Skills Framework for Biopharmaceuticals Manufacturing

A Guide to Occupations and Skills

An initiative of SKILLSFuture

skillsfuture.sg

Contents

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About the Skills Framework

The Skills Framework is a SkillsFuture initiative developed for the Singapore workforce to promote skills mastery and lifelong learning. Jointly developed by SkillsFuture Singapore, Workforce Singapore, and the Singapore Economic Development Board, together with employers, industry associations, education and training providers and unions, the Skills Framework for Biopharmaceuticals Manufacturing provides useful information on:

With the Skills Framework, individuals are equipped to make informed decisions about career choices, as well as take responsibility for skills upgrading and career planning.

Assess Career Interests

- Discover employment opportunities
- Understand career pathways
- Recognise personal attributes required

Prepare for Desired Jobs

- Understand skills and competencies required

Find Avenues to Close Skills Gaps

- Identify relevant training programmes to equip oneself with the required skills and competencies
- Participate in on-the-job training opportunities provided by companies

Renew, Upgrade and Deepen Skills

- Plan for career development/ transition
- Recognise skills and competencies required for the intended job role
- Identify training programmes to upgrade and deepen skills

Singapore's Biopharmaceuticals Manufacturing Sector

Manufacturing is a key engine of growth for Singapore's economy. The Singapore government is committed to building and strengthening the manufacturing sector, which biopharmaceuticals manufacturing is a major contributor.

World Class Manufacturing Capabilities

As a leading biomedical sciences hub, Singapore is the preferred base for pharmaceutical and biotechnology firms to serve the healthcare needs of patients around the world. Singapore attracts global industry leaders to have manufacturing hubs located here. These world-class manufacturing plants produce a wide range of products ranging from small molecule Active Pharmaceutical Ingredients (APIs), drug products and biologics drug substances. Since 2014, the Singapore government has also developed new training programmes in partnership with pharmaceutical companies, with the goal to expand the pool of skilled talent to meet the growing needs of the local industry.

Over the last 30 years, regulators such as the Food and Drug Administration (FDA) and European Medicines Evaluation Agency (EMEA) have made regular audit visits to Singapore-based facilities. The fact that there have been no major observations by these regulators emphasises the quality and reliability of Singapore's infrastructure and workforce, both of which provide pharmaceutical investors with continued confidence to expand their local operations.

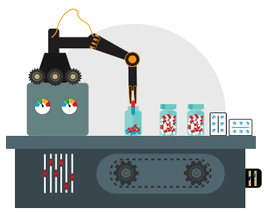
Key Statistics

Contributed **3% to Singapore's 2016 nominal GDP**

Accounts for close to **7,000 jobs**

Singapore has a base of **more than 29 facilities manufacturing products ranging from chemical, biological and cell therapy products, to nutritionals**

In 2016, Biopharmaceuticals Manufacturing Value Add and Manufacturing Output stood at around **SG$11B and SG$17B** respectively



Eight out of top 10 pharmaceutical companies have facilities in Singapore, manufacturing four out of the top 10 drugs by global revenue

Source:
The Singapore Economic Development Board and Ministry of Trade and Industry

The Evolving Landscape (Future Trends)

Biopharmaceuticals manufacturing is evolving to meet the rise in healthcare spending in emerging Asian markets. The emergence of new drug modalities and increased pricing pressures are driving the need for companies to improve productivity and sustainability of manufacturing operations.

Leveraging next-generation manufacturing technologies, such as continuous manufacturing and single-use, disposable technology, to optimise processes, are being explored. Such technologies enable companies to produce more efficiently and support the production of next-generation products, all the while ensuring high standards of quality and reliability. On this technology front, the government has worked closely with biopharmaceutical manufacturers to support them in establishing new teams looking at process and technology development. This will enable not only the adoption of new manufacturing technologies within the Singapore manufacturing sites, but also build up capabilities to develop, testbed and industrialise new technologies from Singapore for companies' global manufacturing networks.

Due to an increasingly sophisticated understanding of disease biology, biopharmaceuticals companies are developing increasingly complex and hard-to-manufacture classes of drugs to treat a wider range of diseases. The increasing number and complexity of products that need to be manufactured have driven the need for novel manufacturing processes and technology. Biopharmaceuticals manufacturing plants would also need greater flexibility to accommodate a pipeline of products across different scales and technology platforms.

Biopharmaceutical manufacturers are enhancing operational excellence by stepping up automation and digitalisation, green manufacturing and quality by design. Improving productivity, speed to market and cost efficiency of the plant are critical for biopharmaceutical manufacturers to maintain competitiveness. Biopharmaceutical manufacturers are increasingly looking to monitor product quality and performance of the plant through the use of new technologies such as data analytics, visualisation and process controls. Biopharmaceuticals companies are also committed to reducing their environmental impact by taking steps to improve energy efficiency, reduce water consumption and curtail carbon emissions.

To ensure that the workforce continues to be equipped with relevant skills, the government will continue to develop the country's talent pool by focusing on three key themes - integrating industry experience into the school curriculum, boosting on-the-job-training and building up the local leadership pipeline for the biopharmaceuticals manufacturing sector. This will be complemented by regular and in-depth consultation with the industry, to ensure that the local workforce has the relevant skills and technological expertise to contribute in this fast-paced and rapidly-evolving sector.

Desired Attributes and Skills in Demand

A career in the biopharmaceuticals manufacturing sector provides diverse opportunities to individuals seeking rewarding and enriching careers. If you enjoy the challenge of working in a highly dynamic and technologically advanced sector, delight in formulating engineering solutions, and are keen in developing deep technical expertise, the biopharmaceuticals manufacturing sector offers opportunities to develop your passion and grow your career.

As the sector continues to transform, these are some examples of skills in demand now and in the future. Those seeking successful careers in the biopharmaceuticals manufacturing sector can set themselves apart by developing these attributes and acquiring these skills in demand.

DESIRED ATTRIBUTES

Analytical
Enjoys analysing things from all angles to solve problems

Integrity
Demonstrates sound moral and ethical principles at work and in relationships with co-workers and stakeholders

Meticulous
Pays attention to details and accuracy

Responsible
Recognises the implicit obligation on accountability to ensure work processes run reliably and efficiently

Safety-minded
Recognises the implicit responsibility for ensuring safe work practices and conditions in a high-risk environment

Team Player
Understands that each person is part of a larger team working together to bring about success at the workplace

SKILLS IN DEMAND

Continuous Manufacturing Skills
Enable continuous flow, end-to-end manufacturing strategies

Compliance and Regulatory Affairs Skills
Manage regulatory issues set by international regulatory authorities to meet regulatory demands throughout the life of a product

Green Manufacturing Skills
Innovate and enable ecologically friendly processes to support sustainable green manufacturing

Multi-product Operations Skills
Apply processes to manufacture variety of products with different specifications

Process Analytical Technology Skills
Apply automated process control methods throughout the value chain of the product

Quality by Design Skills
Integrate target product quality into biopharmaceuticals manufacturing processes

Take Your Career Further

A skilled workforce is essential in sustaining Singapore's global competitiveness as a leading biopharmaceuticals manufacturing hub. There is a wide range of initiatives and schemes available to both individuals and employers to promote skills acquisition and upgrading.

FOR INDIVIDUALS

Education and Career Guidance

Education and Career Guidance (ECG) is about equipping students, as well as adults, with the necessary knowledge, skills and values to make informed education and career decisions. With the help of trained ECG counsellors, students will be exposed to a wide range of education and career options, and given the opportunities to make informed post-secondary education choices. Singaporeans in the workforce can benefit from career coaching, employability skills workshops, networking sessions through the Workforce Singapore (WSG) Career Centres and the Employment and Employability Institute (e2i).

Enhanced Internships

The Enhanced Internships are designed to provide students with a more meaningful internship experience through more structured learning and support at the workplace. Participating companies will work closely with the Institute of Technical Education (ITE) and polytechnics to deliver a positive and meaningful internship experience for their interns. The features of the Enhanced Internships include baseline allowance of $600 a month, structured training plan with clear learning outcomes, assigned mentors to provide guidance to interns and rotation to at least two departments per internship period.

SkillsFuture Credit

Credit of $500 for all Singapore Citizens aged 25 and above to defray costs for a wide range of skills-related courses to encourage skills development and lifelong learning.

SkillsFuture Earn and Learn Programme

A work-learn programme designed to give graduates from the ITE and polytechnics a headstart in careers related to their discipline of study. Suitable candidates will be matched with a job related to their field of study, and undergo structured on-the-job training and mentorship in participating companies. They can also gain industry experience and attain an industry-recognised certification concurrently.

SkillsFuture Fellowships

Monetary award of $10,000 to recognise Singapore Citizens with deep skills, who are champions of lifelong learning, and committed to contributing to the skills development of others.

Take Your Career Further

SkillsFuture Mid-Career Enhanced Subsidy

Singaporeans aged 40 and above will receive higher subsidies of up to 90% of course fees for over 8,000 SkillsFuture Singapore-supported courses and at least 90% of programme cost for Ministry of Education (MOE)-subsidised full-time and part-time courses.

SkillsFuture Series

Targeted at Singaporeans who are keen to either gain a basic understanding or deepen their skills in eight emerging areas*, the SkillsFuture Series comprises training programmes across three proficiency levels, namely Basic, Intermediate and Advanced. Adult learners of different skills proficiency and industry background can therefore benefit from the SkillsFuture Series. Individuals will receive 70-90% course fee subsidy depending on eligibility.

*Eight emerging areas are: *Data analytics, Cybersecurity, Advanced manufacturing, Urban solutions, Finance, Tech-enabled services, Digital media, Entrepreneurship*

SkillsFuture Qualification Award

This award encourages Singapore Citizens to attain full Workforce Skills Qualifications, which equip them with comprehensive and robust sets of skills to perform their jobs competently, pursue career progression and explore new job opportunities.

SkillsFuture Study Award

A monetary award of $5,000 for adults in their early and mid-career to develop and deepen their skills in future growth clusters.

Young Talent Programme

Students from ITE, polytechnics, and universities can embark on overseas internships to take on work and study programmes that will prepare them for international assignments in their future careers.

FOR INDIVIDUALS AND EMPLOYERS

MySkillsFuture

MySkillsFuture is a one-stop online portal that enables Singaporeans to chart their own career and lifelong learning pathways, through access to industry information and tools to search for training programmes to broaden and deepen skills. It incorporates the national Jobs Bank, presenting an integrated platform for users to access resources related to jobs, education and skills training.

P-Max

Singaporeans or Singapore Permanent Residents can gain access to career opportunities with small and medium-sized enterprises (SMEs), and benefit from workshops and progressive HR practices designed to help them adapt to the working environment in an SME.

Career Matching Services

Get guidance in your career development through:

- Career guidance
- Self-help career resources
- Job opportunities
- Career Events
- Workshops and programmes
- Job-matching tools and in-depth profiling

Initiatives and Schemes by:

SkillsFuture Singapore

Workforce Singapore

Career Support Programme (CSP)

Help Singapore Citizen Professionals, Managers, Executives and Technicians (PMETs), who are made redundant and/or unemployed and actively looking for jobs for six months or more, to take on new jobs paying $3,600 or more.

Career Trial

The Career Trial aims to help Singaporean jobseekers try out more jobs and assess new careers through a short term work stint in jobs paying $1,500 or more. Eligible jobseekers who are employed after the Career Trial and stay on the job for at least 3 months can receive retention incentives of up to $1,500. The Career Trial will take effect from 1 Apr 2018.

Professional Conversion Programmes

Reskill and acquire the necessary knowledge and competencies to take on new jobs in growing sectors. Employers will receive 70-90% support for both salary and course fee.

WorkPro

WorkPro encourages employers to implement progressive employment practices to benefit Singaporeans through job redesign, age management practices and flexible work arrangements.

Employers can get funding support to redesign the workplace or job tasks, or implement age management practices and flexible work arrangement.

For more information on the initiatives and schemes, please visit
skillsfuture.sg | wsg.gov.sg | edb.gov.sg

Realise Your Potential - Take the Next Step Forward

Now that you have some idea of what a career in the biopharmaceuticals manufacturing sector can offer and the available government initiatives and schemes to support your career goals, you are ready to take the next step!

NEW ENTRANTS

Use the Skills Framework for Biopharmaceuticals Manufacturing to find out about careers in the sector

UNDERSTAND the career pathways and the attributes needed to take on a particular occupation in the sector

UNDERSTAND the skills and competencies required for the job role and identify relevant training programmes to help you become a qualified personnel

EXPERIENCED PROFESSIONALS

Use the Skills Framework for Biopharmaceuticals Manufacturing to find out how to chart your career

PLAN for vertical career progression within the track that you are currently in, or for lateral career moves across the tracks

IDENTIFY skills gaps that you are lacking in your current or next job role

IDENTIFY relevant training programmes

TRAINING PROGRAMMES

Embark on your career in biopharmaceuticals manufacturing

Programmes that equip new entrants with skills and knowledge for specific occupations in the sector at their respective entry levels

Programmes for experienced employees or individuals to broaden or deepen specific skills and knowledge for various occupations in the sector

Lifelong learning for skills deepening to meet existing and emerging demands of the sector

For a list of training programmes available for the biopharmaceuticals manufacturing sector, please visit: **skillsfuture.sg/skills-framework/biopharmmfg**

Notes

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Process Development/Manufacturing Science and Technology (MS&T)

Operation Excellence Manager

Dorcas Goh
Abbott Manufacturing Singapore

PURSUING EXCELLENCE

Dorcas Goh's desire to make an impact on people's lives led her to take up the role of Operation Excellence Manager at Abbott Manufacturing Singapore. She is responsible for programme management, and driving continuous improvements to Abbott's processes, creating a culture of operational excellence in the way of working in order to deliver the highest quality product to their customers.

Dorcas made a mid-career switch a year ago to the biopharmaceuticals manufacturing sector. She was in the electronics manufacturing sector and the service sector before making the change. A difference she noted was that compliance and regulation is not just an important aspect of her current industry, but a necessity. She also believes that stakeholder management is the key to success for her role, as she works in partnership with stakeholders to arrive at business decisions.

A challenge she faces is driving continuous improvements in a time-constrained business environment. However, she overcomes them by having the right studies and data that cover all scenarios. This allows her to put together a strong, compelling business case that will enable her leadership team to make timely, fact-based decisions.

Dorcas's future goal is to play a more strategic role and be in a position to influence colleagues beyond Abbott's local manufacturing plant, ultimately impacting more customers positively. She says that acquiring leadership skills and increasing her breadth of knowledge on modern manufacturing technology is important. A useful reference for Dorcas in achieving her future goals is the Skills Framework. "The Skills Framework can help to fill the gaps as it provides an overview of where my current skills fit in the industry and the opportunities available for my career growth," Dorcas explains.

Her advice for people who wish to join the biopharmaceuticals manufacturing sector is to have passion. Once you have passion, you constantly want to pursue excellence. Her passion lies at realising the impact she has on consumers. "Every decision that we make has an impact on the lives of our customers. What we do is beyond the delivery of quality products. Our products nourish people at every stage of life, and help them live healthier and fuller lives through good health," Dorcas says.

> "The Skills Framework can help to fill the gaps as it provides an overview of where my current skills fit in the industry and the opportunities available for my career growth."

Process Development/MS&T Engineer

JOB ROLE DESCRIPTION

The Process Development/MS&T Engineer supports process development, monitoring and improvement activities for the biopharmaceuticals manufacturing facilities. He/She will analyse the critical material attributes of biopharmaceutical products, prepare Process Flow Diagrams (PFD), perform pilot tests and support technology transfer activities. He also assists in developing and updating Standard Operating Procedures (SOPs) for the manufacturing facility and supporting the delivery of associated training. The Process Development/MS&T Engineer should have deep understanding of the engineering and scientific concepts underlying the manufacture of the biopharmaceutical product and equipment involved in order to make significant contributions in determining how the product is made within the manufacturing facilities.

The Process Development/MS&T Engineer should have a passion for innovation and continuous improvement and he applies this to his work, driving efficiency and improvement in new and existing manufacturing processes. He must be able to work independently and exercise analytical and innovative thinking to analyse information, solve problems and improve existing methods and processes.

	CRITICAL WORK FUNCTIONS	KEY TASKS
CRITICAL WORK FUNCTIONS AND KEY TASKS	Design biopharmaceuticals manufacturing processes	• Use Quality by Design (QbD) principles and procedures to guide process design work • Define the critical material attributes of the final products that must be controlled to meet the target products quality profiles • Develop a Process Flow Diagram (PFD) • Review technologies for transfer and scale-up of the manufacturing processes • Propose possible process control, sampling and monitoring points and related performance parameters to achieve the critical material attributes of the final products • Analyse the functionality of different process control, sampling and monitoring systems and technologies • Design the layouts of equipment and systems for the manufacturing facilities in collaboration with the Engineering and Maintenance department • Conduct process modelling to identify risks in the proposed manufacturing processes and propose mitigation actions
	Implement technology transfer	• Prepare protocols for pilot tests • Conduct pilot tests and re-trials as necessary • Analyse results of pilot tests and re-trials to verify the new or improved manufacturing processes are robust and repeatable • Maintain records of manufacturing process pilot tests performed • Support the development of implementation plans for technology transfer • Prepare Standard Operating Procedures (SOPs) for new or improved manufacturing processes in line with Current Good Manufacturing Practices (CGMPs) • Support delivery of training on approved SOPs • Support the transfer of scaled-up manufacturing processes to new facilities
	Conduct ongoing validation of existing manufacturing processes	• Monitor manufacturing process performance using Process Analytical Technology (PAT) and other methods • Perform statistical analysis and modelling using manufacturing performance data • Identify gaps, problems or sub-optimal performance in existing processes and their potential causes • Identify Corrective and Preventive Actions (CAPA) to address out-of- control processes

Process Development/MS&T Engineer

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Innovate existing manufacturing processes	• Research ways to innovate and optimise manufacturing processes and equipment • Assess the functionality of new automated technologies, flexible facilities, single-use systems and other manufacturing equipment • Propose alternative sources for raw materials that will reduce costs or improve reliability and quality of the final products • Use process modelling to identify gaps and bottlenecks within existing manufacturing processes • Support implementation of improvements to manufacturing processes • Analyse manufacturing performance indicators such as production time, yield and defective rates after manufacturing process improvements have been implemented

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 4
Big Data Analysis	Level 3
Biological Product Introduction	Level 4
Cell Culture	Level 4
Change Management	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Facility Design	Level 4
Flexible Facilities Implementation	Level 4
Good Manufacturing Practices Implementation	Level 4
Green Manufacturing Design and Implementation	Level 4
Innovation Management	Level 4
Laboratory Data Analysis	Level 3
Manufacturing Process Design	Level 4
Pharmaceutical and Nutritional Product Introduction	Level 4
Pharmacovigilance Integration	Level 4
Process Analytical Technology Implementation	Level 3
Process Modelling	Level 4
Process Monitoring	Level 4
Process Optimisation	Level 4
Process Validation	Level 3
Product Improvement	Level 3
Project Management	Level 4
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Interpersonal Skills	Basic
Problem Solving	Basic
Sense Making	Basic
Teamwork	Basic

Process Development/MS&T Senior Engineer

JOB ROLE DESCRIPTION

The Process Development/MS&T Senior Engineer leads the technical development, monitoring and improvement activities for biopharmaceuticals manufacturing processes within the facilities. He/She oversees the design and piloting of new processes and associated manufacturing facility layouts. The Process Development/MS&T Senior Engineer is the go-to technical expert for manufacturing processes across the facilities. He reviews the Standard Operating Procedures (SOPs) for manufacturing processes, collaborates with other departments to deliver training and implements technology transfer.

The Process Development/MS&T Senior Engineer works primarily in production lines within the manufacturing facilities. He has a passion for innovation and continuous improvement and thoroughly enjoys critically analysing existing manufacturing processes in order to identify improvements or rectify deviations. He has strong communication and teamwork skills in order to successfully implement new and improved manufacturing processes in consultation and collaboration with other stakeholders.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Design biopharmaceuticals manufacturing processes	• Lead Quality by Design (QbD) initiatives and coach others on incorporating principles into design activities • Determine the processes required to manufacture new biopharmaceutical products from the critical material attributes • Review Process Flow Diagrams (PFD) • Determine methods and technologies for transfer and scale-up of the manufacturing processes • Determine process control, sampling and monitoring points and related performance parameters required to achieve the critical material attributes of the final products • Determine the functionality needed from process control, sampling and monitoring systems and technologies and collaborate with the Engineering and Maintenance department to select equipment • Review facility layout designs • Review process modelling results to detect risks of the proposed manufacturing processes and alter the design as necessary
Implement technology transfer	• Review protocols for pilot tests • Oversee conduct of pilot tests and re-trials • Review results of pilot tests and re-trials against target products quality profiles and regulatory requirements • Refine process designs as needed following piloting activities • Develop implementation plans for technology transfer • Review Standard Operating Procedures (SOPs) for new improved manufacturing processes and ensure alignment with Current Good Manufacturing Practices (CGMPs) • Deliver training on approved SOPs in collaboration with the Production department • Facilitate technology transfer and scale-up activities and provide technical troubleshooting expertise as required
Conduct ongoing validation of existing manufacturing processes	• Define process performance parameters for monitoring using Process Analytical Technology (PAT) and other methods • Develop advanced statistical models and parameters for analysis of manufacturing performance data • Review key findings from analyses of manufacturing process performance data and their implications • Review implementation of Corrective and Preventive Actions (CAPA) to address out-of-control processes, ensuring objectives have been achieved

Process Development/MS&T Senior Engineer

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Innovate existing manufacturing processes	• Design technical innovations to optimise manufacturing processes and equipment • Set guidelines for assessing the technical viability of new automated technologies, flexible facilities, single-use systems and other manufacturing equipment • Select alternative sources of raw materials for manufacturing processes • Devise technical solutions to address gaps and bottlenecks within existing manufacturing processes • Lead the implementation of improvements to manufacturing processes from a technical and product quality perspective • Monitor the impact of manufacturing process improvements

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 5
Big Data Analysis	Level 4
Biological Product Introduction	Level 5
Cell Culture	Level 5
Change Management	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 5
Facility Design	Level 5
Flexible Facilities Implementation	Level 5
Good Manufacturing Practices Implementation	Level 5
Green Manufacturing Design and Implementation	Level 5
Innovation Management	Level 5
Laboratory Data Analysis	Level 4
Manufacturing Process Design	Level 5
Pharmaceutical and Nutritional Product Introduction	Level 5
Pharmacovigilance Integration	Level 5
Process Analytical Technology Implementation	Level 5
Process Modelling	Level 5
Process Monitoring	Level 5
Process Optimisation	Level 5
Process Validation	Level 5
Product Improvement	Level 4
Systems Thinking	Level 5
Technical Presentation	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Decision Making	Intermediate
Problem Solving	Intermediate
Sense Making	Intermediate
Teamwork	Intermediate

Process Development/MS&T Manager

JOB ROLE DESCRIPTION

The Process Development/MS&T Manager reviews the operational and financial viability of developing, monitoring and improving biopharmaceuticals manufacturing processes within the facilities. He/She translates the department's objectives and priorities into actionable operating plans and Key Performance Indicators (KPIs) for Process Development/MS&T teams and tracks the progress. He is responsible for optimising internal processes while keeping in line with external guidelines and managing risks for the department. The Process Development/MS&T Manager is responsible for facilitating cross-departmental collaboration in order to successfully implement large-scale manufacturing processes for new biopharmaceutical products or significant changes to equipment, systems and processes for existing products.

The Process Development/MS&T Manager is expected to serve as a role model in the department and should be a personable and inspiring leader who can communicate well to influence internal and external stakeholders. He should be a champion for innovation and particularly enjoys leading efficiency and improvement initiatives across the organisation.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Design biopharmaceuticals manufacturing processes	• Implement Quality by Design (QbD) procedures within the department • Determine the financial and operational viability of scaled-up manufacturing for new biopharmaceutical products • Evaluate financial and operational viability of selected process control, sampling and monitoring systems and technologies • Facilitate cross-departmental collaboration to ensure consistency in approaches for different manufacturing processes and facilities across the organisation • Evaluate potential operational risks for proposed manufacturing processes and alter the designs as necessary
Implement technology transfer	• Manage financial and operational aspects of performing pilot tests and re-trials • Review results of pilot tests and re-trials from a financial and operational perspective • Determine resource and operational requirements for technology transfer implementation plans • Facilitate training for new and revised Standard Operating Procedures (SOPs) • Manage resources and costs for technology transfer implementation
Innovate existing manufacturing processes	• Review the feasibility, costs and potential business value of proposed technical innovations to manufacturing processes • Review new automated technologies, flexible facilities and single-use systems from a financial and operational perspective • Review proposals for alternative raw materials sources • Devise operational solutions to address gaps and bottlenecks within existing manufacturing processes • Lead the implementation of improvements to manufacturing processes from a financial and operational perspective • Consult key internal stakeholders to assess effectiveness of manufacturing process improvements

Process Development/MS&T Manager

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage department operations	• Translate the long-term objectives for the department into tactical plans and objectives for teams • Coordinate team resources to ensure adequate staffing levels • Facilitate collaboration between Process Development/MS&T, Engineering and Maintenance and Production departments for the purposes of ongoing validation and monitoring of manufacturing processes • Develop periodic reports for senior management and regulatory authorities on ongoing process validation • Monitor the department's financial inflow and outflow against allocated budgets and forecasts • Initiate training programmes to build capabilities in the department • Assess feasibility of proposals to improve department workflows • Justify the resources required to support changes in resources, procedures, systems, equipment or technology within the department
Manage risk and regulatory compliance	• Develop risk management plans for the department • Train teams on the Quality and Health, Safety and Environment (HSE) requirements of manufacturing processes that impact process designs • Train teams on Current Good Manufacturing Practices (CGMPs) and the impact on process designs • Develop contingency plans to minimise impact of unforeseen delays in process development activities on manufacturing operations • Activate contingency plans when delays or lapses in process development activities arise

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 5
Biological Product Introduction	Level 5
Budgeting	Level 4
Business Continuity Management	Level 5
Business Performance Management	Level 5
Change Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Good Manufacturing Practices Implementation	Level 5
Green Manufacturing Design and Implementation	Level 5
Innovation Management	Level 5
Manufacturing Process Design	Level 5
Pharmaceutical and Nutritional Product Introduction	Level 5
Process Analytical Technology Implementation	Level 4
Process Optimisation	Level 5
Process Validation	Level 5
Project Management	Level 5
Risk Management	Level 5
Strategy Development	Level 4
Systems Thinking	Level 5
Team Effectiveness Management	Level 5
Technical Presentation	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Intermediate
Developing People	Intermediate
Leadership	Intermediate
Resource Management	Advanced

Process Development/MS&T Director

JOB ROLE DESCRIPTION

The Process Development/MS&T Director approves and guides the development of new or improved processes in the biopharmaceuticals manufacturing facilities and leads subsequent change management initiatives. He/She endorses all major decisions regarding piloting new technology, implementing process scale-up as well as monitoring and optimising existing processes. In addition, he is accountable for the Process Development/MS&T department meeting its operational and financial targets. The Process Development/MS&T Director holds ultimate responsibility for the development, monitoring and improvement of biopharmaceuticals manufacturing processes within the facilities.

The Process Development/MS&T Director is required to maintain a broad, strategic perspective, applying transdisciplinary thinking and a global mindset, to consider issues within the wider context and make effective decisions that will impact the biopharmaceuticals manufacturing facilities. He should be passionate in driving a culture of innovation within and beyond the department to enhance the overall reliability and efficiency of biopharmaceuticals manufacturing facilities. He is a strong leader who applies his interpersonal skills to engage with internal and external stakeholders to drive the department's activities.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Design biopharmaceuticals manufacturing processes	• Formulate Quality by Design (QbD) principles for the organisation • Define the target products quality profiles and strategic business priorities to guide the design of new biopharmaceuticals manufacturing processes • Approve methods and technologies for transfer and scale-up of the manufacturing processes • Endorse performance parameters for new manufacturing processes • Approve selected process control, sampling and monitoring systems and technologies • Approve facility layout designs
Implement technology transfer	• Endorse protocols for pilot tests • Approve refinements to the process designs following piloting activities • Approve technology transfer implementation plans • Endorse new and revised Standard Operating Procedures (SOPs) for manufacturing processes • Establish channels for cross-departmental collaboration to drive successful transition to full scale production
Innovate existing manufacturing processes	• Synthesise the impact of emerging technological changes on the types of technology, facilities and systems used in manufacturing processes to guide process development activities • Approve recommended innovations to manufacturing processes • Approve changes to raw material sourcing • Approve manufacturing process enhancements that align with business requirements • Facilitate cross-departmental collaboration to implement improvements to manufacturing processes
Manage department operations	• Establish long-term objectives for the department that align with the strategies of the manufacturing facilities • Establish robust operating and resourcing structures for the department to support business objectives • Synergise regulatory and business requirements to provide guidance for ongoing process validation • Facilitate periodic cross-departmental reviews of ongoing process validation as per regulatory requirements • Source budgets for the department's activities at a corporate level and allocate to different teams and projects • Define the required capabilities for the department to support business objectives • Approve workflow improvement solutions and initiatives for the department • Approve recommendations on significant changes to department's operations and the required resources

Process Development/MS&T Director

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage risk and regulatory compliance	• Approve the risk management plans for the department • Keep abreast of changes to local and international Quality and Health, Safety and Environment (HSE) regulations • Collaborate with the Quality and Production departments to ensure overall compliance of manufacturing processes with required Current Good Manufacturing Practices (CGMPs) • Approve business continuity policies, strategies and plans • Lead the activation of contingency plans in the event of significant delays, lapses or emergencies in process development activities

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 6
Big Data Analysis	Level 5
Biological Product Introduction	Level 6
Budgeting	Level 5
Business Continuity Management	Level 5
Business Networking	Level 5
Business Performance Management	Level 5
Business Planning	Level 5
Change Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Good Manufacturing Practices Implementation	Level 5
Green Manufacturing Design and Implementation	Level 6
Innovation Management	Level 6
Manufacturing Process Design	Level 6
Pharmaceutical and Nutritional Product Introduction	Level 6
Process Optimisation	Level 5
Product Improvement	Level 5
Project Management	Level 6
Risk Management	Level 5
Strategy Development	Level 5
Systems Thinking	Level 5
Technical Presentation	Level 6

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Advanced
Developing People	Advanced
Global Mindset	Advanced
Leadership	Advanced

Quality Assurance and Quality Control (QA&QC)

Quality Control Analyst

Quek Swee Yee
Lonza Biologics Tuas Pte Ltd

ENSURING QUALITY

Quek Swee Yee has always had an interest in science and laboratory testing. This led her to a career in biopharmaceuticals manufacturing as she was interested to explore the background of how biologics are manufactured. She is currently a Quality Control Analyst at Lonza, where her responsibilities include testing samples, reviewing data results, performing equipment qualification and general laboratory duties.

As part of skills training at Lonza, she underwent three months of theory and laboratory sessions at Temasek Polytechnic, which helped her understand the fundamentals of biologics manufacturing. She also did a year-long on-the-job training stint in Slough, United Kingdom. All these experiences proved beneficial when she came back to Singapore, as she adapted quickly to her job and understood the requirements of her role.

Swee Yee feels that another way to find out the requirements of the industry is to look at the Skills Framework for Biopharmaceuticals Manufacturing. "The skills map provides the job descriptions of each position: the roles and tasks, as well as the required skills and competencies. I am able to identify what I am lacking in and improve on those areas. As technology is changing every day, there may be new technology or skills which I am able to learn," she advises.

Swee Yee says that an important skill needed in the sector is to be team-oriented. "It is important to work well with the team, support your teammates, and have good communication skills," she says. A moment she remembers fondly was when she was swamped with multiple projects, and her team mates rendered their help to share the workload.

One of the challenges she faced in her career was when there were testing issues late one night. She had to run a thorough investigation and inform other departments about the situation. Through this challenge, she managed to rise to the occasion and sort out the problem. "Another issue I encounter, is when new equipment does not meet the qualification requirements that are mandatory for the manufacturing facility. I have to seek help from other departments and other Lonza sites to resolve the issues. However, these moments are memorable as I see the fruits of my labour when the equipment is ready to be operational," she explains.

> "The Skills Framework allows me to identify what I am lacking in and improve on those areas."

Quality Assurance Assistant

JOB ROLE DESCRIPTION

The Quality Assurance Assistant supports validation and audit activities by collecting data and organising information. He/She also assists with document preparation and the proper filing of documents. He applies standard procedures in daily work activities and identifies opportunities to improve Quality Assurance (QA) procedures within his work area. The Quality Assurance Assistant should have a detailed understanding of the Standard Operating Procedures (SOPs) to be followed when supporting QA activities.

The Quality Assurance Assistant is service-oriented and recognises the importance of the organisation's products in improving the lifestyle and health of customers. He has a systematic and organised mindset which he applies to manage documents, data and digital and hardcopy filing systems for the organisation. He demonstrates good team spirit and interacts effectively with others to achieve quality workflow outcomes.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Validate manufacturing methods and processes	• Collect information and data required for validation activities in line with Standard Operating Procedures (SOPs) • Assist with the monitoring of manufacturing processes, according to validation plans and schedules • Collate information for product and process quality metric management reports
Facilitate achievement of quality expectations and standards	• Collect information on quality records and follow-up actions to support internal and external audits • Record results of internal and external audits
Manage document control procedures	• File electronic and hardcopy documents according to standard procedures and requirements • Organise information in the document management system, ensuring its accuracy and accessibility by appropriate stakeholders • Track document updates and distribution • Prepare information needed for audits of the documentation management system
Optimise quality and efficiency of department workflows and activities	• Identify opportunities to improve Quality Assurance (QA) procedures within own work area • Propose QA workflow improvements within own work area • Assist with the implementation of workflow improvements to improve efficiency

Quality Assurance Assistant

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Analytical Method Validation	Level 2
Audit Management	Level 3
Change Management	Level 3
Cleaning Validation	Level 3
Continuous Improvement	Level 3
Document Control	Level 2
Good Manufacturing Practices Implementation	Level 3
Health, Safety and Environment Procedures Implementation	Level 2
Innovation Management	Level 3
Packaging Validation	Level 3
Process Monitoring	Level 3
Process Validation	Level 2
Project Management	Level 3
Systems Thinking	Level 3
Technical Report Writing	Level 3

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Computational Thinking	Basic
Digital Literacy	Basic
Problem Solving	Intermediate
Service Orientation	Intermediate
Teamwork	Basic

Quality Assurance Specialist

JOB ROLE DESCRIPTION

The Quality Assurance Specialist implements validation processes to identify deviations and potential risks in the manufacturing processes. He/She is responsible for first-line verification of quality standards in the organisation and supports the product release and registration process by collaborating with other departments to gather relevant information. In addition, he assists in audits, handles quality queries, delivers quality-related training, and is responsible for ensuring that documents are organised and managed according to standard procedures and requirements. The Quality Assurance Specialist communicates with customers on product enquiries and develops practical solutions to implement workflow improvements and enhance department operations.

The Quality Assurance Specialist is meticulous and systematic in carrying out his tasks, and exercises critical and analytical thinking to identify discrepancies in processes and resolve problems. He applies communication and teamwork skills to interact effectively with others to achieve organisational objectives.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Validate manufacturing methods and processes	• Implement validation processes to review systems, methods and processes utilised in manufacturing facilities • Verify that manufacturing processes are performed in line with established standards and in accordance with validation plans • Implement the organisation's operational excellence model for validation of manufacturing methods and processes • Identify deviations and potential risks in manufacturing systems, processes and methods, and their possible causes • Communicate results of Corrective and Preventative Actions (CAPAs) to relevant stakeholders • Compile quality metric data required for management reporting and prepare sections of quality metric reports
Facilitate registration and release of biopharmaceutical products	• Consolidate and ensure data integrity of information and materials for product registration reports • Assist in the generation of Certificates of Analysis • Collaborate with other departments to collect and organise information required for batch releases
Facilitate achievement of quality expectations and standards	• Record details of customer complaints and the organisation's responses • Support traceability investigations of customer complaints • Present quality records and follow-up actions during internal and external audits • Identify areas of improvement from audit results • Assist in the delivery of training • Collect data on training outcomes and effectiveness
Manage document control procedures	• Check that electronic and hardcopy documents are organised and managed according to Standard Operating Procedures (SOPs) and requirements • Oversee the update and distribution of documents • Review the formatting and editing of documents according to guidelines and templates • Perform document control audits to analyse adequacy and alignment with requirements • Record results of document control audits

Quality Assurance Specialist

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Optimise quality and efficiency of department workflows and activities	• Implement Quality Assurance (QA) policies and procedures • Assess the quality and efficiency of QA procedures to identify areas for improvement • Translate improvement ideas and proposals into practical solutions • Gather information to support feasibility assessments of introducing new procedures and improvements for QA activities • Implement workflow improvements to improve efficiency • Record improvement activities taken and reductions and improvements achieved

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Analytical Method Validation	Level 3
Audit Management	Level 3
Change Management	Level 4
Cleaning Validation	Level 3
Computer Systems Validation	Level 3
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Document Control	Level 3
Good Manufacturing Practices Implementation	Level 4
Health, Safety and Environment Procedures Implementation	Level 3
Innovation Management	Level 4
Packaging Validation	Level 3
Process Monitoring	Level 4
Process Validation	Level 3
Project Management	Level 4
Quality Assurance Management	Level 3
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Interpersonal Skills	Basic
Problem Solving	Basic
Sense Making	Intermediate
Teamwork	Basic

Quality Assurance Senior Specialist

JOB ROLE DESCRIPTION

The Quality Assurance Senior Specialist develops validation plans and procedures to facilitate the identification and correction of deviations in manufacturing methods and processes. He/She prepares the required information for product registrations and batch releases, and recommends solutions to address quality queries, customer complaints and audit requirements. He designs documentation guidelines and templates, as well as delivers quality-related training. The Quality Assurance Senior Specialist also implements initiatives to encourage continuous improvement and reviews recommendations to enhance department operations. He should be well-versed in regulatory affairs and compliance standards in biopharmaceuticals manufacturing, and the processes, documentation and activities required to obtain regulatory approval for biopharmaceutical product releases.

The Quality Assurance Senior Specialist has an analytical mindset and is able to apply problem solving skills to manage priorities and address multi-faceted issues effectively. He has strong communication skills which enables him to interact effectively with diverse groups of internal and external stakeholders.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Validate manufacturing methods and processes	• Develop validation Standard Operating Procedures (SOPs) that align to regulatory requirements, Current Good Manufacturing Practices (CGMPs) requirements and the organisation's policies • Develop validation plans to ensure the achievement of required quality standards • Facilitate the use of the organisation's operational excellence model for validation of manufacturing methods and processes • Lead root cause analyses and investigations into process deviations • Oversee Corrective and Preventative Actions (CAPAs) implementation and documentation in collaboration with other departments • Develop product and process quality metric reports
Facilitate registration and release of biopharmaceutical products	• Prepare and review the data integrity of product registration applications and reports • Generate Certificates of Analysis • Review completed batch records and checklists • Make recommendations on batch usage
Facilitate achievement of quality expectations and standards	• Manage customer feedback and assess need for escalation • Lead traceability investigations on the source of quality lapses and other product issues • Recommend process improvements to address identified product quality issues • Conduct internal audits and facilitate external audits • Prepare business cases for changes to procedures and processes after audits • Deliver training on CGMPs, regulatory and other requirements • Analyse training outcomes to identify gaps and design new and revised training programmes accordingly
Manage document control procedures	• Identify electronic and hardcopy documentation requirements for operations across the organisation • Implement documentation management systems • Review updated documentation in response to changes in manufacturing processes • Design document control guidelines and templates and recommend revisions according to results of document control audits • Develop processes and checks to be followed for conducting document control audits • Review results to recommend revisions to document control guidelines

Quality Assurance Senior Specialist

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Optimise quality and efficiency of department workflows and activities	• Translate Quality Assurance (QA) policies into procedures and checks to be followed • Implement department-wide initiatives to encourage the improvement of QA procedures, activities and workflows • Assess the feasibility and viability of introducing new and improved QA procedures • Oversee the introduction of new workflow improvements to improve efficiency • Review results from improvement activities

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Analytical Method Validation	Level 4
Audit Management	Level 4
Change Management	Level 4
Cleaning Validation	Level 4
Computer Systems Validation	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Document Control	Level 4
Good Manufacturing Practices Implementation	Level 4
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 4
Packaging Validation	Level 4
Pharmacovigilance Integration	Level 4
Process Monitoring	Level 4
Process Validation	Level 4
Project Management	Level 4
Quality Assurance Management	Level 4
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Decision Making	Intermediate
Interpersonal Skills	Intermediate
Problem Solving	Intermediate
Resource Management	Intermediate
Sense Making	Intermediate

Quality Assurance Manager

JOB ROLE DESCRIPTION

The Quality Assurance Manager translates the long-term goals for Quality Assurance (QA) into tactical plans while maintaining oversight of the department's operational and financial status. He/She endorses the Standard Operating Procedures (SOPs) for plants and reviews validation plans and procedures, ensuring alignment with Current Good Manufacturing Practices (CGMPs) and regulatory requirements, respectively. He defines the information required for new product registrations and facilitates registration applications to obtain approval for the release of biopharmaceutical products. He is responsible for building department personnel capability by initiating training programmes, and developing strategies to facilitate operational improvements for the department. The Quality Assurance Manager is responsible for all QA activities within the organisation. He is therefore required to have deep knowledge of regulatory requirements and expertise pertaining to verification of product and process quality for product release.

The Quality Assurance Manager is a leader who provides clear guidance on critical work activities and deliverables, and has the foresight to develop skills and capabilities within and beyond the department to optimise resources, talent and overall performance. He also has the ability to develop creative solutions to resolve problems.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Validate manufacturing methods and processes	• Review and endorse validation Standard Operating Procedures (SOPs) and plans, ensuring alignment with regulatory requirements, Current Good Manufacturing Practices (CGMPs) requirements and the organisation's policies • Devise an operational excellence model for validation of manufacturing methods and processes • Oversee investigations into major process deviations to determine root causes • Evaluate the impact of process deviations on production operations and the need for Corrective and Preventative Actions (CAPAs) • Review product and process quality metric reports
Facilitate registration and release of biopharmaceutical products	• Define the information required and data integrity standards for new product registrations • Review and monitor product registration applications, ensuring alignment with regulatory requirements and other changes that may impact a product's registration status • Endorse Certificates of Analysis • Approve batches for forward processing
Facilitate achievement of quality expectations and standards	• Liaise with customers in the event of major product quality deviations and product recalls • Determine the extent of the plant's control over quality deviation • Initiate product recall procedures and determine responsibilities and accountabilities of impacted organisational personnel • Approve improvements to address identified product quality issues • Translate internal and external audit policies into procedures and checks to be followed • Review audit results and the proposed changes to procedures • Develop training programmes for CGMPs, regulatory and other requirements in line with the training strategy • Introduce additional training programmes to address gaps identified from audits and checks
Optimise quality and efficiency of department workflows and activities	• Design Quality Assurance (QA) policies to prevent issues that could lead to sub-optimal product quality • Develop strategies for the QA department to encourage continuous improvement of QA procedures, activities and workflow management • Recommend changes to resources, procedures, systems, equipment, and technology within the QA department • Monitor effectiveness of improvements and changes made to QA activities and workflows

Quality Assurance Manager

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage Quality department operations	• Communicate and implement QA strategies, objectives, policies and processes • Translate long-term goals for the QA department into tactical plans • Set and communicate individual objectives and review and assess the performance of direct reports • Direct capability development roadmaps and programmes for the QA department • Coordinate department resources to ensure adequate staffing and capability levels • Maintain oversight of the completion of all QA tasks, ensuring proper documentation, progress tracking and reporting • Monitor the QA department's financial inflows and outflows against allocated budgets and forecasts

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Analytical Method Validation	Level 5
Audit Management	Level 5
Budgeting	Level 4
Business Continuity Management	Level 5
Business Performance Management	Level 5
Change Management	Level 5
Computer Systems Validation	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Document Control	Level 4
Good Manufacturing Practices Implementation	Level 5
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 5
Pharmacovigilance Integration	Level 5
Process Validation	Level 5
Project Management	Level 5
Quality Assurance Management	Level 5
Risk Management	Level 5
Strategy Development	Level 4
Systems Thinking	Level 5
Team Effectiveness Management	Level 5
Technical Presentation	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Decision Making	Advanced
Interpersonal Skills	Advanced
Leadership	Intermediate
Problem Solving	Advanced
Resource Management	Advanced

Quality Control Assistant Laboratory Analyst

JOB ROLE DESCRIPTION

The Quality Control Assistant Laboratory Analyst supports sampling, cleanliness and product quality testing activities by preparing tools, equipment and materials, as well as assisting in the execution of tests to identify products that do not meet specified quality requirements. He/She conducts laboratory tests to identify lapses in the plant's conformance to cleanliness or hygiene standards. He assists in the management of the quality control laboratory by performing routine monitoring and maintenance of laboratory infrastructure and equipment, recording laboratory data, and assisting in preparing the laboratory for audits.

The Quality Control Assistant Laboratory Analyst works on a shift, in a cleanroom environment within a laboratory setting. He is structured and systematic, performing checks on materials at hand and verifying protocols to be used before executing quality control tasks in strict accordance to procedures. The Quality Control Assistant Laboratory Analyst should have quick learning abilities to identify and apply areas of improvement within his own area of work. He is a good team player and applies basic analysis to identify issues and solve routine problems.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Perform sampling	• Prepare sampling tools, equipment and materials • Check suitability of sampling conditions according to guidelines • Collect samples from identified points • Preserve sample integrity using appropriate measures and procedures • Document sampling conditions and activities
Monitor product quality compliance	• Prepare testing tools, equipment and materials • Conduct chemical and microbiological tests on materials, products, and packaging • Identify Out-of-Specification (OOS), deviations and quality problems of products, materials, packaging and utilities • Report testing activities and results • Comply with Quality and Health, Safety and Environment (HSE) procedures when carrying out Quality Control (QC) tests
Manage laboratory operations	• Follow the organisation's operational excellence model for laboratory work • Assist in monitoring and inspecting laboratory infrastructure, equipment and utilities • Raise equipment OOS issues and equipment purchase requests • Perform routine calibration and maintenance of laboratory equipment • Maintain integrity, accuracy and completeness of QC data and records
Manage conformance to cleanliness standards	• Prepare materials, chemicals and equipment required to test cleanliness • Perform chemical testing for contamination of cleaned and sterilised items and equipment • Check for particulates and contaminants on equipment and surfaces in the production plant • Identify equipment, products and areas with cleanliness or hygiene lapses • Perform tests and checks on disposed waste
Optimise quality and efficiency of department workflows and activities	• Assist in preparing for, and participate in laboratory inspections and audits • Identify opportunities to improve QC procedures and activities within own work area • Assist with the implementation of workflow improvements to improve efficiency

Quality Control Assistant Laboratory Analyst

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Biorisk Management	Level 2
Change Management	Level 3
Chemical Risk Management	Level 2
Cleanliness Testing	Level 3
Continuous Improvement	Level 3
Good Manufacturing Practices Implementation	Level 3
Hazards and Risk Identification and Management	Level 3
Health, Safety and Environment Procedures Implementation	Level 2
Innovation Management	Level 3
Laboratory Data Analysis	Level 2
Laboratory Management	Level 2
Packaging Testing	Level 3
Product Testing	Level 3
Project Management	Level 3
Raw Materials and Utilities Testing	Level 3
Systems Thinking	Level 3
Technical Report Writing	Level 3

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Lifelong Learning	Basic
Problem Solving	Basic
Sense-Making	Basic
Teamwork	Basic

Quality Control Laboratory Analyst/Chemist/ Microbiologist

JOB ROLE DESCRIPTION

The Quality Control Laboratory Analyst/Chemist/Microbiologist monitors sampling, cleanliness and product quality testing activities, performs non-standard quality tests, and manages associated documentation and data. He/She identifies the operating criteria for the tools, equipment and materials to be used, and collaborates with the Engineering and Maintenance department to ensure that laboratory equipment and infrastructure function as required. In addition, he implements Standard Operating Procedures (SOPs) and workflow improvements in the laboratory.

The Quality Control Laboratory Analyst/Chemist/Microbiologist works in a laboratory setting, primarily in a cleanroom environment, and may be required to work on a shift. He has to exercise critical and analytical thinking to review data and identify discrepancies against set criteria. He requires strong communication and teamwork to collaborate effectively with others in order to fulfil work objectives.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Perform sampling	• Identify sampling tools, equipment and materials needed for sampling • Perform appropriate actions for any abnormal occurrences affecting sampling conditions • Guide sample collection activities in compliance with specified procedures • Oversee the handling, storage and preservation of samples in accordance with Standard Operating Procedures (SOPs) • Verify sampling conditions and related information are accurately documented
Monitor product quality compliance	• Implement processes for testing the quality of products and associated materials and packaging • Check testing tools, equipment and materials for alignment with regulatory guidelines and protocols • Perform routine and non-standard tests on materials and products • Guide testing activities to ensure correct testing volumes, conditions and processes are used • Analyse testing results and the frequency and severity of product defects and quality lapses • Check Quality Control (QC) testing activities for compliance with Quality and Health, Safety and Environment (HSE) procedures
Manage laboratory operations	• Implement the organisation's operational excellence model for laboratory work • Perform inspections and tests on laboratory infrastructure, equipment and utilities • Collaborate with the Engineering and Maintenance department and vendors to ensure functionality of infrastructure and equipment • Verify that calibration requirements for laboratory equipment are met • Verify data integrity and records and perform data analysis
Manage conformance to cleanliness standards	• Verify that the correct materials, chemicals and equipment required to test cleanliness have been prepared • Implement testing procedures and acceptance criteria for cleaned and sterilised items and equipment • Verify that checks for particulates and contaminants have been completed • Investigate cleanliness or hygiene lapses to trace sources of contamination • Implement guidelines and indicators for testing of disposed waste • Verify the safety of waste for disposal and testing

Quality Control Laboratory Analyst/Chemist/ Microbiologist

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Optimise quality and efficiency of department workflows and activities	• Implement SOPs in the laboratory • Compile data to support business and performance metrics reporting • Prepare for and participate in laboratory inspections and audits • Propose solutions to improve QC procedures, activities and workflows • Gather information to support feasibility assessments of introducing new QC procedures, systems and equipment • Implement workflow improvements to improve efficiency of workflow and activities • Record improvement activities implemented and reductions and improvements achieved

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Biorisk Management	Level 3
Change Management	Level 4
Chemical Risk Management	Level 3
Cleanliness Testing	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Good Manufacturing Practices Implementation	Level 4
Hazards and Risk Identification and Management	Level 3
Health, Safety and Environment Procedures Implementation	Level 3
Innovation Management	Level 4
Laboratory Data Analysis	Level 3
Laboratory Management	Level 3
Packaging Testing	Level 4
Product Testing	Level 4
Project Management	Level 4
Raw Materials and Utilities Testing	Level 4
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Computational Thinking	Intermediate
Decision Making	Intermediate
Problem Solving	Intermediate
Sense Making	Intermediate

Quality Control Senior Laboratory Analyst/ Senior Chemist/Senior Microbiologist

JOB ROLE DESCRIPTION

The Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist develops sampling plans and procedures for testing product quality and cleanliness. He/She determines the optimal operating conditions for laboratory infrastructure and equipment, and investigates underlying causes, technical faults or practices that impact laboratory equipment operation. In addition, he develops Standard Operating Procedures (SOPs) for laboratories in line with Good Laboratory Practices (GLPs), and assesses the viability of introducing new or improved Quality Control procedures.

The Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist oversees operations and activities in one or multiple laboratories within the manufacturing facility, and often in a cleanroom environment. He may be expected to work on a shift. He should possess excellent analytical skills and sound judgement in order to establish and communicate critical guidelines, parameters and procedures for laboratory operations, make key decisions and resolve any complex problems that emerge. Often working in a team and having to supervise and guide others, the Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist should have strong teamwork and communication skills.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Perform sampling	• Develop sampling plans for Quality Control (QC) purposes • Cascade guidelines for optimal sampling conditions to laboratory personnel • Determine sample points and sample collection procedures • Establish Standard Operating Procedures (SOPs) and conditions for the handling, storage and preservation of samples • Review sampling documentation to identify anomalies and issues
Monitor product quality compliance	• Develop methods and indicators of success for the testing the quality of materials, products and packaging • Develop inspection and testing protocols for materials, products and packaging • Verify alignment of testing activities and procedures with established protocols • Conduct root cause analyses for product defects and quality lapses • Outline Health, Safety and Environment (HSE) procedures to adhere to during testing and validation
Manage laboratory operations	• Facilitate the application of the organisation's operational excellence model in laboratory work • Specify the protocols for laboratory infrastructure, equipment and utilities to be inspected and tested • Investigate underlying causes, technical faults and practices that impact laboratory equipment operation and infrastructure functionality • Determine optimal calibration standards for laboratory equipment operation • Review reports and develop guidelines and standard practices for data documentation and analysis
Manage conformance to cleanliness standards	• Develop SOPs and conduct training for performing cleanliness tests, identification and removal of contamination sources • Establish objectives and indicators for tests of cleanliness • Develop schedules for tests and inspections of cleaned and sterilised items and equipment • Outline processes and accountabilities for checking of particulates and contaminants • Develop SOPs for testing of disposed waste • Conduct training on waste disposal and testing procedures

Quality Control Senior Laboratory Analyst/ Senior Chemist/Senior Microbiologist

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Optimise quality and efficiency of department workflows and activities	• Develop SOPs and infrastructure requirements for laboratories in line with Good Laboratory Practices (GLPs) requirements • Conduct training on SOP for laboratories • Review data to support business and performance metrics reporting • Articulate commissioning, certification and accreditation requirements for laboratories • Assess the feasibility and viability of introducing new and improved QC procedures, systems and equipment • Oversee the introduction of new workflow improvements to improve efficiency • Implement initiatives to encourage improvement of QC procedures, activities and workflows • Review results from improvement activities

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES		GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Big Data Analysis	Level 3	Communication	Advanced
Biorisk Management	Level 4	Decision Making	Advanced
Change Management	Level 4	Interpersonal Skills	Advanced
Chemical Risk Management	Level 4	Leadership	Intermediate
Cleanliness Testing	Level 4	Problem Solving	Advanced
Conflict Resolution	Level 4		
Continuous Improvement	Level 4		
Good Manufacturing Practices Implementation	Level 4		
Hazards and Risk Identification and Management	Level 4		
Health, Safety and Environment Procedures Implementation	Level 4		
Innovation Management	Level 4		
Laboratory Data Analysis	Level 4		
Laboratory Management	Level 4		
Packaging Testing	Level 4		
Product Testing	Level 4		
Project Management	Level 4		
Quality Control Management	Level 4		
Raw Materials and Utilities Testing	Level 4		
Systems Thinking	Level 4		
Technical Presentation	Level 4		
Technical Report Writing	Level 4		

Quality Control Manager

JOB ROLE DESCRIPTION

The Quality Control Manager holds the overall responsibility for the Quality Control (QC) strategies, objectives, policies and processes for the QC department, while maintaining oversight of the department's operational and financial status. He/She reviews quality testing policies and procedures, ensuring alignment with regulatory standards and best practices. In addition, he plans laboratory decommissioning activities and drives changes to resources, procedures, systems, equipment, or technology within the QC department as needed. The Quality Control Manager should be well-versed in Good Laboratory Practices (GLPs) and requirements of a cleanroom environment, given the laboratory-based context of QC activities. He is also responsible for building personnel capability and facilitating operational improvements for the department.

The Quality Control Manager possesses strong leadership skills and is able to provide clear guidance on critical work activities He requires strong problem-solving skills and is able to consider issues from multiple perspectives in order to make well-informed and effective decisions for the department.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Monitor product quality compliance	• Formulate the organisation's quality testing policy in alignment with regulatory standards and requirements • Establish organisational plans for the testing of products and associated materials and packaging • Introduce industry best practices and trends in quality inspection and testing methods
Manage laboratory operations	• Devise an operational excellence model for laboratory work • Provide expertise on determining the optimal calibration standards for laboratory equipment operation • Establish operational, analytical and documentation standards in line with industry best practices • Communicate potential implications of Quality Control (QC) data trends and results to relevant stakeholders
Manage conformance to cleanliness standards	• Review and approve Standard Operating Procedures (SOPs) for cleanliness tests, identification and removal of contamination sources • Articulate internal and external cleanliness standards and objectives • Oversee the QC department's waste disposal activities, in adherence to environmental regulations
Optimise quality and efficiency of department workflows and activities	• Establish QC objectives and Good Laboratory Practice (GLP) policies for the organisation • Implement business and performance management techniques to drive quality and operational improvements in plants • Facilitate laboratory pre-commissioning, certification and accreditation assessments • Develop strategies for the quality control department to encourage continuous improvement of QC procedures, activities and workflow management • Recommend changes to QC procedures, systems, equipment, and the required resources • Monitor the effectiveness of improvements and changes made to QC activities and workflows

Quality Control Manager

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage Quality department operations	• Communicate and implement QC strategies, objectives, policies and processes • Translate long-term goals for the QC department into tactical plans • Set and communicate individual objectives and review and assess the performance of direct reports • Direct capability development roadmaps and programmes for the QC department • Manage team resources to ensure adequate staffing and capability levels • Maintain oversight of the completion of all QC tasks, ensuring proper documentation, progress tracking and reporting • Monitor the QC department's financial inflow and outflow against allocated budgets and forecasts • Submit capital requests as needed to support equipment replacement, upgrades, and other improvements

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES		GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Biorisk Management	Level 5	Decision Making	Advanced
Budgeting	Level 4	Developing People	Advanced
Business Continuity Management	Level 5	Leadership	Advanced
Business Performance Management	Level 5	Problem Solving	Advanced
Change Management	Level 5	Transdisciplinary Thinking	Advanced
Chemical Risk Management	Level 5		
Cleanliness Testing	Level 5		
Conflict Resolution	Level 5		
Continuous Improvement	Level 5		
Good Manufacturing Practices Implementation	Level 5		
Hazards and Risk Identification and Management	Level 4		
Health, Safety and Environment Procedures Implementation	Level 4		
Innovation Management	Level 5		
Laboratory Management	Level 5		
Packaging Testing	Level 5		
Product Testing	Level 5		
Project Management	Level 5		
Quality Control Management	Level 5		
Raw Materials and Utilities Testing	Level 5		
Risk Management	Level 5		
Strategy Development	Level 4		
Systems Thinking	Level 5		
Team Effectiveness Management	Level 5		
Technical Presentation	Level 5		

Quality Assurance and Quality Control Director

JOB ROLE DESCRIPTION

The Quality Assurance and Quality Control Director approves new or improved processes and systems to ensure that quality standards in biopharmaceuticals manufacturing plants are upheld. He/She holds overall responsibility for the Quality Assurance and Quality Control (QA&QC) departments' activities within the organisation. He is responsible for all major decisions regarding the validation of manufacturing processes, product registration, release and recall, as well as internal and external audit policies. The Quality Assurance and Quality Control Director establishes strategies for biopharmaceuticals manufacturing plants to achieve desired quality levels based on industry best-practices and regulatory requirements. He drives cross-functional collaboration and continuous improvements efforts. In addition, he is accountable for the QA&QC departments meeting their operational and financial targets.

The Quality Assurance and Quality Control Director possesses excellent leadership skills and is able to develop capabilities, build strong teams and engage internal and external stakeholders. He is adept at inspiring and driving a culture of innovation and continuous improvement within and beyond the department to enhance the overall quality of the organisation's products. He possesses the competitive drive to bring the organisation's quality standards to global recognition.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage quality assurance and quality control operations	• Establish department strategies and operating structures to support business objectives and priorities • Establish long-term goals for the Quality Assurance and Quality Control (QA&QC) departments that align with the vision and strategy of the organisation • Work with teams to translate business strategies into annual performance goals and departmental objectives • Review and approve final QA&QC procedures, and associated department capabilities, ensuring alignment with organisational strategies and priorities • Deliver timely and accurate reports on Quality activities and Key Performance Indicators (KPIs) to senior management and leadership teams • Allocate budgets to the QA&QC departments , and monitor cost-effectiveness to optimise resources and prioritise spending • Establish the organisation's external reputation with regulatory agencies and industry groups
Optimise quality and efficiency of department workflows and activities	• Review and approve all quality policies and procedures, ensuring alignment with organisational strategy and priorities • Foster a plant-wide culture that embraces concepts of Quality Risk Management and Quality by Design • Establish cross-department strategies and mechanisms to drive continuous improvement of QA&QC activities • Build a culture of innovation within the QA&QC departments to encourage continuous improvement • Review and approve recommendations on significant changes that need to be made to resources, procedures, systems, equipment, and technology • Maintain business accountability for overall workflow improvements in the QA&QC departments
Facilitate registration and release of biopharmaceutical products	• Approve final product registration documentation • Liaise with internal and external stakeholders to obtain product registration and approval • Endorse batches for release

Quality Assurance and Quality Control Director

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Facilitate achievement of quality expectations and standards	• Approve product recalls • Lead external communications in response to product quality deviations and product recalls • Monitor the implementation of improvements to address identified product quality issues • Develop policies for internal and external audits in line with the organisation's guidelines and regulatory requirements • Approve revisions to procedures and processes based on audit results • Determine training strategies for QA&QC for personnel in manufacturing facilities • Approve the development of training programmes

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Big Data Analysis	Level 5
Biorisk Management	Level 5
Budgeting	Level 5
Business Continuity Management	Level 5
Business Networking	Level 5
Business Performance Management	Level 5
Business Planning	Level 5
Change Management	Level 5
Chemical Risk Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Good Manufacturing Practices Implementation	Level 5
Innovation Management	Level 6
Project Management	Level 6
Quality Assurance Management	Level 6
Quality Control Management	Level 6
Risk Management	Level 5
Strategy Development	Level 5
Systems Thinking	Level 5
Technical Presentation	Level 6

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Decision Making	Advanced
Developing People	Advanced
Leadership	Advanced
Resource Management	Advanced
Transdisciplinary Thinking	Advanced

Production

Biotechnologist

Ong Shin Ran
AbbVie Operations Singapore Pte. Ltd.

IMPACTING OTHERS THROUGH HIS WORK

Ong Shin Ran had been working overseas for years when he decided to return to Singapore to seek opportunities here. When Shin Ran came across a training programme offered by AbbVie Operations Singapore Pte Ltd, he took the chance and applied for the Biotechnologist position. He is now part of the Upstream team in the biomanufacturing department, responsible for the growth of cells for expression of therapeutic proteins.

Being a newcomer in the industry, his biggest challenge was grasping the practices specific to the biopharmaceuticals manufacturing sector. These include Current Good Manufacturing Practices (GMP), Good Documentation Practices (GDP), and working in a clean room environment. However, he overcame these by having a positive mind-set, and applying what he learnt during his on-the-job training. He credits his supportive supervisors, managers and teammates for helping him along the way.

Shin Ran believes an important characteristic to have in the industry is integrity. As someone who has to grow and harvest cells, a key responsibility is to ensure safety and avoid contamination. "Integrity is important to ensure that all requirements and steps in the manufacturing process are adhered to so as not to compromise on product quality and safety," he explains. Being curious and not being afraid to be hands-on are also key traits to have.

One of his most memorable moments in his career at AbbVie was when the first batch of cells was harvested from the Biologics Manufacturing Facility. It is AbbVie's first manufacturing plant in Asia and he also had a hand in presenting the site facilities to the Guest-Of-Honour during its official opening. He feels proud to have contributed to such a milestone.

Shin Ran invites those thinking of joining the industry to be courageous and to take a leap at the chance. He believes the Skills Framework can be a useful guide. "If you're new to the industry like I was, the career map can show you how to progress laterally or vertically. It can help plan your career path, and let you focus on skills sets required," he says. Shin Ran shares the part of his job that he loves: "What motivates me is knowing that I play a small part in bringing a drug to the market, and having an impact on people's lives every day."

> "Integrity is important to ensure that all requirements and steps in the manufacturing process are adhered to so as not to compromise on product quality and safety."

Production Senior Technician/Production Technician/Assistant Biotechnologist

JOB ROLE DESCRIPTION

The Production Senior Technician/Production Technician/Assistant Biotechnologist follows Standard Operating Procedures (SOPs) to operate and monitor manufacturing equipment, and responds to alerts during production. He/She handles biopharmaceutical materials within the facilities and performs cleaning and sterilisation activities. He is tasked with the day-to-day operations of individual manufacturing equipment. He must adhere to Health, Safety and Environment (HSE) regulations at all times in order to protect both employees as well as the quality of the biopharmaceutical products.

The Production Senior Technician/Production Technician/Assistant Biotechnologist works on a rotating shift in the production line of a manufacturing facility that requires strict adherence to regulatory requirements. He may also be assigned to work within a cleanroom environment. He enjoys solving problems independently but has the intuition to seek supervision and help when needed. He is proactive in improving production operations within the scope of his tasks and is a good team player who interacts effectively with his co-workers.

CRITICAL WORK FUNCTIONS AND KEY TASKS	CRITICAL WORK FUNCTIONS	KEY TASKS
	Implement materials management procedures	• Store materials according to Standard Operating Procedures (SOPs) • Dispose degraded and contaminated materials according to SOPs • Input information into the inventory management system • Carry out batch dispensing operations
	Clean equipment and facilities	• Prepare materials, equipment and solvents required for cleaning and sterilisation • Perform manual and automated cleaning and sterilisation of equipment, containers, cleanrooms and facilities • Perform Clean-in-Place (CIP) and Sterilise-in-Place (SIP) procedures for bioreactors, machinery, vessels, piping and other production line components • Deliver cleaning and sterilisation samples to the laboratories for testing
	Produce pharmaceutical and nutritional products	• Perform calibration and pre-startup checks on manufacturing equipment according to SOPs • Monitor manufacturing equipment and systems during production following Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) procedures • Respond to system alerts and malfunctions • Shut down manufacturing equipment and systems upon completion of production processes and offload materials • Operate filling and packaging equipment • Dispose waste and rejected by-products appropriately
	Produce biologics	• Assist to prepare cell culture media and buffers • Perform calibration and pre-start-up checks on bioreactors, purification and final filling equipment according to SOPs • Assist to monitor bioreactors, purification and final filling equipment following HSE procedures and CGMPs • Record parameters of critical production during operations • Assist to harvest cell cultures • Operate filling equipment to place products into packaging containers • Dispose waste and rejected by-products appropriately • Record parameters of critical equipment and updates to batch and log sheets
	Improve production operations	• Identify opportunities to improve production activities within one's work areas • Apply workflows, systems and equipment improvements within one's work areas

Production Senior Technician/Production Technician/Assistant Biotechnologist

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Operation Monitoring	Level 3
Automated Process Control	Level 3
Bioreactor Operation and Control	Level 3
Biorisk Management	Level 2
Cell Culture	Level 3
Change Management	Level 3
Chemical Risk Management	Level 2
Chromatography Equipment Operation and Control	Level 3
Cleaning and Sterilising	Level 2
Continuous Improvement	Level 3
Emergency Shut-down and Restart	Level 2
Engineering Drawing	Level 2
Equipment and Systems Repair	Level 2
Filtration Equipment Operation and Control	Level 3
Flexible Facilities Implementation	Level 2
Good Manufacturing Practices Implementation	Level 3
Hazards and Risk Identification and Management	Level 3
Health, Safety and Environment Procedures Implementation	Level 2
Innovation Management	Level 3
Manufacturing Equipment Operation and Control	Level 3
Manufacturing Systems Operation and Control	Level 3
Materials Management	Level 2
Process Monitoring	Level 3
Production Optimisation	Level 2
Project Management	Level 3
Systems Thinking	Level 3
Technical Report Writing	Level 3
Vendor Management	Level 3

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Digital Literacy	Basic
Interpersonal Skills	Basic
Problem Solving	Basic
Teamwork	Basic

Production Engineer/Biotechnologist

JOB ROLE DESCRIPTION

The Production Engineer/Biotechnologist oversees the operations and monitoring of manufacturing equipment on a section of a production line. He/She develops Standard Operating Procedures (SOPs) for handling materials and operating equipment in the facilities and inspects production anomalies or lapses. He independently performs and ensures the proper handling of biopharmaceutical materials and cleaning and sterilisation activities within the facilities whilst guiding junior staff in their support roles. The Production Engineer/Biotechnologist must adhere to Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) to ensure employee safety and product quality. He should have the technical expertise to work with both automated as well as manual systems in the production line and be able to propose improvements for the systems.

The Production Engineer/Biotechnologist works on a rotating shift and oversees day-to-day manufacturing operations. He is methodical in approaching his tasks and enjoys solving problems independently. He is a proactive and collaborative team player, with strong communication and interpersonal skills.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Implement materials management procedures	• Develop Standard Operating Procedures (SOPs) for materials management in the manufacturing facilities • Verify materials are stored and transported according to SOPs • Implement disposal procedures for degraded and contaminated materials • Analyse inventory levels against plans, escalating any potential supply gaps • Implement plans to reduce unnecessary scrapping of materials within the manufacturing facilities • Verify batches have been dispensed appropriately
Clean equipment and facilities	• Develop SOPs for cleaning and sterilising • Oversee preparation of materials, equipment and solvents required for cleaning and sterilisation • Verify that equipment, containers, cleanrooms and facilities are cleaned and sterilised to acceptable standards • Verify Clean-in-Place (CIP) and Sterilise-in-Place (SIP) procedures are carried out according to SOPs • Collaborate with the Engineering and Maintenance department to complete cleaning and sterilisation for product changeovers • Identify instances where cleaning and sterilisation must be repeated
Produce pharmaceutical and nutritional products	• Set daily productivity, efficiency and volume targets that align with the master production plans • Approve calibration and pre-start-up checks of manufacturing equipment • Oversee equipment monitoring across a production line ensuring compliance with Health, Safety and Environment (HSE) procedures and Current Good Manufacturing Practices (CGMPs) • Investigate major system breakdowns, deviations and suboptimal performance • Document production yields • Conduct inspections on final packaged products to ensure quality standards are being met • Confirm that waste and rejected by-products are disposed appropriately • Check equipment parameter records and batch and log sheets
Produce biologics	• Prepare media, materials and equipment for cell culture processes • Approve calibration and pre-start-up checks of bioreactors, purification and final filling equipment • Monitor bioreactors, purification and final filling equipment following HSE procedures and CGMPs • Harvest culture and record quality, speed and yields of cell propagation • Conduct inspections on final filled products to ensure quality standards are being met • Confirm that waste and rejected by-products are disposed appropriately • Check equipment parameter records and batch and log sheets

Production Engineer/Biotechnologist

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Improve production operations	• Analyse causes of performance problems and process deviations that may impact achievement production objectives and targets • Propose ideas to improve production operations • Gather information to support a feasibility assessment of improving production workflows, equipment and systems • Assist with the implementation of workflows, systems and equipment improvements

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Operation Monitoring	Level 3
Automated Process Control	Level 3
Bioreactor Operation and Control	Level 4
Biorisk Management	Level 3
Cell Culture	Level 4
Change Management	Level 4
Chemical Risk Management	Level 3
Chromatography Equipment Operation and Control	Level 4
Cleaning and Sterilising	Level 3
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Emergency Shut-down and Restart	Level 3
Engineering Drawing	Level 2
Equipment and Systems Repair	Level 3
Filtration Equipment Operation and Control	Level 4
Flexible Facilities Implementation	Level 3
Good Manufacturing Practices Implementation	Level 4
Green Manufacturing Design and Implementation	Level 3
Hazards and Risk Identification and Management	Level 3
Health, Safety and Environment Procedures Implementation	Level 3
Innovation Management	Level 4
Manufacturing Equipment Operation and Control	Level 4
Manufacturing Systems Operation and Control	Level 4
Materials Management	Level 3
Process Monitoring	Level 4
Production Optimisation	Level 3
Project Management	Level 4
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4
Vendor Management	Level 3

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Decision Making	Intermediate
Interpersonal Skills	Intermediate
Problem Solving	Intermediate
Teamwork	Intermediate

Production Executive

JOB ROLE DESCRIPTION

The Production Executive provides technical guidance to production operations within the manufacturing facilities. He/She is expected to develop Standard Operating Procedures (SOPs) and identify technical adjustments that can be made to manufacturing processes in order to improve operational efficiency and quality of the biopharmaceutical products. He provides technical guidance for the performance of Clean-in-Place (CIP) and Sterilise-in-Place (SIP) procedures and technology operations. The Production Executive approves batch and log sheets before a batch is passed to the Quality department for release. He is expected to leverage on his technical expertise to contribute significantly to the troubleshooting and optimisation of production processes. He should have a good understand of the engineering and scientific concepts underlying biopharmaceutical product manufacturing and the processes and equipment involved.

The Production Executive exercises his analytical and innovative thinking to analyse information, solve problems and improve existing methods and processes. Whilst being a specialist contributor, the Production Executive is both self-driven and a keen team player who considers interdependencies and employs strong communication skills when delivering ideas.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Implement materials management procedures	• Provide technical advice on the optimal materials management Standard Operating Procedures (SOPs) to maximise efficiency and reduce loss • Advise on industry best practices and environmental standards in disposal of degraded and contaminated materials
Clean equipment and facilities	• Approve lines for production after intra-product cleaning • Provide technical guidance for the performance of Clean-in-Place (CIP) and Sterilise-in-Place (SIP) procedures and technology operations • Lead investigations with the Quality department if cleaning and sterilisation tests are showing abnormal results and patterns
Produce pharmaceutical and nutritional products	• Develop SOPs for the calibration and set-up of manufacturing equipment in collaboration with the Process Development/Manufacturing Science and Technology department • Identify technical adjustments that can be made to manufacturing equipment to improve operational efficiency • Lead troubleshooting of major defects, faults and breakdowns in equipment and system parts • Approve equipment parameters applied and batch and log sheets
Produce biologics	• Establish propagation targets for cell culture activities in line with organisation's expectations • Develop SOPs for the calibration and set-up of manufacturing equipment in collaboration with the Process Development/Manufacturing Science and Technology department • Approve selection and preparation of appropriate media, materials and equipment for cell culture processes in line with organisation's standards • Identify technical adjustments that can be made to bioreactors, purification and final filling equipment to improve operational efficiency • Troubleshoot any malfunctions during the biologics manufacturing processes • Devise changes to plans and procedures to ensure titer production meets established targets
Improve production operations	• Review production workflows to streamline processes • Devise technical solutions to address bottlenecks, inefficiencies or deviations in production processes • Assess the technical feasibility of improving production workflows, equipment and systems • Verify new and improved manufacturing equipment and systems are installed and programmed correctly

Production Executive

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Control	Level 4
Big Data Analysis	Level 3
Bioreactor Operation and Control	Level 4
Biorisk Management	Level 4
Cell Culture	Level 5
Change Management	Level 4
Chemical Risk Management	Level 4
Chromatography Equipment Operation and Control	Level 4
Cleaning and Sterilising	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Emergency Shut-down and Restart	Level 4
Filtration Equipment Operation and Control	Level 4
Flexible Facilities Implementation	Level 4
Good Manufacturing Practices Implementation	Level 4
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 4
Manufacturing Equipment Operation and Control	Level 5
Manufacturing Systems Operation and Control	Level 5
Materials Management	Level 4
Process Analytical Technology Implementation	Level 3
Process Monitoring	Level 4
Process Optimisation	Level 3
Production Optimisation	Level 5
Production Planning	Level 4
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4
Vendor Management	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Decision Making	Intermediate
Problem Solving	Intermediate
Sense Making	Intermediate
Teamwork	Intermediate

Production Team Supervisor

JOB ROLE DESCRIPTION

The Production Team Supervisor is responsible for allocating responsibilities and overseeing operations on one or a few production lines whilst monitoring productivity rates against established targets. He/She also has oversight of materials management and reviews the Standard Operating Procedures (SOPs) for materials management, cleaning and sterilising activities. He is expected to propose and implement improvements to production workflows, equipment and systems to achieve production targets in a timely manner. The Production Team Supervisor must be able to plan and manage production activities in a way which drives operational efficiency and excellence, and should possess underlying technical knowledge of equipment and systems within the facilities.

The Production Team Supervisor works in a production facility that needs to comply strictly with highly regulated standards. He is therefore meticulous and precise in his work and is confident in leading and motivating teams to perform their tasks in such an environment. He is analytical and systematic in investigating problems and decisive in implementing optimal solutions in the course of his work.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Implement materials management procedures	• Review Standard Operating Procedures (SOPs) for materials management in the manufacturing facilities • Define appropriate Health, Safety and Environment (HSE) methods for disposal of degraded and contaminated materials • Determine activities and materials required for production to guide inventory management • Develop plans to reduce unnecessary scrapping of materials within the manufacturing facilities
Clean equipment and facilities	• Review SOPs for cleaning and sterilising • Integrate cleaning and sterilising activities with other systems and processes in the biopharmaceuticals manufacturing facilities • Facilitate collaboration with the Engineering and Maintenance department and verify cleanliness of equipment after maintenance and repairs are performed • Collaborate with the Quality department to investigate instances where cleaning and sterilisation levels are not reaching the required standards • Develop follow-up actions to maintain cleanliness and sterility standards across product lines following lapses
Produce pharmaceutical and nutritional products	• Set short-term productivity, efficiency and volume targets that align with the master production plans • Allocate responsibilities within manufacturing teams and oversee equipment monitoring across multiple production lines • Facilitate collaboration with the Engineering and Maintenance department to conduct equipment and system repairs • Monitor actual production rates against targets and escalate issues • Review equipment parameter records and batch and log sheets
Produce biologics	• Set short-term productivity, efficiency and volume targets that align with the master production plans • Oversee selection and preparation of appropriate media, materials and equipment for cell culture processes • Allocate responsibilities within manufacturing teams and supervise operations of bioreactors, purification and final filling equipment • Record titers against targets and escalate issues • Review equipment parameter records and batch and log sheets

Production Team Supervisor

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Improve production operations	• Identify manufacturing bottlenecks and inefficiencies and evaluate their root causes • Develop proposals to improve production operations • Assess the operational feasibility of improving production workflows, equipment and systems • Evaluate the impact of disruptive events on critical business functions of the department to assist with business continuity planning • Implement risk controls within the department • Implement operational improvements to production department workflows

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES		GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Biorisk Management	Level 4	Communication	Intermediate
Budgeting	Level 3	Decision Making	Intermediate
Business Continuity Management	Level 4	Leadership	Intermediate
Business Performance Management	Level 4	Problem Solving	Intermediate
Change Management	Level 4	Teamwork	Intermediate
Chemical Risk Management	Level 4		
Cleaning and Sterilising	Level 4		
Conflict Resolution	Level 4		
Continuous Improvement	Level 4		
Emergency and Crisis Situation Management	Level 3		
Emergency Shut-down and Restart	Level 4		
Flexible Facilities Implementation	Level 4		
Good Manufacturing Practices Implementation	Level 4		
Hazards and Risk Identification and Management	Level 4		
Health, Safety and Environment Procedures Implementation	Level 4		
Innovation Management	Level 4		
Materials Management	Level 5		
Production Optimisation	Level 4		
Production Planning	Level 4		
Production Resource Management	Level 4		
Project Management	Level 4		
Risk Management	Level 4		
Systems Thinking	Level 4		
Team Effectiveness Management	Level 4		
Vendor Management	Level 4		

Production Manager

JOB ROLE DESCRIPTION

The Production Manager communicates the production strategies, objectives, policies and processes to teams while maintaining oversight of the department's operational and financial status. He/She develops materials management strategies and approves Standard Operating Procedures (SOPs), ensuring alignment with regulatory standards and best practices. He prepares the production master plans and promotes collaboration and efficiency efforts to meet productivity objectives and targets. The Production Manager plans and manages the end-to-end production operations within the biopharmaceuticals manufacturing facilities and should be well-versed in Quality and Health, Safety and Environment (HSE) standards and Current Good Manufacturing Practices (CGMPs).

The Production Manager works in a production facility that needs to comply with highly regulated standards. He makes important decisions fast and possesses excellent leadership and resource management capabilities. He should be able to consider a broad range of factors to arrive at optimal decisions to ensure business continuity especially during unforeseen production delays. He possesses flexibility to work under changing demands of production targets and is adept at building capabilities in the teams under his care towards common objectives.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Implement materials management procedures	• Develop strategies to manage the flow of materials into, within and out of the manufacturing facilities • Approve Standard Operating Procedures (SOPs) for the management of materials in the manufacturing facilities • Determine an appropriate inventory system for materials management • Approve types and quantities of materials required for production to guide inventory management • Formulate solutions for reducing loss of materials within the manufacturing facilities
Manage production operations	• Prepare master production plans to deliver on set productivity, efficiency and volume targets • Delegate production responsibilities to teams across the manufacturing facilities • Approve adjustments to manufacturing activities when necessary to achieve targeted production levels • Initiate training programmes to build capabilities in the Production department • Monitor the department's financial inflow and outflow against allocated budgets and forecasts
Improve production operations	• Review proposals to improve Production department operations • Make recommendations for changes to workflows, equipment and systems within the Production department • Facilitate implementation of improvements to production workflows, systems and equipment • Review the impact of improvement activities on Production department operations and key performance metrics
Manage risk and regulatory compliance	• Develop risk management plans for the Production department • Facilitate training for the Production department on Health, Safety and Environment (HSE) requirements of manufacturing processes in collaboration with the Quality department • Facilitate training for the Production department on Current Good Manufacturing Practices (CGMPs) • Develop Business Continuity Plans (BCPs) to minimise impact of unforeseen production delays • Activate BCPs in the event of emergencies that affect production delivery expectations • Manage emergency shut-down and restart of production processes ensuring maximum safety to personnel and minimum impact to the biopharmaceuticals manufacturing facilities and production productivity

Production Manager

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Biorisk Management	Level 5
Budgeting	Level 4
Business Continuity Management	Level 5
Business Performance Management	Level 5
Change Management	Level 5
Chemical Risk Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Emergency and Crisis Situation Management	Level 4
Emergency Shut-down and Restart	Level 4
Flexible Facilities Implementation	Level 5
Good Manufacturing Practices Implementation	Level 5
Hazards and Risk Identification and Management	Level 4
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 5
Materials Management	Level 5
Process Analytical Technology Implementation	Level 4
Process Optimisation	Level 4
Production Optimisation	Level 5
Production Planning	Level 5
Production Resource Management	Level 5
Project Management	Level 5
Risk Management	Level 5
Strategy Development	Level 4
Systems Thinking	Level 5
Team Effectiveness Management	Level 5
Technical Presentation	Level 5
Vendor Management	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Advanced
Developing People	Intermediate
Leadership	Advanced
Resource Management	Advanced

Production Director

JOB ROLE DESCRIPTION

The Production Director is responsible for all major decisions for the Production department such as production plans, targets, budgets and improvements. He/She establishes the strategies for the biopharmaceuticals manufacturing plants to achieve production targets and spearheads cross-functional collaboration and continuous improvements for the manufacturing facility. The Production Director manages the distribution of department budgets to different teams and projects based on organisational needs and has overall accountability for the management of production operations within the biopharmaceuticals manufacturing facilities. He is responsible for the department's operations meeting Quality and Health, Safety and Environment (HSE) regulations, Current Good Manufacturing Practices (CGMPs) and other regulatory standards. He approves Business Continuity Plans (BCPs) and steps in to lead in situations where significant delays, lapses and emergencies threaten to affect production operations.

The Production Director adopts a broad perspective and a global mindset especially when making key strategic decisions. He displays superior leadership and interpersonal skills in developing capabilities and building strong teams to drive the department's activities.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage production operations	• Set productivity, efficiency and volume targets for the Production department in line with organisational objectives • Establish robust operating structures for the department to support business objectives and priorities • Deliver regular reports on productivity to senior management • Define the required capabilities for the Production department to support business objectives • Allocate the overall production budgets to different teams and projects
Improve production operations	• Foster a culture of cross-departmental collaboration and continuous improvement to drive operational excellence • Approve improvement solutions and initiatives for the Production department
Manage risk and regulatory compliance	• Approve the risk management plans for the department • Keep abreast of changes to local and international Quality and Health, Safety and Environment (HSE) regulations that the organisation needs to comply with • Collaborate with the Quality department to review overall compliance of manufacturing processes with required Current Good Manufacturing Practices (CGMPs) • Approve business continuity policies, strategies and plans • Lead the implementation of Business Continuity Plans (BCPs) in the event of emergencies that affect production operations

Production Director

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Big Data Analysis	Level 5
Biorisk Management	Level 5
Budgeting	Level 5
Business Continuity Management	Level 5
Business Networking	Level 5
Business Performance Management	Level 5
Business Planning	Level 5
Change Management	Level 5
Chemical Risk Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Emergency and Crisis Situation Management	Level 4
Good Manufacturing Practices Implementation	Level 5
Innovation Management	Level 6
Process Optimisation	Level 5
Production Planning	Level 6
Production Resource Management	Level 6
Project Management	Level 6
Risk Management	Level 5
Strategy Development	Level 5
Systems Thinking	Level 5
Technical Presentation	Level 6

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Advanced
Developing People	Advanced
Global Mindset	Advanced
Leadership	Advanced

Engineering and Maintenance

Senior Manager (Engineering and Maintenance)

Syed Yousuff S/O Jakkariya Mohamed
MSD International GmbH (Singapore Branch)

EQUIPPED TO REACH HIS GOALS

Syed Yousuff S/O Jakkariya Mohamed is a Senior Manager (Engineering & Maintenance) at MSD International GmbH. His responsibility is to provide leadership and technical expertise for all production, facilities and utilities equipment-related activities in the biopharmaceuticals manufacturing process.

His first foray into the industry was a stint at a pharmaceuticals packaging materials manufacturer. From there, he gained exposure to Current Good Manufacturing Practices (GMP). He realised how regulatory compliance is of utmost importance in the industry and proceeded to join MSD International GmbH. "Working for a biopharmaceuticals manufacturing company gives me a high level of personal satisfaction because what we do matters, and can play a huge part in life-saving missions," Yousuff explains.

He has been in the sector for more than 12 years, with his experience covering asset maintenance and reliability management to improve the performance of equipment. He says he constantly strives to reach his career goals. "I never give up, even when the tasks assigned to me seem daunting or impossible. In 2011, I was asked to drive site-wide energy efficiency and conservation measures targeted at reducing energy consumption by 30% within three years. I took it as a challenge and formulated an energy optimisation framework and hit the target within two years," he says. As a result of this achievement, the National Environmental Agency recognised his contribution to the nation's energy efficiency initiatives, and he was awarded "Outstanding Energy Manager of the Year 2014".

Yousuff says that a challenge faced in the sector is the recruitment and retention of talent. To overcome this, there needs to be active employee engagement and partnership amongst all team members. Another way to attract the best talent could be through using the Skills Framework for Biopharmaceuticals Manufacturing. "The Skills Framework is an industry-wide initiative. The information is shared with the public and this transparency can be helpful to future entrants in knowing what to expect," he explains.

> "Working for a biopharmaceuticals manufacturing company gives me a high level of personal satisfaction because what we do matters."

Engineering and Maintenance Technician

JOB ROLE DESCRIPTION

The Engineering and Maintenance Technician supports the Engineering and Maintenance team by carrying out small-scale installations of manufacturing equipment and documenting installations and assembly works performed. He/She provides basic engineering technical support to ensure smooth running of manufacturing processes, including the maintenance of equipment and systems. He is expected to be able to interpret indicators of equipment and system damage and malfunction, and identify possible faults. The Engineering and Maintenance Technician also assists in the upkeep of systems that provide energy and utilities to the manufacturing facility. He must follow Standard Operating Procedures (SOPs) when conducting work and adhere to Health, Safety and Environment (HSE) regulations at all times to protect both employees as well as the quality of the biopharmaceuticals product.

The Engineering and Maintenance Technician works on a rotating shift in the manufacturing facility to provide continuous technical support. He should have an inquisitive mind and enjoy solving problems. While he should be disciplined and rigorous in following instructions and SOPs, he should also enjoy the interaction and camaraderie of working in a team environment.

CRITICAL WORK FUNCTIONS AND KEY TASKS	CRITICAL WORK FUNCTIONS	KEY TASKS
	Install equipment and systems	• Assist in installations and assembly of equipment and systems under guidance • Document installations and assembly works • Move portable manufacturing equipment, machinery and materials • Connect flexible facilities equipment and parts
	Maintain equipment and systems	• Monitor equipment condition • Assist in the performance of maintenance activities, following Health, Safety and Environment (HSE) and Current Good Manufacturing Practices (CGMPs) procedures • Support testing of equipment and systems • Interpret indicators of equipment and system damages and malfunctions • Perform repair works on standard equipment and systems • Document testing, maintenance and repair works in accordance with organisational procedures • Assist in cleaning equipment after performing maintenance and repairs • Perform housekeeping of tools after maintenance and repairs
	Manage energy resources and utilities	• Maintain operations of heating, ventilation and air conditioning (HVAC), water for injection, clean steam systems and other CGMP equipment • Maintain operations of boilers, compressors, water systems and other plant utility equipment • Identify disruptions in the stability of energy resource and utilities supply

Engineering and Maintenance Technician

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Operation Monitoring	Level 2
Cleaning and Sterilising	Level 2
Continuous Improvement	Level 2
Engineering Drawing	Level 1
Equipment and Systems Repair	Level 2
Equipment and Systems Testing	Level 2
Facility Maintenance	Level 2
Flexible Facilities Implementation	Level 2
Good Manufacturing Practices Implementation	Level 2
Hazards and Risk Identification and Management	Level 2
Health, Safety and Environment Procedures Implementation	Level 2
Innovation Management	Level 2
Installation and Assembly	Level 2
Preventive Maintenance	Level 2
Systems Thinking	Level 2
Technical Report Writing	Level 2

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Interpersonal Skills	Basic
Problem Solving	Basic
Service Orientation	Basic
Teamwork	Basic

Engineering and Maintenance Senior Technician

JOB ROLE DESCRIPTION

The Engineering and Maintenance Senior Technician performs installation of equipment and systems, and also supervises installation and assembly work conducted by his team and external vendors. He/She maintains equipment and systems and is expected to conduct testing of equipment and systems independently. He is the first person to investigate equipment and system failures to determine the cause and repair work required. He manages the upkeep of systems that provide energy and utilities to the manufacturing facility, perform checks and rectify disruptions in energy supply. The Engineering and Maintenance Senior Technician has specialised technical knowledge of equipment and systems within the manufacturing facility and supports the innovation of equipment, systems and controls in the manufacturing facility. He should apply Standard Operating Procedures (SOPs) and Health, Safety and Environment regulations while carrying out his duties.

The Engineering and Maintenance Senior Technician may be required to work on a shift to provide consistent technical support within the manufacturing facility. He should have an analytical mind and enjoy exploring solutions to problems independently. He possesses the intuition to step up to guide and supervise his team and interact with others to provide support across teams.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Install equipment and systems	• Modify technical drawings following changes in engineering plans • Perform installations and assembly of equipment and systems • Connect single use facilities with fixed process equipment • Reconfigure flexible facilities and equipment as directed to accommodate scaling up of production • Oversee installations and assembly works performed by vendors • Maintain updated documentations for installations and assembly works
Maintain equipment and systems	• Conduct non-destructive testing to support predictive maintenance activities • Perform maintenance activities following Health, Safety and Environment (HSE) and Current Good Manufacturing Practices (CGMPs) procedures • Conduct testing of equipment and systems • Investigate equipment failures to identify underlying issues • Perform repair works of non-standard equipment and systems • Maintain updated documentations for testing, maintenance and repair activities and results • Clean equipment after performing maintenance and repairs • Check that housekeeping of tools is performed in line with set procedures
Manage energy resources and utilities	• Perform checks on operations of heating, ventilation and air conditioning (HVAC), water for injection, clean steam systems and other CGMP equipment • Perform checks on operation of boilers, compressors, water systems and other plant utility equipment • Rectify disruptions in the stability of energy resources and utilities supply • Consolidate data on energy and utility efficiency
Innovate equipment, systems and controls	• Assist in the installations of automated equipment and system components • Support the testing and calibration of new automated equipment, systems and controls • Identify malfunctions of automated equipment and systems • Monitor performance of automated equipment and systems

Engineering and Maintenance Senior Technician

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Equipment and Control Systems Configuration	Level 3
Automated Operation Monitoring	Level 3
Automated Process Control	Level 3
Automated Process Design	Level 3
Change Management	Level 3
Cleaning and Sterilising	Level 2
Continuous Improvement	Level 3
Engineering Drawing	Level 2
Equipment and Systems Repair	Level 3
Equipment and Systems Testing	Level 2
Facility Maintenance	Level 2
Flexible Facilities Implementation	Level 3
Good Manufacturing Practices Implementation	Level 3
Hazards and Risk Identification and Management	Level 3
Health, Safety and Environment Procedures Implementation	Level 2
Innovation Management	Level 3
Installation and Assembly	Level 2
Manufacturing Equipment Operation and Control	Level 3
Manufacturing Systems Operation and Control	Level 3
Preventive Maintenance	Level 2
Project Management	Level 3
Systems Thinking	Level 3
Technical Report Writing	Level 3
Utilities Management	Level 3
Vendor Management	Level 3

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Basic
Computational Thinking	Basic
Interpersonal Skills	Intermediate
Problem Solving	Basic
Teamwork	Intermediate

Engineering and Maintenance Supervisor

JOB ROLE DESCRIPTION

The Engineering and Maintenance Supervisor is responsible for overseeing and verifying installation and assembly work conducted within the manufacturing facility. He/She also has oversight of maintenance, testing and repair work carried out by his team. He contributes to the proactive management of energy and utilities within the system and liaises with vendors. The Engineering and Maintenance Supervisor also supports in the management of the department by recommending ways to improve department workflows and facilitating equipment replacements and improvements. He must have sound technical knowledge of equipment and systems within the facility whilst also being able to plan and manage Engineering and Maintenance activities to maximise resources and minimise equipment downtime.

The Engineering and Maintenance Supervisor should be organised, have a systematic approach to solving problems and be able to communicate with team members and external parties to achieve the desired organisational outcomes.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Install equipment and systems	• Plan manpower, equipment installations and assembly works schedules • Supervise installations and assembly works • Verify quality of documentation for installations and assembly works • Develop guidelines and procedures for the changeover and implementation of flexible facilities • Oversee product and facility changeover for multiple product lines
Maintain equipment and systems	• Plan maintenance work schedules • Assign responsibilities and resources to perform maintenance activities • Supervise testing, maintenance and repair work to ensure compliance with Health, Safety and Environment (HSE) and Current Good Manufacturing Practices (CGMPs) procedures • Verify that approved repair solutions are implemented • Verify accuracy of testing, maintenance and repair works documentation • Verify cleanliness of equipment after maintenance and repairs are performed • Take stock of machine parts, equipment, and other supplies
Manage energy resources and utilities	• Oversee day-to-day operations of CGMP utility equipment and systems • Monitor resolution of disruptions to energy resources and utilities supplies
Manage the department	• Recommend solutions to improve Engineering and Maintenance department workflows • Submit capital requests to support equipment replacement, upgrades, and other improvements to the Engineering and Maintenance department • Evaluate the impact of disruptive events on critical business functions of the department to assist with business continuity planning • Implement risk controls within the department • Manage vendors for equipment and facility repairs, maintenance, and upgrades

Engineering and Maintenance Supervisor

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Budgeting	Level 3
Business Continuity Management	Level 4
Business Performance Management	Level 4
Change Management	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Equipment and Systems Repair	Level 3
Equipment and Systems Testing	Level 3
Facility Maintenance	Level 3
Flexible Facilities Implementation	Level 4
Good Manufacturing Practices Implementation	Level 4
Hazards and Risk Identification and Management	Level 4
Health, Safety and Environment Procedures Implementation	Level 3
Innovation Management	Level 4
Installation and Assembly	Level 3
Maintenance Strategy Development	Level 4
Preventive Maintenance	Level 3
Project Management	Level 4
Risk Management	Level 4
Systems Thinking	Level 4
Team Effectiveness Management	Level 4
Utilities Management	Level 4
Vendor Management	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Interpersonal Skills	Intermediate
Resource Management	Intermediate
Service Orientation	Intermediate
Teamwork	Intermediate

Engineering and Maintenance Manager

JOB ROLE DESCRIPTION

The Engineering and Maintenance Manager is responsible for managing and deploying resources to install, maintain and repair equipment and systems in the facility in line with organisational objectives. He/She translates the organisational strategies into tactical plans for the department and facilitates cross-functional collaborations and continuous improvements efforts. He manages resources to ensure that utilities and systems are adequate to support the achievement of organisational targets. He also develops plans to validate equipment and manage risks within the department. In addition, he is responsible for cascading key objectives to teams and individuals and managing team and project budgets. As a people manager, the Engineering and Maintenance Manager oversees manpower, financial, training and resource planning deployment within the Engineering and Maintenance department.

The Engineering and Maintenance Manager is expected to serve as a role model in operational excellence in the department, and should be a personable and inspiring leader who can communicate well and influence internal and external stakeholders. He should also have a strategic, analytical mind to resolve problems and make effective decisions for the department when faced with complex situations.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage the department	• Translate the long-term objectives for the Engineering and Maintenance department into tactical plans • Communicate team and individual objectives within the Process Development department and monitor progress • Coordinate team resources to ensure adequate staffing levels • Monitor the department's financial inflow and outflow against allocated budgets and forecasts • Initiate training programmes to build capability in the Engineering and Maintenance department • Assess operational and financial feasibility of recommendations to improve engineering and maintenance workflows • Justify the resources required to support changes in resources, procedures, systems, equipment, or technologies within the Engineering and Maintenance department • Oversee vendor performance to ensure that products and services are delivered according to plans or contracts
Maintain equipment and systems	• Monitor progress against key performance indicators (KPIs) of the Maintenance Excellence Programme (MEP) • Manage maintenance, repair activities and deployment of resources to achieve target performance and return on investment (ROI) • Review viability of solutions that require new capital investments
Manage energy resources and utilities	• Manage resources to ensure that Current Good Manufacturing Practices (CGMPs) utility equipment and systems operate at a level that supports achievement of organisational targets • Evaluate financial and operational viability of energy-optimisation initiatives
Validate equipment	• Co-develop Validation Master Plan (VMP) with Quality Assurance departments and relevant stakeholders • Manage resources and schedules for the performance of equipment qualification and validation in the facility

Engineering and Maintenance Manager

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage risk and regulatory compliance	• Develop risk management plans for the Engineering and Maintenance department • Communicate the Quality and Health, Safety and Environment (HSE) requirements and procedures to Engineering and Maintenance teams • Communicate CGMP requirements and procedures to Engineering and Maintenance teams • Ensure that engineering teams operate in accordance with Quality and HSE requirements • Develop contingency plans to minimise impact of delays in Engineering and Maintenance activities • Activate contingency plans when delays or lapses in Engineering and Maintenance activities arise

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 5
Budgeting	Level 4
Business Continuity Management	Level 5
Business Performance Management	Level 5
Change Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Equipment Qualification	Level 4
Flexible Facilities Implementation	Level 5
Good Manufacturing Practices Implementation	Level 5
Hazards and Risk Identification and Management	Level 4
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 5
Installation and Assembly	Level 4
Maintenance Strategy Development	Level 5
Preventive Maintenance	Level 5
Process Analytical Technology Implementation	Level 4
Project Management	Level 5
Risk Management	Level 5
Strategy Development	Level 4
Systems Thinking	Level 5
Team Effectiveness Management	Level 5
Technical Presentation	Level 5
Test Planning	Level 5
Utilities Management	Level 5
Vendor Management	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Advanced
Interpersonal Skills	Advanced
Leadership	Advanced
Problem Solving	Advanced

Engineering and Maintenance Engineer

JOB ROLE DESCRIPTION

The Engineering and Maintenance Engineer applies engineering principles and techniques to optimise the equipment and systems within the manufacturing facility. He/She provides technical guidance and direction for the installation of equipment and systems. He develops plans for the maintenance of equipment and systems, and recommends engineering solutions to troubleshoot faults. The Engineering and Maintenance Engineer innovates equipment and systems, and contributes to manufacturing equipment and systems improvement projects by conducting feasibility assessments and tests on new technologies. He is also expected to manage energy resources and utilities by developing solutions to optimise machine availability and energy efficiency. The Engineering and Maintenance Engineer must ensure compliance with Standard Operating Procedures (SOPs), Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) within his purview. He develops guidelines and conducts equipment qualification and validation in line with biopharmaceuticals manufacturing regulatory requirements.

The Engineering and Maintenance Engineer should possess an enquiring and analytical mind and have a knack for investigating issues, analysing multifaceted engineering problems and developing solutions. He must also be a strong team player who can guide and mentor others, and communicate technical advices and solutions to colleagues beyond the team.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Install equipment and systems	• Perform feasibility studies and cost-benefit analysis on the introduction of new equipment • Recommend equipment to be installed • Develop technical installation, assembly, integration and engineering plans for equipment and systems • Provide technical guidance and directions on the installations and assembly of new equipment • Verify that all installations and assembly works conform to technical specifications • Check that installations and assembly documentations and records are aligned with engineering plans
Maintain equipment and systems	• Review equipment conditions and non-destructive testing data to support schedule for maintenance activities • Facilitate the Maintenance Excellence Programme (MEP) for the manufacturing facility • Develop maintenance and spare parts plans and Standard Operating Procedures (SOPs) for all equipment and systems • Establish plans, guiding procedures, and parameters for equipment and systems testing and repair • Recommend repair works and solutions to address equipment and system failures • Conduct root cause analysis of equipment and system failures and malfunctions • Analyse testing, maintenance and repair records to identify trends, potential malfunctions and solutions applied • Outline cleaning procedures and cleanliness standards to be adhered to following maintenance and repair works
Manage energy resources and utilities	• Evaluate energy resources and utilities usage requirements for the plant • Establish requirements for energy resources and utilities supply and operational standards • Develop technical guidelines to resolve disruptions to energy resources and utilities supply • Analyse data to identify areas where energy efficiency can be optimised • Develop solutions to optimise machine availability while managing energy resources and utilities

Engineering and Maintenance Engineer

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Innovate equipment, systems and controls	• Conduct feasibility assessments for new automated equipment, systems and controls • Install and calibrate automated equipment and system components • Troubleshoot system bugs or malfunctions of automated equipment and systems • Review performance of automated equipment and systems to identify modifications required
Validate equipment	• Keep abreast of regulatory changes and their implications on equipment usage • Develop protocols and parameters for equipment qualifications and validations • Perform equipment qualifications and validations to verify their conditions and performances • Develop equipment qualifications and validations reports

Engineering and Maintenance Engineer

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Equipment and Control Systems Configuration	Level 4
Automated Process Control	Level 4
Automated Process Design	Level 4
Big Data Analysis	Level 3
Change Management	Level 4
Cleaning and Sterilising	Level 3
Computer Systems Validation	Level 4
Conflict Resolution	Level 4
Continuous Improvement	Level 4
Engineering Drawing	Level 3
Equipment and Systems Repair	Level 4
Equipment Qualification	Level 3
Facility Maintenance	Level 4
Flexible Facilities Implementation	Level 4
Good Manufacturing Practices Implementation	Level 4
Green Manufacturing Design and Implementation	Level 3
Health, Safety and Environment Procedures Implementation	Level 3
Innovation Management	Level 4
Manufacturing Equipment Operation and Control	Level 4
Manufacturing Systems Operation and Control	Level 4
Preventive Maintenance	Level 4
Process Analytical Technology Implementation	Level 3
Process Optimisation	Level 3
Systems Thinking	Level 4
Technical Presentation	Level 4
Technical Report Writing	Level 4
Test Planning	Level 4
Utilities Management	Level 4
Vendor Management	Level 4

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Intermediate
Decision Making	Intermediate
Interpersonal Skills	Intermediate
Problem Solving	Intermediate
Teamwork	Intermediate

Engineering and Maintenance Principal/ Senior Engineer

JOB ROLE DESCRIPTION

The Engineering and Maintenance Principal/Senior Engineer applies advanced engineering principles and techniques to troubleshoot complex engineering problems encountered within the manufacturing facility and provides expert technical advice to guide the installation and maintenance of equipment and systems. He/She is expected to lead the technical cross-collaboration with the Process Development/Manufacturing Science and Technology (PD/MSAT) department in order to identify appropriate biopharmaceuticals manufacturing equipment and optimise their functionalities. The Engineering and Maintenance Principal/Senior Engineer leads manufacturing equipment and systems innovation projects by guiding feasibility assessments and tests on new technologies. He is expected to review and approve solutions and initiatives to optimise machine availability while managing energy and utility use. He sets parameters for equipment qualification and validation in line with biopharmaceuticals manufacturing regulatory requirements. The Principal/Engineer must ensure compliance with Standard Operating Procedures (SOPs), Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) within his purview.

The Engineering and Maintenance Principal/Engineer carries the responsibility of the in-house technical expert. He should possess a deep passion for analysing and resolving multifaceted engineering problems and be able to apply advanced critical and analytical thinking skills to deal with immediate situations. He should have a developmental and amiable approach in his interactions working as part of a team while guiding and mentoring others. He must also be able to communicate engineering concepts in a manner that will be understood by others within and beyond the team.

	CRITICAL WORK FUNCTIONS	KEY TASKS
CRITICAL WORK FUNCTIONS AND KEY TASKS	Install equipment and systems	• Approve all installations and assembly works prior to use for full-scale productions • Guide the development of engineering plans to ensure technical drawings are produced in an optimal manner • Review installations and assembly documentations periodically to ensure compliance with organisational procedures • Review recommendations and approve equipment to be installed
	Maintain equipment and systems	• Formulate predictive maintenance techniques for the manufacturing facility to predict when maintenance should be performed • Approve recommended repair works for major equipment and system failures • Draw insights and trends from testing, maintenance and repair records that may impact manufacturing operations and quality • Drive the Maintenance Excellence Programme (MEP) for the manufacturing facility • Evaluate root cause analysis reports of major equipment and system failure, and develop potential solutions • Provide expert technical guidance on maintenance requirements of new or complex equipment and systems • Review and approve maintenance and spare parts plans and Standard Operating Procedures (SOPs) • Review and approve plans, guiding procedures, and parameters for equipment and systems testing and repair
	Manage energy resources and utilities	• Anticipate changes to energy resources and utilities usage requirements for the plant • Evaluate technical viability of initiatives to optimise energy and utility efficiencies • Provide expert technical advice to resolve significant or non-standard lapses or disruptions to energy resources and utilities supplies • Review and approve requirements for energy resource and utilities supply and operational standards

Engineering and Maintenance Principal/ Senior Engineer

	CRITICAL WORK FUNCTIONS	KEY TASKS
CRITICAL WORK FUNCTIONS AND KEY TASKS	Innovate equipment, systems and controls	• Approve proposed modifications to automated equipment, systems and controls • Commission feasibility assessments for new automated equipment, systems and controls • Conduct training on the operations and maintenance of new automated equipment, systems and controls • Establish technical guidelines for the calibrations and alignments of robot motors, sensors and encoders • Optimise the motion, functions, and routes of robots and other equipment and system components • Oversee test-runs of new processes involving automated equipment, systems and controls • Provide expert technical guidance on troubleshooting automated equipment malfunctions and system bugs
	Validate equipment	• Oversee equipment qualification and validation activities in the facility • Review and approve protocol and parameters for equipment qualification and validation • Review equipment qualification and validation reports to identify areas for improvement

Engineering and Maintenance Principal/ Senior Engineer

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Equipment and Control Systems Configuration	Level 5
Automated Process Control	Level 4
Automated Process Design	Level 5
Big Data Analysis	Level 4
Change Management	Level 4
Computer Systems Validation	Level 5
Conflict Resolution	Level 4
Continuous Improvement	Level 5
Engineering Drawing	Level 4
Equipment and Systems Repair	Level 5
Equipment Qualification	Level 4
Facility Maintenance	Level 4
Flexible Facilities Implementation	Level 5
Good Manufacturing Practices Implementation	Level 5
Green Manufacturing Design and Implementation	Level 4
Health, Safety and Environment Procedures Implementation	Level 4
Innovation Management	Level 5
Installation and Assembly	Level 4
Maintenance Strategy Development	Level 5
Manufacturing Equipment Operation and Control	Level 5
Manufacturing Systems Operation and Control	Level 5
Preventive Maintenance	Level 5
Process Analytical Technology Implementation	Level 5
Process Monitoring	Level 5
Process Optimisation	Level 4
Systems Thinking	Level 5
Technical Presentation	Level 5
Test Planning	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Intermediate
Interpersonal Skills	Advanced
Problem Solving	Advanced
Teamwork	Intermediate

Engineering and Maintenance Director

JOB ROLE DESCRIPTION

The Engineering and Maintenance Director is responsible for the overall management of the department and all major decisions regarding the selection, maintenance and repair of equipment and systems in the facility. He/She establishes the strategies for the biopharmaceuticals manufacturing plant to achieve desired efficiency levels from equipment and systems and drives cross-functional collaborations and continuous improvements efforts. He is accountable for meeting the department's operational and financial targets.

The Engineering and Maintenance Director champions innovation of equipment and systems within the facility and drives new applications of analytics, technology and automation to enhance the maintenance and management of equipment, systems and energy resources. He retains accountability for risks and regulatory compliance for the department and approves contingency plans in the event of disruptions and emergencies.

The Engineering and Maintenance Director should be an inspiring and influential leader, highly skilled in developing capabilities, building strong teams and engaging internal and external stakeholders to drive organisational success. He should have a passion for driving a culture of innovation within and beyond the department to enhance the overall reliability and efficiency of biopharmaceuticals manufacturing operations.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage the department	• Establish long-term objectives for the Engineering and Maintenance department in alignment with the strategies of the manufacturing facility • Deliver reports on engineering and maintenance activities and achievement objectives to senior management • Establish the operating and resourcing structure for the department to support business objectives • Manage sourcing and allocation of budgets for the department's activities • Define the required capabilities for the Engineering and Maintenance department to support business objectives • Approve workflow improvement solutions and recommendations for the Engineering and Maintenance Department • Approve recommendations on changes to Engineering and Maintenance department's operations and the required resources • Negotiate supplier and vendor contracts to secure terms that are in the organisation's best interest
Innovate equipment, systems and controls	• Spearhead opportunities to automate equipment and systems to maximise efficiency and minimise waste • Provide expert guidance on the selection, implementation, operations and maintenance of new technology and automated equipment • Drive innovation and performance improvements for equipment and systems
Maintain equipment and systems	• Transform strategies for the maintenance and repair work by introducing new applications of analytics • Facilitate cross-departmental collaboration on maintenance and repair activities to minimise equipment downtime
Manage energy resources and utilities	• Articulate implications of organisational targets and priorities on energy resource requirements • Establish consultative mechanisms to promote the energy-efficiency of manufacturing processes

Engineering and Maintenance Director

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Manage risk and regulatory compliance	• Approve the risk management plan for the department • Keep abreast of changes to local and international Health, Safety and Environment (HSE) and Quality regulations • Collaborate with the Quality and Production departments to ensure overall compliance of manufacturing processes with required Current Good Manufacturing Practices (CGMPs) • Collaborate across all departments to ensure engineering and maintenance activities comply with required quality standards • Approve business continuity policies, strategies and plans • Lead the implementation of business continuity plans in the event of emergencies that affect engineering and maintenance operations

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES	
Automated Process Design	Level 6
Big Data Analysis	Level 5
Budgeting	Level 5
Business Continuity Management	Level 5
Business Networking	Level 5
Business Performance Management	Level 5
Business Planning	Level 5
Change Management	Level 5
Conflict Resolution	Level 5
Continuous Improvement	Level 5
Good Manufacturing Practices Implementation	Level 5
Innovation Management	Level 6
Maintenance Strategy Development	Level 6
Process Optimisation	Level 5
Project Management	Level 6
Risk Management	Level 5
Strategy Development	Level 5
Systems Thinking	Level 5
Technical Presentation	Level 5
Utilities Management	Level 5

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Communication	Advanced
Decision Making	Advanced
Developing People	Advanced
Interpersonal Skills	Advanced
Leadership	Advanced

Site Director/Head

JOB ROLE DESCRIPTION

The Site Director/Head is responsible for steering the manufacturing site towards achieving its strategic objectives by establishing and cascading key performance indicators (KPI), fostering a culture of collaboration across departments and overseeing financial planning and budgeting activities. He/She explores and identifies opportunities for investments to grow manufacturing operations and upgrade facilities. He also mentors and develops talents for future leaders and oversees the learning and development, succession planning and talent management activities. He is responsible for compliance across the manufacturing site with Health, Safety and Environment (HSE) policies, international regulations and Current Good Manufacturing Practices (CGMPs). He oversees the development of business continuity plans and spearheads response to major incidents or events.

The Site Director/Head has overall accountability for the performance of the manufacturing site. He is an inspirational and people-oriented leader with the energy and commitment to drive large teams toward achieving excellence. He possesses a strategic and forward-thinking mindset and a global sense of perspective when spearheading plans and decisions for the organisation.

CRITICAL WORK FUNCTIONS AND KEY TASKS

CRITICAL WORK FUNCTIONS	KEY TASKS
Drive organisational strategies	• Establish long term objectives, plans and key performance indicators for the manufacturing site based on the organisation's strategies • Oversee the development of policies and processes to meet the long-term objectives • Steer the organisation to achieve excellence in a globalised environment • Spearhead growth strategies and drive value-creation • Lead organisational change initiatives
Lead business development efforts	• Develop strategic business networks • Collaborate with business partners to maintain and strengthen business relationships • Support regional leadership team in gaining investments for the manufacturing site
Direct manufacturing operations	• Oversee allocation of resources, equipment and infrastructure to support manufacturing operations • Facilitate collaborations between departments to ensure manufacturing processes meet required performance levels and Current Good Manufacturing Practices (CGMPs) standards • Direct financial planning and budgeting activities across the site • Foster a culture of high performance amongst employees • Oversee succession planning and management, capability development and employee engagement initiatives • Act as a mentor to develop talents
Strive for continuous improvement	• Drive efficiency in the manufacturing site • Keep abreast of key trends and best practices in the biopharmaceuticals manufacturing industry • Innovate and create a culture that encourages innovation • Challenge new ideas while actively balancing risks and opportunities • Leverage synergies among teams and departments • Establish the change management strategies and policies to support critical transformation
Manage risk and regulatory compliance	• Establish the organisation's governance, compliance and Health, Safety and Environment (HSE) policies and procedures • Approve the risk management strategies for the manufacturing site • Lead development of business continuity frameworks, policies, strategies and plans • Lead response to major business disruptions or incidents

Site Director/Head

SKILLS AND COMPETENCIES	TECHNICAL SKILLS AND COMPETENCIES	
	Budgeting	Level 5
	Business Continuity Management	Level 6
	Business Networking	Level 6
	Business Performance Management	Level 6
	Business Planning	Level 6
	Change Management	Level 6
	Conflict Resolution	Level 6
	Continuous Improvement	Level 5
	Good Manufacturing Practices Implementation	Level 5
	Innovation Management	Level 6
	Risk Management	Level 6
	Strategy Development	Level 6
	Technical Presentation	Level 6

GENERIC SKILLS AND COMPETENCIES (TOP 5)	
Decision Making	Advanced
Global Mindset	Advanced
Leadership	Advanced
Managing Diversity	Advanced
Transdisciplinary Thinking	Advanced

Notes

Overview of Technical Skills and Competencies

Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
Engineering and Maintenance	Automated Equipment and Control Systems Configuration	Configure automated equipment and control systems to support biopharmaceuticals manufacturing processes			●	●	●	
	Automated Operation Monitoring	Monitor automated equipment and control systems to ensure quality execution of the manufacturing process flow		●	●			
	Automated Process Design	Design processes that utilise automated manufacturing equipment and control systems			●	●	●	●
	Engineering Drawing	Create technical drawings for design specifications to guide electrical, mechanical and structural installation works	●	●	●	●		
	Equipment and Systems Repair	Execute equipment and systems repair procedures to correct faults and restore functionalities		●	●	●	●	
	Equipment and Systems Testing	Execute equipment and systems testing procedures to ensure continuity of operations and meet standards of performance		●	●			
	Equipment Qualification	Verify that biopharmaceuticals manufacturing equipment are installed, operate and perform as per expectations and requirements			●	●		
	Facility Maintenance	Manage facility system maintenance activities to manufacturing and business operations		●	●	●		
	Installation and Assembly	Install equipment and system components by evaluating product specifications and manufacturers' recommendations and aligning them with the needs of the manufacturing facility		●	●	●	●	
	Maintenance Strategy Development	Develop a corrective and preventive maintenance strategy				●	●	●
	Preventive Maintenance	Perform scheduled maintenance procedures on biopharmaceuticals manufacturing equipment without halting manufacturing production to reduce the likelihood of failure		●	●	●	●	
	Test Planning	Develop testing plans and procedures by determining scope and risks, identifying the objects of testing, selecting test methods and tools, and controlling test implementation				●	●	
	Utilities Management	Develop plans to meet manufacturing utilities and energy requirements while conserving and managing the use of energy and utilities by the facility			●	●	●	
General Management	Budgeting	Prepare organisational budgets to support short- and long-term business plans through forecasting, allocation and financial policy setting			●	●	●	
	Business Continuity Management	Execute business impact analysis, risk analysis, testing and exercising to ensure the currency of the organisation's Business Continuity Plans				●	●	●
	Business Networking	Establish mutually beneficial relationships with business stakeholders, potential clients and customers					●	●

Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
General Management	Business Performance Management	Implement the organisation's performance systems to meet business plans and objectives by establishing performance indicators, tracking progress and addressing gaps				●	●	●
	Business Planning	Develop business plans by reviewing existing resources to identify growth opportunities for achieving sustainable competitive advantage					●	●
	Change Management	Drive successful change outcomes by preparing, equipping and supporting adoption of change			●	●	●	●
	Conflict Resolution	Resolve conflicts by evaluating and implementing resolution approaches, analysing mediation outcomes and finding solutions				●	●	●
	Continuous Improvement	Apply continuous improvement strategies to improve products, services or processes across the organisation		●	●	●	●	
	Innovation Management	Respond to external or internal opportunities by using creativity to introduce new ideas and processes		●	●	●	●	●
	Project Management	Execute projects by managing stakeholder engagement, resources, budgets and resolving problems			●	●	●	●
	Risk Management	Implement risk management strategies to support business operations				●	●	●
	Strategy Development	Develop organisational strategies and policies by analysing the impact of internal and external influencing factors				●	●	●
	Systems Thinking	Integrate understanding of biopharmaceuticals manufacturing with interactions between components when developing manufacturing processes or overseeing manufacturing activities		●	●	●	●	
	Team Effectiveness Management	Set goals with team and evaluate team's effectiveness in achieving the defined goals and objectives				●	●	
	Technical Presentation	Deliver effective and engaging presentations for a variety of audiences				●	●	●
	Technical Report Writing	Produce reports with specific information and evidence presented in a clear and structured format		●	●	●		
	Vendor Management	Manage vendor relationships by ensuring performance as per contracts, operations within standards established by the organisation such as adherence to safety, security, and compliance standards			●	●	●	
Health, Safety and Environment	Biorisk Management	Identify and implement biosafety and biosecurity practices to ensure a safe work environment		●	●	●	●	
	Chemical Risk Management	Implement chemical safety and security practices to ensure a safe work environment		●	●	●	●	
	Emergency and Crisis Situation Management	Implement emergency and crisis response and recovery activities to minimise the impact of disruptive events to the organisation			●	●		

Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
Health, Safety and Environment	Hazards and Risk Identification and Management	Implement a systematic approach for hazard identification and risk assessment to manage hazards that may occur within biopharmaceuticals manufacturing facilities		●	●	●		
	Health, Safety and Environment Procedures Implementation	Implement Health, Safety and Environment procedures in accordance with legislative requirements to ensure a safe work environment		●	●	●		
Process Development/ Manufacturing Science and Technology	Big Data Analysis	Apply data analytics techniques and tools to analyse significant volumes of data and draw patterns and trends for investigating business problems			●	●	●	
	Biological Product Introduction	Facilitate the introduction of new biological products by designing manufacturing processes needed to achieve cost-effective production and meet design specifications				●	●	●
	Facility Design	Design and integrate biopharmaceuticals manufacturing facilities to optimise operational efficiency and effectiveness				●	●	
	Green Manufacturing Design and Implementation	Design and implement manufacturing processes that reduce waste, conserve energy and use replacements for hazardous substances			●	●	●	●
	Manufacturing Process Design	Design cost-efficient, robust and reliable manufacturing processes aligned with stakeholder expectations, business priorities and industry best practices				●	●	●
	Pharmaceutical and Nutritional Product Introduction	Develop manufacturing plans and processes for new pharmaceutical or nutritional products to achieve cost-effective production and Research and Development design specifications				●	●	●
	Pharmacovigilance Integration	Integrate patient-outcome factors into the design of biopharmaceuticals manufacturing processes				●	●	
	Process Analytical Technology Implementation	Apply Process Analytical Technology to design, analyse and control manufacturing processes to enhance production efficiency and quality			●	●	●	
	Process Modelling	Model manufacturing processes in order to ensure successful implementation				●	●	
	Process Monitoring	Verify that routine manufacturing processes are consistently within a state of control			●	●	●	
	Process Optimisation	Analyse biopharmaceuticals manufacturing processes and identify adjustments that will reduce costs of manufacturing and increase quality, throughput and efficiency			●	●	●	
	Product Improvement	Analyse technical specifications of nutritional products and identify ways to make improvements			●	●	●	

Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
Production	Automated Process Control	Use automated process control to reduce process variations and detect process deviations			●	●		
	Bioreactor Operation and Control	Operate bioreactors in biopharmaceuticals manufacturing facilities			●	●		
	Cell Culture	Maintain both microbial and mammalian cell cultures as pure cultures during the upstream stages of production			●	●	●	
	Chromatography Equipment Operation and Control	Operate chromatography systems in biopharmaceuticals manufacturing facilities			●	●		
	Cleaning and Sterilising	Clean and sterilise equipment, systems and materials for biopharmaceuticals production		●	●	●		
	Emergency Shut-down and Restart	Manage shut-down and restart of production processes to minimise loss and damage of assets as well as ensure the safety of personnel during emergency situations		●	●	●		
	Filtration Equipment Operation and Control	Operate filtration equipment in biopharmaceuticals manufacturing facilities			●	●		
	Flexible Facilities Implementation	Facilitate implementation and changeover of flexible facilities, integrating single-use technologies with flexible manufacturing operations		●	●	●	●	
	Good Manufacturing Practices Implementation	Implement Current Good Manufacturing Practices in the design, monitoring, and control of manufacturing processes and facilities to ensure the potency, quality, and purity of biopharmaceutical products		●	●	●	●	
	Manufacturing Equipment Operation and Control	Operate production equipment ensuring optimal conditions for biopharmaceuticals manufacturing production			●	●	●	
	Manufacturing Systems Operation and Control	Operate technical systems in the manufacturing of biopharmaceuticals			●	●	●	
	Materials Management	Manage biopharmaceuticals materials and materials flow according to established procedures for meeting batch requirements		●	●	●	●	
	Production Optimisation	Manage production processes and resources to maximise performance		●	●	●	●	
	Production Planning	Execute the production plans to meet production targets and cycle time indices				●	●	●
	Production Resource Management	Define productivity targets and allocate resources to support and synchronise production processes				●	●	●

Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
Quality Assurance	Analytical Method Validation	Verify analytical methods used to ensure accuracy, validity and reliability of methods		●	●	●	●	
	Audit Management	Review organisational objectives, policies, procedures, structure, controls and systems to verify that the organisation's activities are efficiently managed		●	●	●	●	
	Cleaning Validation	Validate processes and methods for achieving required standards of cleanliness			●	●		
	Computer Systems Validation	Commission computerised systems for use in biopharmaceuticals manufacturing facilities			●	●	●	
	Document Control	Implement documentation policies to facilitate the referencing of information for processes, systems and equipment, and to comply with regulatory requirements		●	●	●		
	Packaging Validation	Validate the methodologies and processes applied to package biopharmaceutical products to maintain quality standards and regulatory compliance			●	●		
	Process Validation	Verify that processes are reproducible and consistent in delivering quality products according to specifications, and in line with international regulations		●	●	●	●	
	Quality Assurance Management	Implement quality assurance procedures and conduct audits to ensure compliance			●	●	●	●
Quality Control	Cleanliness Testing	Perform tests to verify that residue and contaminants are at risk-free levels during the manufacture of subsequent products			●	●	●	
	Laboratory Data Analysis	Analyse laboratory data		●	●	●		
	Laboratory Management	Implement Good Laboratory Practice procedures to ensure that performance, quality, health, and safety standards are met		●	●	●	●	
	Packaging Testing	Verify that biopharmaceutical packaging materials maintain the desired level of compliance			●	●	●	
	Product Testing	Test biopharmaceutical products to verify that they have been produced to the required quality and regulatory standards			●	●	●	
	Quality Control Management	Establish quality control procedures for biopharmaceuticals manufacturing processes, products, equipment and systems, to ensure the desired level of compliance at all stages				●	●	●
	Raw Materials and Utilities Testing	Test raw materials and utilities before the start of biopharmaceuticals manufacturing processes to verify that they meet the desired quality standards			●	●	●	

Overview of Technical Skills and Competencies

General Descriptors for Technical Skills and Competencies (TSCs)

Level	Responsibility (Degree of supervision and accountabiity)	Autonomy (Degree of decision-making)	Complexity (Degree of difficulty of situations and tasks)	Knowledge and Abilities (Required to support work as described under Responsibility, Autonomy and Complexity)
6	Accountable for significant areas of work, strategy or overall satisfaction	Empowered to chart direction and practices within and outside of work (including professional field/ community), to achieve/exceed work results	Complex	• Synthesise knowledge issues in a field of work and the interface between different fields, and create new forms of knowledge • Employ advanced skills, to solve critical problems and formulate new structures, and/or to redefine exisiting knowledge or professional practice • Demonstrate exemplary ability to innovate, and formulate new ideas and structures
5	Accountable for achieving assigned objectives, decisions made by self and others	Provide leadership to achieve desired work results; Manage resources, set milestones and drive work	Complex	• Evaluate factual and advanced conceptual knowledge within a field of work, involving critical understanding of theories and principles • Select and apply an advanced range of cognitive and technical skills, demonstrating mastery and innovation, to devise solutions to solve complex and unpredictable problems in a specialised field of work • Manage and drive complex work activities
4	Work under broad direction Hold accountability for performances of self and others	Exercise judgement; adapt and influence to achieve work performance	Less routine	• Evaluate and develop factual and conceptual knowledge within a field of work • Select and apply a range of cognitive and technical skills to solve non-routine/ abstract problems • Manage work activities which may be unpredictable • Facilitate the implementation of innovation
3	Work under broad direction May hold some accountability for performance of others, in addition to self	Use discretion in identifying and responding to issues, work with others and contribute to work performance	Less routine	• Apply relevant procedural and conceptual knowledge and skills to perform differentiated work activities and manage changes • Able to collaborate with others to identify value-adding opportunities
2	Work with some supervision Accountable for a broader set of tasks assigned	Use limited discretion in resolving issues or enquiries. Work without frequently looking to other for guidance	Routine	• Understand and apply factual and procedural knowledge in a field of work • Apply basic cognitive and technical skills to carry out defined tasks and to solve routine problems using simple procedures and tools • Present ideas and improve work
1	Work under direct supervision assigned Accountable for tasks	Minimal discretion required. Expected to seek guidance	Routine	• Recall factual and procedural knowledge • Apply basic skills to carry out defined tasks • Identify opportunities for minor adjustments to work tasks

Overview of Generic Skills and Competencies

Generic Skills and Competencies (GSCs)

GSC	GSC Description	Proficiency Levels		
		Basic	Intermediate	Advanced
Communication	Convey and exchange thoughts, ideas and information effectively through various mediums and approaches.	Communicate information with others to respond to general inquiries and to obtain specific information.	Articulate and discuss ideas and persuade others to achieve common outcomes.	Negotiate with others to address issues and achieve mutual consensus.
Computational Thinking	Develop and use computational models, tools and techniques to interpret and understand data, solve problems and guide decision-making.	Use computational models, tools and techniques to identify patterns in a problem and develop a solution.	Modify existing computational models, tools and techniques to develop different solutions.	Develop and create computational models, tools and techniques to implement new solutions and apply to other problems.
Creative Thinking	Adopt a fresh perspective to combine ideas or information in new ways and make connections between seemingly unrelated fields to create new ideas and applications.	Connect ideas or information from related fields or applications to address an immediate issue.	Connect or combine ideas or information from unrelated fields or applications to generate multiple ideas to bring about a specific outcome.	Create original applications or ideas to reveal new possibilities and reshape goals through high level of innovativeness.
Decision Making	Choose a course of action from various alternatives using a reasoned process to achieve intended goals.	Make decisions of simple or routine nature to achieve intended goals using given information and guidelines.	Make decisions in a complex setting to achieve intended goals using a structured process and multiple sources of available information.	Make decisions in a volatile and ambiguous setting using a structured process and limited sources of available information to achieve intended goals.
Developing People	Help others to learn and develop their capabilities to enhance their performance and achieve personal or professional goals.	Use demonstration and explanation to teach a familiar task to inexperienced co-workers.	Provide coaching to others to develop their skills and knowledge on their jobs to enhance performance.	Provide mentorship to help others in their professional and personal development to improve performance and further their careers.
Digital Literacy	Use ICT tools, equipment and software to create, evaluate and share information digitally with others.	Perform basic functions using software programmes pertaining to computer operating systems and file management, and search online information.	Use available software features to create and edit documents, customise templates and reports and evaluate online information.	Use available software features to enhance documents, analyse and manipulate data, and use ICT to organise, share and communicate information clearly and coherently.
Global Mindset	Awareness of diversity across global cultures and markets. Seek opportunities to adopt successful practices and ideas.	Demonstrate understanding of global challenges and opportunities and how to transfer best practices across cultures. Respect cultural differences and needs of a diverse workforce.	Develop global networks and manage virtual relationships while balancing both local and global perspectives. Adopt a local and global perspective when making decisions.	Build the organisation's capabilities to compete in a global environment. Manage tension between corporate requirements, global and cultural differences.

Overview of Generic Skills and Competencies

Generic Skills and Competencies (GSCs)

GSC	GSC Description	Proficiency Levels		
		Basic	Intermediate	Advanced
Interpersonal Skills	Manage relationships efficiently and communicate with others effectively to achieve mutual consensus and outcomes.	Recognise own internal feelings and emotional states to manage interpersonal relationships in social situations.	Detect and decipher emotions of others to manage interpersonal relationships in social situations.	Influence, guide and handle others' emotions to build instrumental relationships and manage conflicts and disagreements.
Leadership	Lead others to achieve objectives in the most effective way. Provide an inclusive workplace that cultivates workplace relationships and teamwork, and foster the development of others.	Demonstrate professionalism to set a good example at peer level. Support others through own initiative and enthuse others through own positive and energetic approach.	Lead by example at team level. Encourage and guide others to adopt a point of view, make changes or take action. Provide a team environment that facilitates relationships building, teamwork and the development of others.	Lead by example at organisational level. Inspire, motivate and guide others to adopt a point of view, make changes or take action. Cultivate an open, cooperative and collaborative learning culture for the organisation.
Lifelong Learning	Seek out opportunities to enhance one's knowledge and skills. Access and acquire new knowledge and skills actively for continual learning.	Organise and manage own learning by setting learning targets. Identify learning approaches to achieve work or career goals.	Engage in collaborative learning by discussing one's learning with others and soliciting feedback to continually improve oneself.	Conduct self-reflective practices to review one's learning to facilitate continual growth in one's career or profession.
Managing Diversity	Work well with people from different ethnic, social, cultural and educational backgrounds and understand the concerns and interests of diverse work groups.	Demonstrate sensitivity to the cultural characteristics, values, beliefs, and behaviors of another ethnic or cultural group.	Build relationships with different ethnic or cultural groups by engaging in cross-cultural cooperative projects.	Manage conflicts arising from different ethnic or cultural groups and work effectively in cross-cultural settings.
Problem Solving	Generate feasible and efficient solutions to solve problems and capitalise on new opportunities.	Identify easily perceivable problems and follow given guidelines and procedures to solve the problems.	Identify less perceivable problems and use problem solving tools and techniques to solve the problems.	Anticipate potential problems beyond the current scope and apply higher order problem solving tools and techniques to turn problems into opportunities.
Resource Management	Efficient and effective deployment and allocation of resources when and where they are needed. Include planning, allocating and scheduling of resources to tasks, which typically include manpower, machines, money and materials.	Use resources to ensure optimum and efficient use of resources.	Deepen insights into the planning, allocation and deployment of resources to anticipate needs. Plan the allocation and deployment of resources efficiently and effectively.	Establish strategies for the allocation and deployment of resources efficiently and effectively.

Overview of Generic Skills and Competencies

Generic Skills and Competencies (GSCs)

GSC	GSC Description	Proficiency Levels		
		Basic	Intermediate	Advanced
Sense Making	Organise and analyse data and information accurately to identify relationships and detect patterns and trends to gain insights for decision-making.	Identify relationships and linkages within different components of data.	Interpret data to uncover patterns and trends between various sources of data.	Analyse data relationships, patterns and trends to gain important insights and make informed decisions.
Service Orientation	Commit to exceeding both internal and external customers' needs. Proactively identify customer needs and sustain a culture of service excellence within the organisation.	Exceed customer needs and expectations and handle service challenges with a positive mindset. Demonstrate an understanding of the organisation's service vision, mission and values.	Anticipate customer needs and expectations and elicit feedback from customers to improve service. Build relationships with customers to create and sustain customer loyalty.	Model, lead, train and motivate staff with a focus on sustaining a culture that encourages commitment to service excellence and high performance.
Teamwork	Work collaboratively and effectively with others to contribute to group efforts to achieve identified objectives.	Contribute to a positive and cooperative working environment by fulfilling own responsibilities and providing support to co-workers to achieve team goals.	Facilitate work team activities, provide assistance and support needed by team members and promote ownership and commitment among team members to work goals to improve team performance.	Establish teams, design and assess tasks to continually improve team effectiveness and cultivate a sense of organisational ownership and a cooperative working environment.
Transdisciplinary Thinking	Understanding of concepts across multiple disciplines, with the capacity to synthesise the knowledge and insights to guide decisions and foster cooperation.	Research and adapt concepts from outside one's field of expertise to supplement one's core knowledge and proficiency.	Co-relate material from diverse knowledge bases to guide decisions and policy making. Participate in reflective and trans-disciplinary communities within and outside the organisation.	Synthesise knowledge and insights across disciplinary boundaries to aid strategic decisions and foster cooperation within and outside of the organisation.
Virtual Collaboration	Use online collaborative communication tools to work as teams to accomplish tasks or projects.	Participate and contribute in a virtual team. Set up appropriate online collaborative tools and supporting equipment.	Use interactive collaborative tools to foster cohesion and commitment among virtual team members to achieve goals. Keep up-to-date with innovative online collaborative tools and applications to enhance one's proficiency in engaging in virtual collaboration.	Leverage on diverse team talent, latest online collaborative technologies and virtual platforms to produce collaborative behaviour and achieve technological savviness in virtual collaboration.

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Mead Johnson (S) Pte Ltd

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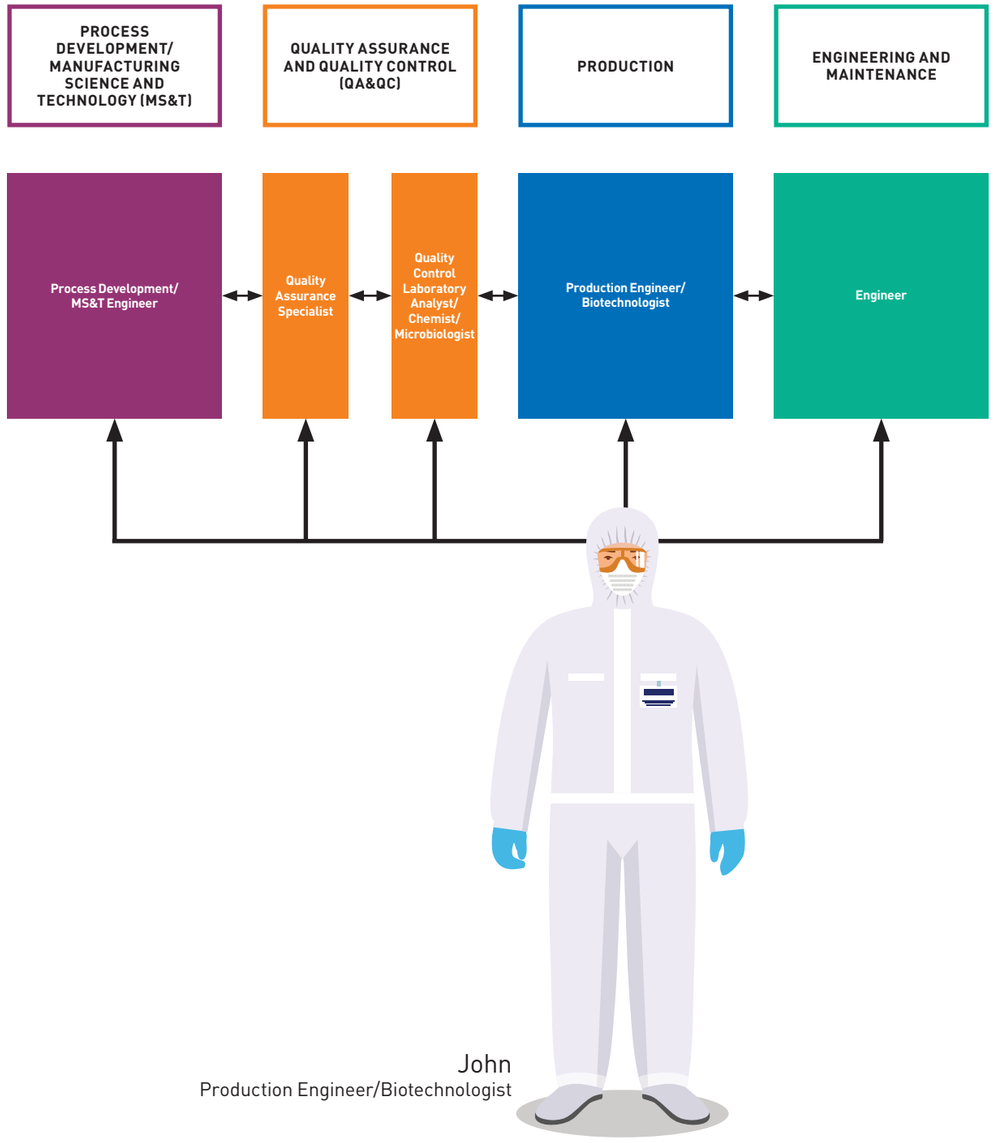
Notes

Illustration of Possible Career Pathways of a Production Engineer/Biotechnologist

This illustration depicts the ability of the Production Engineer/Biotechnologist to move into any of the roles indicated. Progression in the biopharmaceuticals manufacturing does not only occur vertically, it can occur laterally as well. This opens up a wide range of opportunities for those pursuing a fruitful career in biopharmaceuticals manufacturing.



Note: The career pathway would depend on individual performance, capability (skills and competencies), experience and company needs.

Wage Information

MONTHLY GROSS WAGES OF SELECTED OCCUPATIONS IN MANUFACTURING, JUNE 2016

Occupations	Gross Wage	
	25th Percentile ($)	75th Percentile ($)
Chief Operating Officer/General Manager	8,357	18,810
Managing Director/Chief Executive Officer	5,000	15,000
Manufacturing Plant/Production Manager	5,477	10,100
Premises and Facilities Maintenance Manager (including Building Security Manager)	5,721	10,232
Quality Assurance Manager	5,850	10,900
Research and Development Manager	6,915	11,815
Technical/Engineering Services Manager (e.g. Shipyard Manager)	6,341	11,067
Chemical Engineer	4,050	6,239
Chemist	4,095	6,272
Electrical Engineer	3,987	6,156
Industrial and Production Engineer	4,200	6,350
Mechanical Engineer	4,070	6,068
Assistant Manufacturing Engineer	3,306	5,351
Chemical Engineering Technician	3,028	5,466
Chemistry Technician	2,519	3,985
Electrical Engineering Technician	2,878	5,000
Food Science Technician	2,308	3,778
Manufacturing Engineering Technician	2,859	4,320
Mechanical Engineering Technician	3,001	4,425
Chemical Processing and Chemical Products Plant and Machine Operator	2,440	4,150

Source: Occupational Wage Survey, Manpower Research & Statistics Department, Ministry of Manpower

Notes:

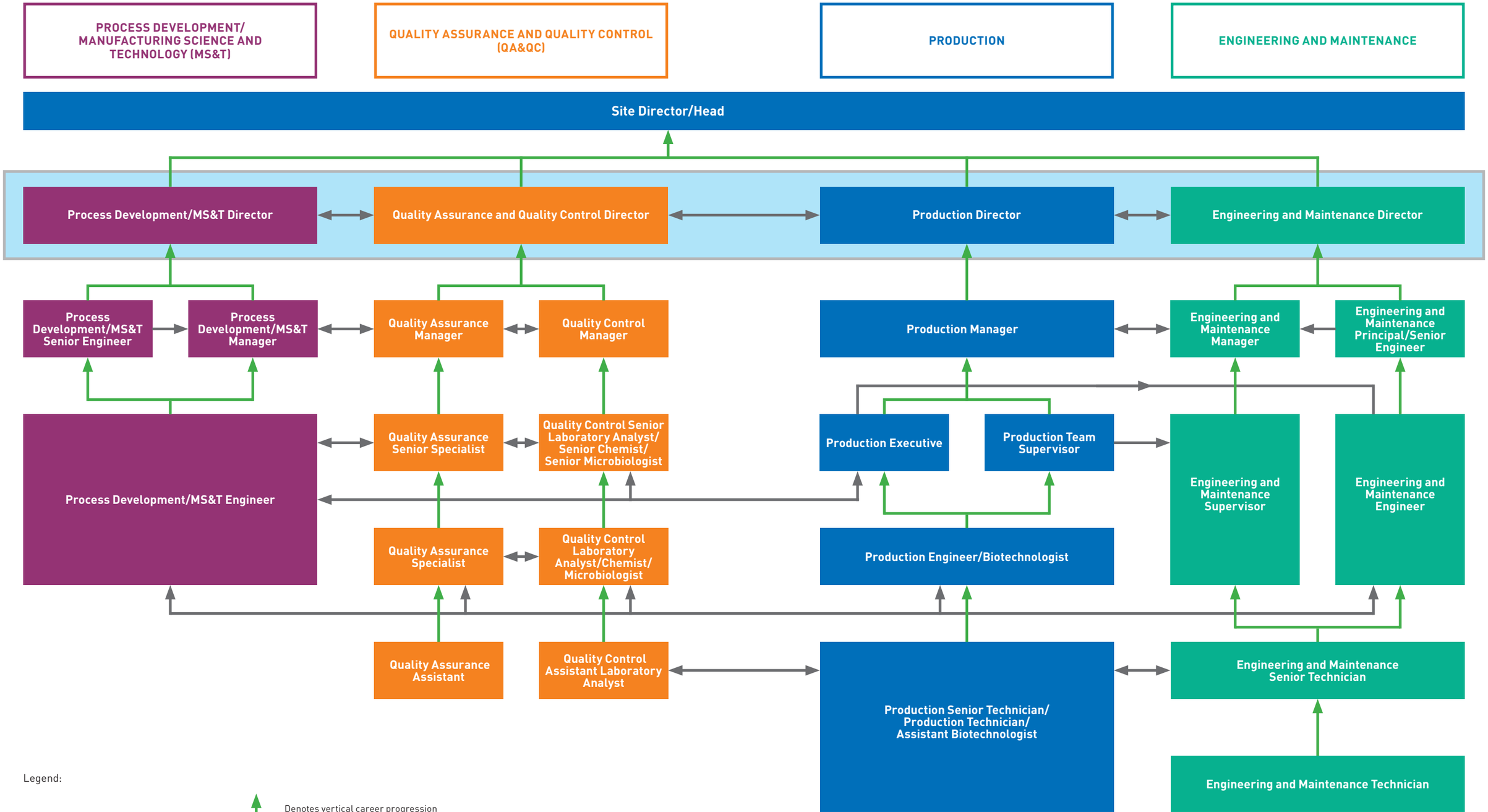
1) Data pertain to full-time resident employees in the private sector establishments each with at least 25 employees.

2) Monthly Gross Wage refers to the sum of the basic wage, overtime payments, commissions, allowances, and other regular cash payments. It is before deduction of employee CPF contributions and personal income tax and excludes employer CPF contributions, bonuses, stock options, other lump sum payments and payments-in-kind.

3) 25th Percentile Wage refers to the wage level which divides the bottom 25% of wage earners from the rest.

4) 75th Percentile Wage refers to the wage level which divides the top 25% of wage earners from the rest.

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING
Career Pathways



Legend:

Denotes vertical career progression

Denotes lateral (cross-functional) career progression

The Career Map serves as a reference to reflect the available job roles and possible career pathways in the biopharmaceuticals manufacturing industry, which may vary depending on the organisation's structure and business context. The Career Pathway would depend on individual aspiration, performance, capability, experience and the organisation's needs.

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