for signal detection in accordance with standard operating procedures (SOPs) and guidelines
- Assist with clinical development plans, protocol development (inclusion/exclusion criteria, collection and monitoring of safety data), statistical analysis and reporting of study data
- Conduct pharmacovigilance (PV) and drug safety management activities including monthly meetings, action item tracking and ensuring adequate documentation
- Perform quality check of cases to ensure that the quality and monitoring of all cases moving through the workflow steps are compliant with local regulations and SOPs
- Assist with complex timelines to achieve on-time completion with cross-functional collaboration and delivery of key documents
- Maintain current knowledge of relevant regulations for PV and drug safety practices
- Assist and contribute to continuous process improvement related to PV and drug safety activities
- Respond to safety-related requests from health authorities

Compliance

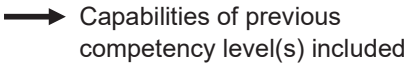
- Assist and contribute to safety reports in accordance with standard procedures and local/global regulatory requirements
- Identify potential compliance issues and contribute in preventative and corrective action plans arising from audits and inspections
- Provide input on standards and processes for ensuring compliance with regulatory requirements as well as departmental procedures
- Manage safety reports received and ensure they are processed in a consistent and fully compliant manner

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Biological Sciences, Medicine, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, pharmacovigilance

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Signal detection • Review and synthesis • Data analysis • Report writing • Drug safety regulations • Risk management • Document management	→	
		• Project management • Business process improvement • Quality management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→	
		• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Other

R&D Quality

Director, Research Quality

Roles and responsibilities

Core responsibilities

- Regularly inform R&D Head of any significant research quality development
- Develop and drive Research Quality's strategy, as well as communicate it with the team
- Oversee gap analysis and risk assessment for critical study-level activities that may impact subject safety and/or the quality and reliability of data
- Oversee regulatory inspections related to R&D quality management (i.e., procedural documents, training, issue management and risk management)
- Oversee the development and maintenance of policies and procedures according to good clinical practice (GCP)/good laboratory practice (GLP)
- Oversee enhancements to existing quality system process in a manner that effectively supports the growth of the business
- Chairs select quality management system (QMS) governance boards and quality forums, and drives an aligned escalation of QMS priorities and issues to senior management and governance boards

Leadership and team management

- Manage and lead multiple teams across Research Quality
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Oversee that all quality control (QC) activities are in accordance with regulatory and industry guidance and standard operating procedures (SOPs) and provide guidance where needed

Stakeholder management and communication

- Conduct periodic reviews of the documents in QMS to ensure documents remain current and compliant to internal requirements and regulations
- Educate the organisation about critical developments and regulatory changes related to R&D quality and ensure data quality and integrity are upheld within the organisation in accordance with SOPs and regulations

Finance and resource planning

- Oversee the development of Research Quality budgets
- Oversee adherence to Research Quality budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Nursing, Medical Technology, Chemistry, Biological Sciences, Pharmacy, Medicine
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, laboratory operations

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good clinical practice (GCP) • Good clinical laboratory practice (GCLP) • Regulatory requirements • Risk management • Document and records management • Vendor management • Project management • Business process improvement • Budgeting

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

Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Quality Control

Quality control: Manager, Clinical Quality Control

Roles and responsibilities

Core responsibilities

- Manage and ensure proper review of study files after study completion and ensure the documentation is in accordance with protocols, standard operating procedures (SOPs), good clincal practice (GCP) and regulations
- Manage and review all quality control (QC) related documents in support of vaccine substance, intermediates, vaccine products and stability samples including specifications, method qualification/validation and stability protocols/reports
- Manage the ensure proper review study files upon data entry at the check-in, on-study and post-study procedures
- Oversee the adherence to SOPs to uphold quality of R&D activities across the different functions within the organisation
- Lead quality testing including, but not limited to, clinical and/or commercial product, raw materials and validation samples
- Oversee the analysis and interpretation of results and make decisions regarding their accuracy, completeness and compliance
- Address issues and manage issue resolution
- Manage QC lab investigations, compliance and audits
- Contribute to inspection readiness through performing gap assessments of corporate standards and continuous improvement of data integrity within QC operations

Leadership and team management

- Lead the Quality Control 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

Compliance

- Manage and ensure all activities adhere to relevant practices, SOPs and regulations

Stakeholder management and communication

- Communicate with organisational functions to address quality-related issues, coordinate quality control activities and ensure the quality of upcoming activities

Finance and resource planning

- Assist with development of Quality Control budgets and syndicate with Research Quality leadership
- Support adherence to Quality Control budgets

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

Indicative summary

Minimum years of experience required	8
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medical Laboratory Technician, Chemistry, Biological Sciences, Pharmacy, Medicine
Knowledge-based understanding	Laboratory operations, infectious diseases, immunology, pharmaceuticals, clinical trials

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	**Semi-specialist FTE**	**Specialist FTE**	
Technical capabilities			• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good clinical practices (GCP) • Good laboratory practice (GLP) • Regulatory requirements • Risk management	• Document and records management • Vendor management • Project management • Business process improvement • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Associate, Clinical Quality Control

Roles and responsibilities

Core responsibilities

- Review study files after study completion and ensure the documentation is in accordance with protocols, standard operating procedures (SOPs), good clinical practice (GCP) and regulations
- Assist in the review of study files upon data entry at the check-in, on-study and post-study procedures
- Assist in ensuring adherence to SOPs to uphold quality of R&D activities across the different functions within the organisation
- Perform quality testing including, but not limited to, clinical and/or commercial product, raw materials and validation samples
- Analyse and interpret results and make decisions regarding their accuracy and completeness
- Assist with creating and reviewing documentation (test records and, as assigned, validation protocols/reports, test methods, equipment records, etc.) ensuring adherence to SOPs and regulations
- Report issues to management and participate in issue resolution (such as reporting results and participating in associated laboratory investigation, reporting instrument issues and assisting with troubleshooting, etc.)
- Assess existing situations and suggest improvements to increase compliance and innovation
- Support quality control (QC) lab investigations, compliance and audits
- Contribute to inspection readiness through performing gap assessments of corporate standards and continuous improvement of data integrity within QC operations
- Act as first responder for on-the-floor quality issues in a timely manner, documenting all events/investigations and the required immediate corrective actions to facilitate right first time performance
- Review study protocols, informed consent forms, case report forms and other essential documents to verify accuracy, completeness and compliance

Compliance

- Ensure all activities adhere to relevant practices, SOPs and regulations

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Medical Laboratory Technician, Chemistry, Biological Sciences, Pharmacy, Medicine
Knowledge-based understanding	Laboratory operations, infectious diseases, immunology, pharmaceuticals, clinical trials

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • Laboratory equipment qualification • System validation • Change control • Good clinical practices (GCP) • Good clinical laboratory practice (GCLP) • Regulatory requirements • Risk management • Document and records management	→ • Business process improvement • Project management • Assay development and technology transfer	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Quality Assurance

Manager, Clinical Quality Assurance

Roles and responsibilities

Core responsibilities

- Develop and drive the Quality Assurance strategy, as well as communicate it with the team
- Lead role in risk and issue management
- Lead the development of quality assurance programs, policies and procedures to ensure compliance with regulatory requirements, industry standards and best practices
- Lead and contribute to creating, implementing and maintaining standard operating procedures (SOPs) to uphold the quality of R&D activities across the different functions within the organisation
- Manage audits and inspections to evaluate the quality and compliance of clinical research processes, protocols and documentation
- Lead on-site visits to investigate and evaluate clinical trial sites, monitor the conduct of trials and verify that data collection and management procedures are being followed appropriately
- Oversee quality issues and ensure that complaints are adequately investigated and documented
- Oversee audits of vendors; provide input on the resolution of non-conformances, deviations and investigations

Leadership and team management

- Oversee the Quality Assurance team and provide training and coaching to direct and indirect reports
- Ensure the Quality Assurance team's competencies are developed and skill gaps are identified and addressed

Compliance

- Oversee and monitor application of SOPs created and re-evaluate as needed

Stakeholder management and communication

- Interact with regulatory agencies to ensure compliance with regulations and address any quality-control-related inquiries or audits
- Communicate with vendors and suppliers to address quality-related issues, coordinate quality control activities and ensure the quality of incoming materials
- Promote collaboration with cross-functional teams across the organisation to identify areas of improvement, provide guidance on quality issues and support the implementation of quality improvement initiatives

Finance and resource planning

- Lead development of Quality Assurance budgets and syndicate with Research Quality leadership
- Manage adherence to Quality Assurance budgets

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

Indicative summary

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Nursing, Chemistry, Biochemistry, Biology, Pharmacy, Medicine
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials

Capabilities across proficiency levels

	Basic-skilled FTE	**Semi-specialist FTE**	**Specialist FTE**	
Technical capabilities			• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good clinical practices (GCP) • Good laboratory practice (GLP) • Good pharmacovigilance practices (GVP) • Good manufacturing practices (GMP) • Regulatory requirements	• Risk management • Document and records management • Vendor management • Project management • Business process improvement • Clinical site auditing • Internal QMS auditing • Standard operating procedure (SOP) management • Inspections • Budgeting

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

Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Clinical Quality Assurance Auditor

Roles and responsibilities

Core responsibilities

- Conduct audits and inspections to evaluate the quality and compliance of clinical research processes, protocols and documentation
- Assist with creating, implementing and maintaining standard operating procedures (SOPs) to maintain quality of R&D activities across the different functions within the organisation
- Plan, schedule, conduct, report and close audit in accordance with regulation requirements, SOPs and project-specific guidelines/instructions
- Perform assessments of clinical activities to ensure adherence to applicable regulations, guidelines and SOPs
- Conduct on-site visits to investigate and evaluate clinical trial sites, monitor the conduct of trials and verify that data collection and management procedures are being followed appropriately
- Generate audit reports, identify areas of non-compliance or potential risks and provide recommendations for corrective actions
- Evaluate audit findings and prepare and distribute reports to operations staff and management
- Perform vendor audits; assist in the resolution of non-conformances, deviations and investigations

Compliance

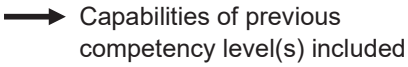
- Conduct audits and inspections to assess compliance with regulations and SOPs

Indicative summary

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Nursing, Biological Sciences
Knowledge-based understanding	Infectious diseases, immunology

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good laboratory practice (GLP) • Good pharmacovigilance practices (GVP) • Regulatory requirements • Risk management • Document and records management • Clinical site auditing • Internal QMS auditing • SOP management • Inspections	→ • Business process improvement • Project management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Clinical Quality Assurance Specialist

Roles and responsibilities

Core responsibilities

- Assist with implement and maintain quality systems and processes across the organisation
- Develop and monitor quality assurance (QA) programmes, policies and procedures to ensure compliance with regulatory requirements, industry standards and best practices
- Collaborate with cross-functional teams across the organisation to identify areas of improvement, provide guidance on quality issues and support the implementation of quality improvement initiatives
- Evaluate policies and procedures for compliance with applicable regulations/guidelines and provide recommendations to management for continuous process improvements
- Develop and maintain various clinical QA trackers and metrics
- Contribute to the development of training programs and conduct quality-related training sessions
- Increase compliance awareness and promote a culture of quality
- Contribute to standard operating procedure (SOP) reviews and support SOP creation and revision as part of continuous improvement effort
- Provide interpretation and consultation to project teams on regulations, guidelines, compliance status and policies and procedures

Compliance

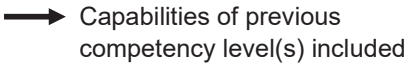
- Develop and maintain quality systems and processes to ensure quality compliance to regulations and SOPs
- Maintain a contemporary knowledge of current regulatory requirements, industry trends, standards and methodologies

Indicative summary

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Nursing, Biological Sciences
Knowledge-based understanding	Infectious diseases, immunology

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good clinical practices (GCP) • Good pharmacovigilance practices (GVP) • Regulatory requirements • Risk management • Document and records management • Clinical site auditing • Internal QMS auditing • SOP management • Inspections	→ • Business process improvement • Project management	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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, Clinical Documentation

Roles and responsibilities

Core responsibilities

- Manage and facilitate the system(s) for creation and revision of master documents, including standard operating procedures (SOPs) companywide
- Oversee the process of archival, retrieval, and provision of controlled documents, including hardcopy and electronic files
- Manage and monitor the processing, review, and approval of revision-controlled documents in the electronic document management system (eDMS)
- Oversee the compliance with controlled document format and content
- Oversee the maintenance of master documents and records to ensure documentation is retrievable and files are accurate, complete and well organized
- Manage a periodic document review process
- Oversee the issuance of batch records, forms, logbooks, validation documents, labels and other controlled documents as required
- Oversee the generation of quality assurance document control metrics
- Take into account feedback towards improvement of the document control program, implement changes and communicate them with the wider organisation

Leadership and team management

- Lead the Clinical Documentation 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

Compliance

- Be the point of contact for internal and regulatory audits and inspections
- Manage and ensure activities adhere to practices and standard operating procedures (SOPs), including good documentation practices

Stakeholder management and communication

- Collaborate with authors, reviewers and approvers to ensure successful implementation of new/revised SOPs, primarily through the management of document lifecycle (new or existing documents) and review/approval workflows

Finance and resource planning

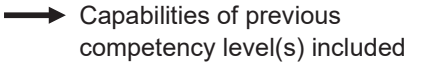
- Assist with development of Clinical Documentation budgets and syndicate with Research Quality leadership
- Support adherence to Clinical Documentation budgets

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

Indicative summary

Minimum years of experience required	6
Minimum educational level required	Bachelors
Degree majors typically studied	Nursing, Biological Sciences
Knowledge-based understanding	Infectious diseases, immunology

Capabilities across proficiency levels



	Basic-skilled FTE	**Semi-specialist FTE**	**Specialist FTE**	
Technical capabilities			• Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good clinical practices (GCP) • Good laboratory practice (GLP) • Good pharmacovigilance practices (GVP) • Regulatory requirements • Risk management	• Document and records management • Vendor management • Project management • Business process improvement • Internal QMS Auditing • SOP management • Inspections • Formatting • Achieving • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Analyst, Clinical Documentation

Roles and responsibilities

Core responsibilities

- Assist with facilitating system(s) for creation and revision of master documents, including standard operating procedures (SOPs) companywide
- Perform archiving, retrieval and provision of controlled documents including hardcopy and electronic files
- Monitor the processing, review, and approval of revision-controlled documents in the electronic document management system (eDMS)
- Ensure compliance with controlled document format and content
- Maintain master documents and records to ensure documentation is retrievable and files are accurate, complete, and well organised
- Assist with managing the periodic document review process
- Issue batch records, forms, logbooks, validation documents, labels and other controlled documents as required
- Assist with generating quality assurance document control metrics
- Provide continuous feedback on improvement of the document control program

Compliance

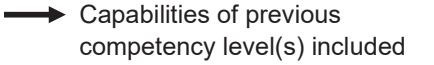
- Provide support for internal and regulatory audits and inspections
- Ensure activities adhere to regulatory requirements, practices, SOPs and good documentation practices

Indicative summary

Minimum years of experience required	3
Minimum educational level required	Bachelors
Degree majors typically studied	Nursing, Biological Sciences
Knowledge-based understanding	Infectious diseases, immunology

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Quality management system (QMS) • Good clinical practices (GCP) • Standard operating procedures (SOPs) • Regulatory requirements • Risk management • Quality management • Document management • Formatting • Achieving		
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving		

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

Clinical Trials Laboratory

Laboratory Manager

Roles and responsibilities

Core responsibilities

- Oversee and manage day-to-day laboratory operations within the clinical trials setting, with a focus on conducting complicated assays at a high standard using complex equipment
- Implement, optimise and validate intricate laboratory techniques required for immunologic assessments
- Ensure the proper functioning, calibration and maintenance of specialised laboratory equipment used for intricate assays
- Coordinate and collaborate with research scientists to conduct experiments and analyses, particularly those requiring high technical precision
- Ensure the integrity of data collected in complicated assays, adhering to organisational standard operating procedures (SOPs) and regulatory requirements
- Develop and maintain rigorous quality control measures for complex immunologic assessments, ensuring the highest standards of data accuracy
- Collaborate with the Quality Assurance team to conduct internal audits and inspections, focusing on the intricacies of complex assays
- Establish and maintain a comprehensive system for the storage of clinical samples, ensuring compliance with regulatory guidelines and the highest standards of sample integrity
- Implement 24-hour monitoring systems for sample storage, addressing any deviations promptly to safeguard sample viability

Compliance

- Ensure compliance with regulatory requirements related to complicated assays, data integrity and clinical sample storage
- Maintain data integrity and security, following established protocols and ensuring compliance with clinical data standards (e.g., CDISC)

Stakeholder management and communication

- Communicate findings and progress related to complicated assays and clinical sample storage to multidisciplinary teams across organisational functions
- Prepare and present precise technical reports, protocols and quantitative analyses specific to intricate assays

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

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Immunology, Chemical Engineering, Biotechnology, Biochemistry
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good laboratory practice (GLP) • Regulatory requirements		
Leadership & functional capabilities	• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • 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

Laboratory Operator

Roles and responsibilities

Core responsibilities

- Lab readouts and antibodies testing: perform laboratory experiments and analyses to support the evaluation of vaccines and vaccine candidates. This includes conducting tests to assess the presence and levels of antibodies in clinical trial samples
- Data analysis: utilise data analysis techniques to process and interpret lab results, ensuring data integrity and accuracy in support of clinical trials
- Quality control: maintain high standards of quality in all laboratory activities, adhering to good laboratory practices (GLP) to ensure the reliability of research findings
- Documentation: record and document all experimental procedures, results and observations accurately in compliance with organisational SOPs and regulatory requirements
- Instrument maintenance: ensure proper functioning and maintenance of laboratory equipment and instruments and troubleshoot any technical issues that may arise during experiments
- Collaboration: work closely with multidisciplinary teams to share findings, discuss research progress and provide support for the vaccine development process

Compliance

- Regulatory adherence: ensure all laboratory activities adhere to regulatory requirements specific to clinical trials, maintaining the highest level of ethical and scientific standards
- Data integrity: maintain data integrity and security, following established protocols and ensuring compliance with clinical data standards (e.g., CDISC)

Stakeholder management and communication

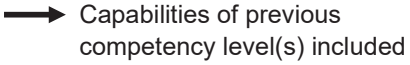
- Reporting: prepare clear and concise technical reports and documentation, summarising laboratory procedures, results and conclusions
- Collaboration: collaborate with internal and external stakeholders, including scientists, researchers and regulatory bodies to share research findings and support the vaccine development process
- Documentation: contribute to scientific publications and assist in drafting and submitting patent claims when appropriate

Indicative summary

Minimum years of experience required	2
Minimum educational level required	Bachelors
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Clinical monitoring • Deviation management • Corrective actions and preventive actions (CAPAs) • Quality management system (QMS) • System validation • Change control • Good laboratory practice (GLP) • Regulatory requirements		
Leadership & functional capabilities	• Written and oral communication • Persuasion • Teamwork • Interpersonal skills		

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

CMC/Process Development

Director, CMC/Process Development

Roles and responsibilities

Core responsibilities

- Provide strategic direction and leadership to the CMC/Process Development team, including setting clear goals, defining priorities and establishing a roadmap for the development and manufacturing of drug products
- Oversee and help identify potential opportunities and risks with chemistry, manufacturing and controls (CMC) gaps in existing portfolio and devise strategies to address them
- Oversee improvements in process robustness, bioburden risk reduction and yield increase and further increase product/process understanding
- Oversee process development and improvement including cell culture, purification, virology and drug product
- Ensure the CMC/Process Development team delivers its assigned work in a sustainable and safe manner and to the highest quality standards
- Oversee the development and adoption of new technologies to ensure discipline excellence and industry-leading capability and value
- Oversee and guide CMC/Process Development team activities, ensuring goals are set, progress is formally measured and project requirements are met in terms of quality, cost and timeliness
- Act as a technical consultant to the wider R&D team in streamlining timelines to begin manufacturing
- Oversee capacity management for the CMC/Process Development function
- Manage and resolve conflict between CMC/Process Development sub-functions

Leadership and team management

- Oversee and lead the sub-functional teams across the CMC/Process Development function
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Oversee and ensure adherence to quality standards, such as good manufacturing practices (GMPs) and guide the implementation of robust quality management systems
- Oversee the development of protocols and reports and collaborate with quality assurance teams to ensure compliance with applicable regulations and standards

Stakeholder management and communication

- Partner with Operations to transfer processes into manufacturing and provide technical support during technology transfer and validation (i.e., process performance qualification) activities

Finance and resource planning

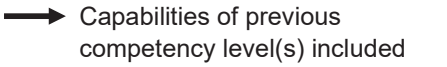
- Oversee the development of CMC/Process Development budgets
- Oversee adherence to CMC/Process Development budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Biochemical assays • Chromatography • Filtration • Purification • Cell cultures • Flow cytometry • Bioreactors • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	• Viral vector • RNA/DNA • Technology transfer • Regulatory requirements • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMPs) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Upstream Process Development

Manager, Upstream Process Development

Roles and responsibilities

Core responsibilities

- Lead the design and execution of experiments to develop and optimise upstream processes to produce the desired vaccine, which includes selecting appropriate cell lines, culture media and bioreactor systems and optimising growth conditions, such as pH, temperature, dissolved oxygen and nutrient supplementation
- Manage the cultivation of microbial cultures including different technologies using different scales (Shaker, Waves/Rocker, stirred tank bioreactors different volumes, Ambr250)
- Lead studies to determine the expression level of the protein of interest in the bioreactor using assays such as ELISA, Octet, Lentil Lectin affinity chromatography, etc.
- Lead advanced statistical and data models to provide actionable insights for bioprocess development
- Oversee the operation of bioreactors, ensuring optimal conditions for temperature, pH, dissolved oxygen and agitation speed
- Oversee routine maintenance and calibration of laboratory equipment and bioreactors
- Oversee data-driven design of robust and scalable processes
- Lead innovation with the aim of implementing technology of the future at bench scale and helping to prepare the process for use in larger-scale and late-stage manufacturing
- Manage troubleshooting technical issues that arise during process development and manufacturing, manage investigating deviations and propose solutions to address challenges and optimise process performance
- Manage and review technical documents such as experimental plan, reports and presentations
- Create and maintain a database for the data generated under various conditions and perform trending analyses to compare experimental conditions
- Establish and maintain an understanding of current trends and emerging cell line and upstream process development technologies
- Develop and implement functional capacity management strategies and strategic workforce plans to ensure adequate resources, skills and capabilities are available within the Upstream Process Development function to meet project objectives and regulatory requirements
- Manage scope, delivery, planning and forecasting, team operations and development and risk mitigation

Leadership and team management

- Lead the Upstream Process Development 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

Compliance

- Ensure the processes developed comply with regulatory requirements and industry standards
- Manage preparation of chemistry, manufacturing and controls (CMC) documentation for regulatory and/or patent filings

Stakeholder management and communication

- Ensure clear communication to CMC teams and functional line management regarding progress against technical objectives/milestones

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

Finance and resource planning

- Assist with development of Upstream Process Development budgets and syndicate with CMC leadership
- Support adherence to Upstream Process Development budgets

Indicative summary

Minimum years of experience required	8
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Computer Science, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Biochemical assays • Chromatography • Cell cultures • Flow cytometry • Bioreactors • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Regulatory requirements • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMPs) • Budgeting • Data analysis • Advanced analysis tools • Programming • Data visualisation tools • Experimental design
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Downstream Process Development

Manager, Downstream Process Development

Roles and responsibilities

Core responsibilities

- Lead design of experiment (DOE) studies to develop or optimise processes to ensure a phase-appropriate, consistent, high-yielding and scalable downstream process
- Manage purification activities, including column chromatography and filtration operations for vaccine production, process development, process characterisation and scale-up
- Lead the development and optimisation of purification strategies and techniques such as chromatography, filtration, centrifugation and precipitation to separate and purify the target protein
- Lead and determine the sequence and conditions of purification steps required to remove impurities, including host cell proteins, DNA, endotoxins and other contaminants
- Oversee and guide the optimisation of process parameters such as buffer compositions, pH, temperature and flow rates to maximize protein recovery, purity and yield
- Oversee the development and implementation of analytical methods to monitor protein purity, concentration and structural integrity at different purification stages
- Guide and help resolve technical issues that arise during process development
- Manage technical reports, summaries, protocols and quantitative analyses
- Lead the development of new methods and technologies for project advancement
- Maintain high level of professional expertise through familiarity with scientific literature
- Develop and implement functional capacity management strategies and strategic workforce plans to ensure adequate resources, skills, and capabilities are available within the Downstream Process Development function to meet project objectives and regulatory requirements
- Manage scope, delivery, planning and forecasting, team operations and development and risk mitigation

Leadership and team management

- Lead the Downstream Process Development 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

Compliance

- Lead and ensure all activities adhere to regulatory requirements, best practices and standard operating procedures (SOPs)
- Manage and ensure data integrity, participating in validation activities, and preparing for audits and inspections
- Manage chemistry, manufacturing and controls (CMC) documentation for regulatory and/or patent filings and prepare/reconcile responses for responsible topics

Stakeholder management and communication

- Ensure clear communication to CMC teams and functional line management regarding progress against technical objectives/milestones

Finance and resource planning

- Assist with development of Downstream Process Development budgets and syndicate with CMC leadership
- Support adherence to Downstream Process Development budgets

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

Indicative summary

Minimum years of experience required	8
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Computer Science, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Chromatography • Filtration • Purification • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Regulatory requirements • Risk management	• Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP) • Budgeting • Data analysis • Advanced analysis tools • Programming • Data visualisation tools • Experimental design
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Analytical Development

Manager, Analytical Development

Roles and responsibilities

Core responsibilities

- Lead the development, qualification and validation of analytical methods
- Coordinate testing with contract manufacturing organisations (CMOs) for clinical and commercial stage biologics, drug substance and drug product
- Lead technology transfer activities, including gap analyses, risk assessments, driving assay development, optimisation, validation and transfer for in-process, release, stability and characterisation testing
- Lead the development of analytical methods, troubleshooting, new product introduction, contaminant characterisation, investigation of new technologies and more
- Lead the use of high-performance liquid chromatography (HPLC), germinal centre (GC), mass spectrometry (MS), HPLC/GC-MS, Fourier transform infrared spectroscopy (FTIR), nuclear magnetic resonance (NMR) spectroscopy, X-Ray spectroscopy, electron microscopy and more to develop methods and deliver investigative results to support the site's manufacturing commitments
- Lead the design and execution of analytical method development activities focused on liquid and gas chromatography, size separation and capillary electrophoretic assays
- Manage the analysis of APIs and intermediates to support laboratory synthesis through to atypical manufacturing investigations
- Lead the continuous improvement in analytical development to support site objectives
- Manage analytical procedures and guide interpretation of results/technical data
- Manage novel analytical technologies, drive new assays and improvements to current methods
- Manage technical documents, including validation protocols and reports, analytical test procedures, investigation reports and change controls
- Develop and implement functional capacity management strategies and strategic workforce plans to ensure adequate resources, skills, and capabilities are available within the Analytical Development function to meet project objectives and regulatory requirements
- Manage scope, delivery, planning and forecasting, team operation and development and risk mitigation

Leadership and team management

- Lead the Analytical Development 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

Compliance

- Manage and ensure all experimental procedures and documentation are compliant with highest quality in accordance with standard operating procedures (SOPs) and regulatory standards
- Manage the necessary documentation for regulatory submissions as required and write deficiency responses

Stakeholder management and communication

- Communicate progress, plans, requirements and risks to cross-functional project teams to meet expectations, project milestones, good manufacturing practice (GMP) standards and regulatory requirements

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

Finance and resource planning

- Assist with development of Analytical Development budgets and syndicate with CMC leadership
- Support adherence to Analytical Development budgets

Indicative summary

Minimum years of experience required	8
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Computer Science, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Biochemical assays • Chromatography • Titration • Spectroscopy • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Regulatory requirements • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Formulation/Drug Product Development

Engineer, Drug Product Development

Roles and responsibilities

Core responsibilities

- Assist with providing technical and scientific support for ongoing manufacturing operations at contract manufacturing organisations (CMOs) as well as internal sites as needed
- Design and execute commercial scale drug product process characterisation and validation for vial, prefilled syringe (PFS) and other presentations
- Contribute to equipment and process design for large-scale fill-finish operations for unadjuvanted and adjuvanted vaccine products
- Design, test, optimise and build next-generation manufacturing systems to produce vaccine delivery vehicles
- Design and execute formulation and process studies to maximise drug product stability
- Support production of reports and manufacturing support documents in support of various project development stages
- Enable a continuous manufacturing paradigm by linking individual drug product unit operations together in an end-to-end manner
- Integrate process analytical technologies (PAT) and process modelling to enable the creation and deployment of manufacturing digital twins

Compliance

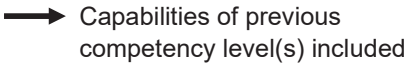
- Ensure that all drug product development activities comply with regulatory guidelines and requirements

Indicative summary

Minimum years of experience required	4
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, -pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Chromatography • Filtration • Purification • Formulation • Good manufacturing practices (GMP) • Data analysis • Regulatory requirements • Risk management	• Freeze-drying • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Project management • Business process improvement • Programming • Data analytics and visualisation • Modelling and simulation	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Technician, Drug Product Development

Roles and responsibilities

Core responsibilities

- Operate and maintain manufacturing equipment, performing routine maintenance, troubleshooting and calibration
- Assist in providing technical and scientific support for ongoing manufacturing operations at contract manufacturing organisations (CMOs) as well as internal sites as needed
- Assist with the design and execution of commercial scale drug product process characterisation and validation for vial, prefilled syringe (PFS) and other presentations
- Contribute to equipment and process design for large-scale fill-finish operations for unadjuvanted and adjuvanted vaccine products
- Assist with designing, testing, optimising and building next-generation manufacturing systems to produce vaccine delivery vehicles
- Assist with reports and manufacturing support documents in support of various project development stages

Compliance

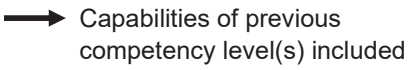
- Ensure drug product development activities comply with regulatory guidelines and requirements

Indicative summary

Minimum years of experience required	0-2
Minimum educational level required	Bachelors
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Chromatography • Filtration • Purification • Formulation • Good manufacturing practices (GMP) • Data analysis • Regulatory requirements • Risk management • Equipment operations		
Leadership & functional capabilities			

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

Director, Drug Product Development

Roles and responsibilities

Core responsibilities

- Develop the Drug Product Development function strategy, aligning it with organisational goals and overseeing the implementation of initiatives
- Oversee the execution of drug product development activities (develop, improve and scale up processes in alignment with quality by design (QBD) principles and provide material and documentation for pre-clinical studies) within platform to ensure scientific and technical excellence for the project
- Oversee the formulation development process, which includes selecting appropriate excipients, establishing formulation composition and optimising the drug product design. Consider factors such as stability, bioavailability and patient acceptability in developing a robust formulation
- Oversee the development and optimisation of formulation of drug products, including selecting appropriate excipients, determining the dosage form (tablets, capsules, injections, etc.) and optimising drug delivery
- Lead stability studies to assess the shelf life and stability of drug products under different storage conditions
- Oversee the design, execution, documentation and presentation of relevant strategies and experimentation to support Drug Product teams in advancing formulation development, fill/finish process development, process characterisation, technology transfer and regulatory authoring
- Oversee the development and execution of strategies, plans, processes and methods to enable product and process development, process transfers and improvements
- Oversee study protocols, technical reports and standard operating procedures (SOPs)

Leadership and team management

- Oversee the Drug Product Development team and provide training and coaching to direct and indirect reports
- Oversee that team's competencies are developed and skill gaps are identified and addressed
- Compliance
- Oversee that all drug product development activities comply with regulatory guidelines and requirements

Stakeholder management and communication

- Oversee collaboration with other organisational functions to meet project timelines
- Oversee collaboration with Research in evaluation of developability of antigen candidates, novel delivery and fill-finish technologies

Finance and resource planning

- Lead development of Drug Product Development budgets and syndicate with CMC leadership
- Manage adherence to Drug Product Development budgets

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

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Computer Science, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Chromatography • Filtration • Freeze-drying • Purification • Formulation • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	• Regulatory requirements • Programming • Data analytics and visualisation • Modelling and simulation • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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, Drug Product Development

Roles and responsibilities

Core responsibilities

- Lead the execution of drug product development activities (develop, improve, scale-up processes in alignment with quality by design (QBD) principles and provide material and documentation for pre-clinical studies) within platform to ensure scientific and technical excellence for the project
- Manage the formulation development process, which includes selecting appropriate excipients, establishing formulation composition, and optimising the drug product design. Consider factors such as stability, bioavailability and patient acceptability in developing a robust formulation
- Lead the development and optimisation of formulation of drug products, including selecting appropriate excipients, determining the dosage form (tablets, capsules, injections, etc.) and optimising the drug delivery
- Lead stability studies to assess the shelf life and stability of drug products under different storage conditions
- Lead the design, execution, documentation and presentation of relevant strategies and experimentation to support Drug Product teams in advancing formulation development, fill-finish process development, process characterisation, technology transfer and regulatory authoring
- Lead the development and execution of strategies, plans, processes and methods to enable product and process development, process transfers and improvements
- Oversee study protocols, technical reports and standard operating procedures (SOPs)
- Manage troubleshooting technical issues that arise during drug product development and analyse data, investigate deviations and propose solutions to overcome challenges and ensure the successful development of the drug product
- Oversee the preparation of internal and external presentations, patent filings, research manuscripts and review articles as required
- Oversee, manage and integrate process analytical technologies (PAT) and process modelling to enable the creation and deployment of manufacturing digital twins
- Manage scope, delivery, planning and forecasting, team operations and development and risk mitigation

Leadership and team management

- Lead the Drug Product Development 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

Compliance

- Manage and ensure that all drug product development activities comply with regulatory guidelines and requirements
- Oversee and review regulatory documentation

Stakeholder management and communication

- Collaborate with other organisational functions to meet project timelines
- Collaborate with Research in evaluating the developability of antigen candidates, novel delivery and fill-finish technologies

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

Finance and resource planning

- Assist with development of Drug Product Development budgets and syndicate with CMC leadership
- Support adherence to Drug Product Development budgets

Indicative summary

Minimum years of experience required	8
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Chromatography • Filtration • Freeze-drying • Purification • Formulation • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Regulatory requirements • Programming • Data analytics and visualisation • Modelling and simulation • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Scientist, Drug Product Development

Roles and responsibilities

Core responsibilities

- Assist with execution of drug product development activities (develop, improve, scale-up processes in alignment with quality by design (QBD) principles and provide material and documentation for pre-clinical studies) within platform to ensure scientific and technical excellence for the project
- Assist with the formulation development process, which includes selecting appropriate excipients, establishing formulation composition and optimising the drug product design. Consider factors such as stability, bioavailability and patient acceptability in developing a robust formulation
- Assist with developing and optimising the formulation of drug products, including selecting appropriate excipients, determining the dosage form (tablets, capsules, injections, etc.), and optimising drug delivery
- Conduct stability studies to assess the shelf life and stability of drug products under different storage conditions
- Assist with design, execution, documentation and presentation of relevant strategies and experimentation to support Drug Product teams in advancing formulation development, fill-finish process development, process characterisation, technology transfer and regulatory authoring
- Support the development and execution of strategies, plans, processes and methods to enable product and process development, process transfers and improvements
- Use a data-driven approach to progress development deliverables
- Author study protocols, technical reports and SOPs
- Assist with assessment of technical capabilities of key external partners and oversee third party labs
- Support in troubleshooting technical issues that arise during drug product development and analyse data, investigate deviations and propose solutions to overcome challenges and ensure the successful development of the drug product
- Prepare internal and external presentations, patent filings, research manuscripts and review articles as required
- Integrate process analytical technologies (PAT) and process modelling to enable the creation and deployment of manufacturing digital twins

Compliance

- Ensure that all drug product development activities comply with regulatory guidelines and requirements
- Prepare and reviewing regulatory documentation

Indicative summary

Minimum years of experience required	6
Minimum educational level required	Masters (PhD preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Chromatography • Filtration • Purification • Formulation • Good manufacturing practices (GMP) • Data analysis • Regulatory requirements • Risk management	→ • Freeze-drying • Live attenuated • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Project management • Business process improvement • Programming • Data analytics and visualisation • Modelling and simulation	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	→ • Presentation • Coaching and mentoring • Decision making • Innovation	

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

Drug Substance Pilot Plant

Director, Pilot Plant

Roles and responsibilities

Core responsibilities

- Develop the Pilot Plant function strategy, aligning it with organisational goals and overseeing the implementation of initiatives
- Oversee the scaling up of manufacturing processes developed in the laboratory to pilot-scale or production-scale equipment
- Ensure that processes are successfully transferred to pilot plants while maintaining product quality, efficacy and safety
- Oversee and guide the design of experiments, collecting and analysing data to improve process robustness and productivity
- Identify and evaluate critical process parameters and their impact on product quality and efficiency
- Oversee operational efficiency improvements for pilot plant work processes and determine how advancements in the field and new technology can be integrated into those work processes
- Provide expert technical and scientific support to licensing, ongoing commercial manufacturing and lifecycle management activities
- Oversee the mining and analyses of process data; model and generate reports to support manufacturing campaigns
- Ensure equipment is properly installed, calibrated and validated to meet regulatory standards, good manufacturing processes (GMP) and manufacturing requirements
- Oversee the training of technical personnel for safe and effective operations in the Pilot Plant and conducting process safety assessments

Leadership and team management

- Oversee the Pilot Plant team and provide training and coaching to direct and indirect reports
- Oversee that team's competencies are developed and skill gaps are identified and addressed

Compliance

- Oversee reports required for regulatory filings and ensure timely submissions
- Oversee and guide technology development study protocols and reports, and standard operating procedures (SOPs) in support of tech transfer and regulatory documents

Stakeholder management and communication

- Oversee collaboration with other organisational functions to meet project timelines
- Oversee presentations to communicate results, progress and plans within the department and across organisational functions effectively
- Oversee equipment vendors to select appropriate equipment and systems that align with manufacturing processes, taking into account capacity, functionality, regulatory compliance and cost

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

Finance and resource planning

- Lead development of Pilot Plant budgets and syndicate with CMC leadership
- Manage adherence to Pilot Plant budgets

Indicative summary

Minimum years of experience required	10
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE	
Technical capabilities			• Biochemical assays • Chromatography • Filtration • Purification • Cell cultures • Flow cytometry • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	• Viral vector • RNA/DNA • Regulatory requirements • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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, Pilot Plant

Roles and responsibilities

Core responsibilities

- Lead the scaling up of manufacturing processes developed in the laboratory to pilot-scale or production-scale equipment
- Manage and ensure that the processes are successfully transferred to pilot plants, while maintaining product quality, efficacy and safety
- Lead the design of experiments, collecting and analysing data to improve process robustness and productivity
- Identify and evaluate critical process parameters and their impact on product quality and efficiency
- Manage operational efficiency improvements for pilot plant work processes and determine how advancements in the field and new technology can be integrated into those work processes
- Oversee equipment capabilities and compatibility with the process and ensure equipment validation in compliance with regulatory requirements and GMP
- Oversee critical process parameters, perform process performance qualification, and ensure compliance with regulatory guidelines and GMP
- Provide expert technical and scientific support to licensing, ongoing commercial manufacturing and life-cycle management activities
- Lead the mining and analyses of process data; model and generate reports to support manufacturing campaigns
- Contribute to training of technical personnel for safe and effective operations in the Pilot Plant and conducting process safety assessments
- Manage scope, delivery, planning and porecasting, team operations and development and risk mitigation

Leadership and team management

- Lead the Pilot Plant 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

Compliance

- Manage and review reports required for regulatory filings and ensure timely submissions
- Manage and review technology development study protocols and reports and standard operating procedures (SOPs) in support of tech transfer and regulatory documents

Stakeholder management and communication

- Collaborate with other organisational functions to meet project timelines
- Lead presentations to communicate results, progress and plans within the department and across organisational functions effectively
- Manage equipment vendors to select appropriate equipment and systems that align with the manufacturing processes, taking into account capacity, functionality, regulatory compliance and cost

Finance and resource planning

- Assist with development of Pilot Plant budgets and syndicate with CMC leadership
- Support adherence to Pilot Plant budgets

Indicative summary

Minimum years of experience required	8

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

Minimum educational level required	Masters
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

Capabilities across proficiency levels

	Basic-skilled FTE	**Semi-specialist FTE**	**Specialist FTE**	
Technical capabilities			• Biochemical assays • Chromatography • Filtration • Purification • Cell cultures • Flow cytometry • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine	• Virus-like particle • Viral vector • RNA/DNA • Regulatory requirements • Risk management • Project management • Vendor management • Business process improvement • Good manufacturing practices (GMP)
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management	• Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Scientist, Pilot Plant

Roles and responsibilities

Core responsibilities

- Assist with scaling up manufacturing processes developed in the laboratory to pilot-scale or production-scale equipment
- Ensure that the processes are successfully transferred to pilot plants, while maintaining product quality, efficacy and safety
- Design experiments, collect and analyse data and make necessary adjustments to improve process robustness and productivity
- Contribute to identifying and evaluating critical process parameters and their impact on product quality and efficiency
- Plan and execute operational efficiency improvements for pilot plant work processes, and determine how advancements in the field and new technology can be integrated into those work processes
- Assess equipment capabilities and its compatibility with process; ensure equipment validation is in compliance with regulatory requirements and good manufacturing practice (GMP)
- Monitor and evaluate critical process parameters, perform process performance qualification and ensure compliance with regulatory guidelines and GMP
- Mine and analyse process data; model and generate reports to support manufacturing campaigns
- Prepare presentations and datasets to communicate results, progress and plans within the department and across organisational functions effectively
- Assist with training of technical personnel for safe and effective operations in the Pilot Plant and conducting process safety assessments

Compliance

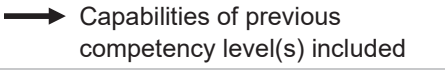
- Prepare and author internal documentation and reports required for regulatory filings
- Prepare technology development study protocols and reports, and SOPs in support of tech transfer and regulatory documents

Indicative summary

Minimum years of experience required	6
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Chromatography • Data analysis • Good manufacturing practices (GMP) • Regulatory requirements • Risk management	• Biochemical assays • Filtration • Purification • Flow cytometry • Skilled in various tech platforms incl. Live attenuated virus; Inactivated virus; Subunit vaccine; Virus-like particle; Viral vector; RNA/DNA vaccine • Project management • Business process improvement	
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving	• Presentation • Coaching and mentoring • Decision making • Innovation	

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

Engineer, Pilot Plant

Roles and responsibilities

Core responsibilities

- Assist with scaling up the manufacturing processes developed in the laboratory to pilot-scale or production-scale equipment
- Contribute to the design and layout of the pilot plant facility
- Assist with ensuring that equipment is properly installed, calibrated and validated to meet regulatory standards, good manufacturing practices (GMP) and manufacturing requirements
- Contribute to developing and implementing systems to monitor critical process parameters, collecting real-time data and capturing process data for analysis and optimisation
- Provide engineering input during troubleshooting events and contribute to issues resolution
- Manage equipment inventories and support equipment validation activities
- Evaluate new technologies and equipment for potential use in the area
- Perform activities in support of equipment maintenance and engineering
- Collaborate with architects and equipment vendors to select appropriate equipment and systems that align with the manufacturing processes, taking into account capacity, functionality, regulatory compliance and cost

Compliance

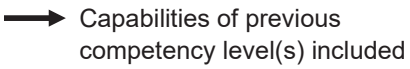
- Ensure compliance with safety regulations and industry standards within the pilot plant and identify potential safety hazards, develop safety protocols, conduct risk assessments and implement safety measures to protect personnel, equipment and the environment
- Prepare and contribute to technical documentation, protocols, reports, and standard operating procedures (SOPs) related to pilot plant operations

Indicative summary

Minimum years of experience required	4
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medicine, Pharmacy, Biological Sciences, Biochemical Engineering, Chemical Engineering, Biotechnology, Biochemistry, Business Administration
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, microenvironments, manufacturing

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Chromatography • Data analysis • Good manufacturing practices (GMP) • Regulatory requirements • Risk management		
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving		

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

Toxicology

Principal Scientist, Toxicology

Roles and responsibilities

Core responsibilities

- Manage the design and coordination of toxicology programmes, including vendor selection, budgeting and monitoring of nonclinical safety studies as well as interpretation, communication and reporting of the data generated
- Lead a team of toxicology scientists and manage the performance of homogeneity and conduct stability analyses on toxicology dosing formulations under good laboratory practices (GLP) conditions in compliance with all GLP regulations, protocol, standard operating procedures (SOPs), policies, methods and safety procedures
- Serve as subject matter expert on assigned general toxicology studies
- Lead a team of scientists in preparation of formulations to be used for toxicology studies
- Lead the design and execution of new methods and protocols related to toxicology and proactively incorporate new technology and techniques into practice
- Critically analyse and interpret toxicology data and communicate results within established timelines
- Lead troubleshooting problems in the execution of toxicology experiments

Leadership and team management

- Lead a team of Toxicology Scientists/Associates 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

Compliance

- Collaborate with Regulatory Affairs, Research Quality and process development groups to drive projects through licensing pathway
- Manage the integrity of data collected and ensure documentation of results is according to quality standards and in accordance with regulatory requirements, working towards first-in-human (FIH) trials
- Manage the drafting and submission of patent claims as appropriate

Stakeholder management and communication

- Support preparation for governance meetings, adequately representing Toxicology function and clearly outlining its progress, opportunities for improvement and help needed from broader organisation
- Build positive external reputation for the Toxicology function by managing and leading research publications in high-tier journals and representing the function at scientific events and to external parties such as regulatory authorities

Finance and resource planning

- Assist with development of Toxicology budgets and syndicate with R&D leadership
- Support adherence to Toxicology budgets

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

Indicative summary

Minimum years of experience required	8
Minimum educational level required	PhD
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, pharmaceuticals, genomics, pathogenesis, pharmacology, pharmacokinetics, pharmacodynamics, microenvironments

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Biochemical assays • Immunoprecipitation • Cell cultures • Flow cytometry • Animal models • Animal handling • Formulation preparation • Chromatography • Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Budgeting • Data analysis
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Animal Scientist, Toxicology

Roles and responsibilities

Core responsibilities

- Execute experiments to understand the toxicological pathways related to vaccine development in animal models
- Analyse data to identify and comprehend the impact of potential toxicological effects in animals
- Conduct scientific literature reviews on relevant topics in toxicology and animal science
- Design and propose research projects in toxicology, incorporating laboratory research and animal studies
- Demonstrate expertise in the ethical and humane handling of animals for toxicological studies
- Conduct experiments involving animals, ensuring compliance with animal welfare regulations

Compliance

- Ensure the integrity of toxicological data collection and documentation in adherence to organisational standard operating procedures (SOPs) and regulatory requirements

Stakeholder management and communication

- Collaborate with multidisciplinary teams to present toxicological findings and insights from animal studies
- Engage with external public health organisations and regulatory authorities to communicate toxicological aspects of vaccine development with a focus on animal studies

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Masters, PhD
Degree majors typically studied	Animal Science, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Infectious diseases, molecular biology, immunology, animal health

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Data analysis techniques in toxicology, specifically those involving animal models • Understanding of regulatory requirements in toxicology studies involving animals • Risk management in toxicology research • Project management skills. • Business process improvement in toxicology studies • Database management for toxicological data involving animal models
Leadership & functional capabilities			• Written and oral communication • Presentation • Persuasion • Teamwork • Interpersonal skills • Decision making • Problem solving • Innovation

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

Medical Affairs

Medical Affairs Specialist

Roles and responsibilities

Core responsibilities

- Lead the development and implementation of the medical strategy for the institution's vaccine portfolio
- Provide medical expertise for clinical trials, including protocol development, data analysis and safety reporting
- Support regulatory submissions for vaccine products
- Provide medical and scientific input to marketing and sales activities
- Build and maintain relationships with key stakeholders, such as healthcare professionals, public health officials and patient advocacy groups
- Stay up to date on the latest medical and scientific advances in vaccines

Compliance

- Ensure all medical affairs activities adhere to relevant regulations, guidelines and ethical standards
- Collaborate with regulatory affairs to support regulatory submissions and responses

Stakeholder management and communication

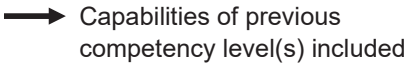
- Collaborate closely with cross-functional teams, including commercial, regulatory affairs, market access and research and development to align medical affairs activities with overall business strategies
- Provide medical review and input for promotional materials and ensure compliance with regulations

Indicative summary

Minimum years of experience required	2-5
Minimum educational level required	Masters
Degree majors typically studied	Medicine, Biological Sciences, Pharmacy, Chemistry, Biochemistry, Biotechnology
Knowledge-based understanding	Pharmaceuticals, clinical trials, clinical operations

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities	• Cell cultures • Formulation preparation • Chromatography • Good laboratory practices (GLP) • Data analysis • Regulatory requirements • Risk management		
Leadership & functional capabilities	• Written and oral communication • Teamwork • Interpersonal skills • Problem solving		

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

Support Functions

Programme Manager

Roles and responsibilities

Core responsibilities

- Manage and oversee multiple vaccine research programmes from inception to completion, ensuring alignment with organisational goals and timelines
- Efficiently allocate resources, including personnel, budget and equipment, to support programme objectives
- Identify potential risks and develop mitigation strategies to ensure the successful execution of research programmes
- Develop and execute strategic plans for vaccine R&D programmes, aligning them with the institution's overall research objectives
- Drive innovation within research programmes by staying informed about emerging trends, technologies, and methodologies in vaccine development

Leadership and team management

- Manage and lead multiple teams within the R&D organisation
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Ensure all research activities adhere to regulatory requirements and industry best practices

Stakeholder management and communication

- Foster effective collaboration and communication among cross-functional teams, both internally and externally

Finance and resource planning

- Manage programme budgets, including forecasting, track expenses and ensure cost-effective resource utilisation

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Nursing, Medical Technology, Chemistry, Biological Sciences, Pharmacy, Medicine
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, laboratory operations

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Good clinical practice (GCP) • Fundraising • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Purchasing

Purchasing Manager

Roles and responsibilities

Core responsibilities

- Manage and oversee multiple vaccine research programmes from inception to completion, ensuring alignment with organisational goals and timelines
- Efficiently allocate resources, including personnel, budget and equipment to support programme objectives
- Identify potential risks and develop mitigation strategies to ensure the successful execution of research programmes
- Develop and execute strategic plans for vaccine R&D programmes, aligning them with the institution's overall research objectives
- Drive innovation within research programmes by staying informed about emerging trends, technologies and methodologies in vaccine development

Leadership and team management

- Manage and lead multiple teams within the R&D organisation
- Oversee the development of staff competencies and the identification and addressing of skill gaps

Compliance

- Ensure all research activities adhere to regulatory requirements and industry best practices

Stakeholder management and communication

- Foster effective collaboration and communication among cross-functional teams, both internally and externally

Finance and resource planning

- Manage programme budgets, including forecasting, tracking expenses and ensuring cost-effective resource utilisation

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Medical Technology, Chemistry, Biological Sciences, Pharmacy, Medicine
Knowledge-based understanding	Infectious diseases, immunology, pharmaceuticals, clinical trials, laboratory operations

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Good clinical practice (GCP) • Fundraising • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Thought leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Purchasing Manager

Roles and responsibilities

Core responsibilities

- Develop and implement procurement strategies to ensure a timely and cost-effective supply of materials, equipment and services required for vaccine R&D projects
- Identify, evaluate and select suppliers and vendors. Establish and maintain strong relationships with suppliers to ensure quality and reliability
- Negotiate contracts, terms and conditions with suppliers, ensuring favorable pricing, delivery schedules and service agreements
- Monitor and control procurement costs, finding opportunities for cost savings and cost avoidance while maintaining quality and compliance
- Maintain optimal inventory levels, reduce excess or obsolete materials and ensure adequate stock for ongoing projects
- Ensure procurement practices adhere to organisational policies, industry regulations and ethical standards. This includes conducting due diligence on suppliers to ensure ethical and sustainable sourcing
- Collaborate with quality control and assurance teams to ensure that materials and equipment meet required quality standards and specifications
- Stay updated on market trends, pricing fluctuations and new suppliers. Provide recommendations for sourcing decisions based on market analysis
- Optional: issue requests for quotation (RFQs) and requests for proposal (RFPs) to potential suppliers. Evaluate and compare supplier responses to make informed decisions

Compliance

- Ensure procurement processes align with relevant regulations, including good laboratory practices (GLP) and good clinical practice (GCP) for vaccine materials

Stakeholder management and communication

- Work closely with cross-functional teams, including researchers, scientists, finance and manufacturing to understand procurement needs and priorities

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Economics, Pharmacy
Knowledge-based understanding	Purchasing, vendor management, inventory 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

Capabilities across proficiency levels

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement • Good laboratory practices (GLP) • Good clinical practice (GCP) • Budgeting
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Thought leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Strategic thinking • Decision making • Problem solving • Innovation

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

Human Resources Manager

Roles and responsibilities

Core responsibilities

- Lead the recruitment process, including job postings, candidate sourcing, interviewing and selection
- Collaborate with department heads to understand their staffing needs and proactively identify future hiring requirements
- Develop and maintain a pipeline of talent for critical roles
- Implement effective onboarding processes to ensure new employees integrate smoothly
- Identify training needs and coordinate employee training and development programmes
- Encourage a culture of continuous learning and development
- Monitor the effectiveness of training initiatives
- Manage compensation and benefits programmes, ensuring competitiveness and fairness
- Review and update salary structures, job classifications and benefits packages
- Stay informed about market trends and benchmarks
- Collaborate with department heads to forecast future workforce needs
- Develop and implement strategies for workforce planning and talent management

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Psychology, Human Relations
Knowledge-based understanding	Human relations

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

Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Regulatory requirements • Risk management • Project management • Business process improvement
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Health, Safety & Environment Manager

Roles and responsibilities

Core responsibilities

- Develop and implement health, safety and environmental programmes and policies specific to vaccine research and development
- Identify, assess and mitigate health, safety and environmental risks associated with vaccine R&D processes, laboratories and facilities
- Establish and manage incident response protocols for emergencies, accidents and safety breaches
- Develop and deliver safety training programmes for employees and researchers, emphasizing best practices, hazard recognition and emergency procedures
- Conduct regular safety audits and inspections of laboratories, facilities and equipment to ensure compliance with safety regulations and standards and collaborate with authorities for inspection
- Oversee the safe handling, storage and disposal of chemicals and hazardous materials used in vaccine development, ensuring compliance with relevant regulations
- Develop and maintain emergency response plans, including evacuation procedures, first aid stations and communication protocols. Coordinate drills and exercises to prepare staff for emergencies

Compliance

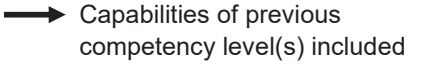
- Ensure the institution complies with all relevant health, safety and environmental regulations
- Maintain accurate records of safety and environmental activities, incidents and inspections. Prepare and submit reports to regulatory authorities as required

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Business Administration, Psychology, Human Relations, Pharmacy
Knowledge-based understanding	Environmental health and safety, occupational health and safety

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

Capabilities across proficiency levels



	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Safety programme development • Emergency response planning • Environmental sustainability practices • Incident investigation and reporting • Regulatory requirements • Risk management • Project management • Business process improvement
Leadership & functional capabilities			• Written and oral communication • Presentation • Stakeholder management • Persuasion • Negotiation • Leadership • Coaching and mentoring • Team management • Teamwork • Interpersonal skills • Thought leadership • Strategic thinking • Decision making • Problem solving • Innovation

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

Finance & Accounting Manager

Roles and responsibilities

Core responsibilities

- Oversee the financial operations, including budgeting, forecasting and financial reporting
- Manage and optimise financial resources to support vaccine research and development projects
- Ensure compliance with accounting standards, tax regulations and internal financial policies
- Collaborate with department heads and project managers to develop annual budgets
- Monitor budget performance, identify variances and recommend corrective actions
- Conduct financial analyses to assess the cost-effectiveness of research projects and optimise resource allocation
- Identify opportunities to reduce costs and improve financial efficiency
- Manage cashflow, investments and banking relationships
- Evaluate investment opportunities to maximise returns on surplus funds

Compliance

- Ensure compliance with financial regulations, reporting standards and tax laws.
- Stay updated on changes in financial regulations that may impact the institution

Indicative summary

Minimum years of experience required	5
Minimum educational level required	Bachelors (Masters preferred)
Degree majors typically studied	Finance, Accounting, Business Administration
Knowledge-based understanding	Financial management and accounting principles, financial regulations and compliance, grant management and reporting

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Capabilities across proficiency levels

→ Capabilities of previous competency level(s) included

	Basic-skilled FTE	Semi-specialist FTE	Specialist FTE
Technical capabilities			• Safety programme development • Emergency response planning • Environmental sustainability practices • Incident investigation and reporting • Regulatory requirements • Risk management • Project management • Business process improvement
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