Skills Framework for Biopharmaceuticals Manufacturing

A Guide to Occupations and Skills

An initiative of

skillsfuture.sg
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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:

1. Sector and Employment Opportunities
2. Career Pathways
3. Occupations and Job Roles
4. Existing and Emerging Skills
5. Training Programmes for Skills Upgrading and Mastery

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

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

Renew, 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 nutrionals

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

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, test 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.

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

### FOR INDIVIDUALS

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.

**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).

**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.

**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 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.
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.

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

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.

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.

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

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.

Initiatives and Schemes by:
- SkillsFuture Singapore
- Workforce Singapore

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

**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](http://skillsfuture.sg/skills-framework/biopharmmfg)
Skills Maps

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

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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, so the team 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.

Process Development/MS&T Engineer

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 AND KEY TASKS

**Process Development/MS&T Engineer**

**JOB ROLE DESCRIPTION**

**CRITICAL WORK FUNCTIONS**

- **Design biopharmaceuticals manufacturing processes**
- **Propose possible process control, sampling and monitoring points and related performance parameters to achieve the critical material attributes of the final products**
- **Analyze the functionality of different process control, sampling and monitoring systems and technologies**
- **Analyze results of pilot tests and re-trials to verify the new or improved processes**
- **Conduct process modeling to identify risks in the proposed manufacturing facilities in collaboration with the Engineering and Maintenance department**
- **Conduct ongoing validation of existing manufacturing processes**
- **Monitor manufacturing process performance using Process Analytical Technology (PAT) and other methods**
- **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**

**KEY TASKS**

- **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**
- **Support technology transfer activities.**
- **Conduct technical transfer of manufacturing processes and propose mitigation actions**
- **Conduct ongoing validation of existing manufacturing processes**
- **Monitor manufacturing process performance using Process Analytical Technology (PAT) and other methods**
- **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**

- Innovate existing manufacturing processes
- Conduct ongoing validation of existing manufacturing processes
- Oversee the design and piloting of new processes and associated manufacturing facility layouts

**KEY TASKS**

- 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**

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** 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/She reviews the Standard Operating Procedures (SOPs) for manufacturing processes, collaborates with other departments to deliver training and implements technology transfer.

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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**

- Lead Quality by Design (QbD) initiatives and coach others on incorporating principles into design activities
- Determine the processes required to manufacture new biopharmaceuticals 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

**KEY TASKS**

- 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

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

**CRITICAL WORK FUNCTIONS**

- Design biopharmaceuticals manufacturing processes
- Implement technology transfer
- Conduct ongoing validation of existing manufacturing processes

**KEY TASKS**

- 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

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

**FUNCTIONS AND CRITICAL WORK**

- 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)
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**TECHNICAL SKILLS AND COMPETENCIES**

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- Process Monitoring
- Process Optimisation
- Process Validation
- Product Improvement
- Project Management
- Systems Thinking
- Technical Presentation
- Technical Report Writing

**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

**CRITICAL WORK FUNCTIONS**

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**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- 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

### 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**

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<tr>
<th>KEY TASKS</th>
<th>TECHNICAL SKILLS AND COMPETENCIES</th>
</tr>
</thead>
</table>

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- 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

**CRITICAL WORK FUNCTIONS**

<table>
<thead>
<tr>
<th>KEY TASKS</th>
<th>TECHNICAL SKILLS AND COMPETENCIES</th>
</tr>
</thead>
</table>

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- 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

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 to impact 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

FUNCTIONS AND KEY TASKS

TECHNICAL SKILLS AND COMPETENCIES

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

GENERIC SKILLS AND COMPETENCIES (TOP 5)

- Communication
- Decision Making
- Developing People
- Interpersonal
- Leadership

SKILLS AND COMPETENCIES

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

- Design biopharmaceuticals manufacturing processes
- Implement technology transfer
- Innovate existing manufacturing processes
- Manage department operations

TECHNICAL SKILLS AND COMPETENCIES

- 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
- 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
- Establish cross-departmental collaboration to implement improvements to manufacturing processes

GENERIC SKILLS AND COMPETENCIES (TOP 5)

- 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

SKILLS AND COMPETENCIES
Process Development/MS&T Director

**CRITICAL WORK FUNCTIONS AND 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.

**TECHNICAL SKILLS AND COMPETENCIES**

<table>
<thead>
<tr>
<th>Skill</th>
<th>Level</th>
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</thead>
<tbody>
<tr>
<td>Automated Process Design</td>
<td>6</td>
</tr>
<tr>
<td>Big Data Analysis</td>
<td>5</td>
</tr>
<tr>
<td>Biological Product Introduction</td>
<td>6</td>
</tr>
<tr>
<td>Budgeting</td>
<td>5</td>
</tr>
<tr>
<td>Business Continuity Management</td>
<td>5</td>
</tr>
<tr>
<td>Business Networking</td>
<td>5</td>
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<tr>
<td>Business Performance Management</td>
<td>5</td>
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<tr>
<td>Business Planning</td>
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<tr>
<td>Change Management</td>
<td>5</td>
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<tr>
<td>Conflict Resolution</td>
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<tr>
<td>Continuous Improvement</td>
<td>5</td>
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<tr>
<td>Good Manufacturing Practices Implementation</td>
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<tr>
<td>Green Manufacturing Design and Implementation</td>
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<tr>
<td>Innovation Management</td>
<td>6</td>
</tr>
<tr>
<td>Manufacturing Process Design</td>
<td>6</td>
</tr>
<tr>
<td>Pharmaceutical and Nutritional Product Introduction</td>
<td>6</td>
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<tr>
<td>Process Optimisation</td>
<td>5</td>
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<tr>
<td>Product Improvement</td>
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<td>Project Management</td>
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<tr>
<td>Risk Management</td>
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<tr>
<td>Strategy Development</td>
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<tr>
<td>Systems Thinking</td>
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<tr>
<td>Technical Presentation</td>
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</table>

**GENERIC SKILLS AND COMPETENCIES (TOP 5)**

<table>
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<tr>
<th>Skill</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>Advanced</td>
</tr>
<tr>
<td>Decision Making</td>
<td>Advanced</td>
</tr>
<tr>
<td>Developing People</td>
<td>Advanced</td>
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<tr>
<td>Global Mindset</td>
<td>Advanced</td>
</tr>
<tr>
<td>Leadership</td>
<td>Advanced</td>
</tr>
</tbody>
</table>

**CRITICAL WORK FUNCTIONS**

**KEY TASKS**

- **Manage risk and regulatory compliance**
  - Approve the risk management plans for the department.
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**JOB ROLES**

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<td>Quality Assurance Specialist</td>
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<td>Quality Assurance Senior Specialist</td>
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<td>Quality Assurance Manager</td>
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<tr>
<td>Quality Control Assistant Laboratory Analyst</td>
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<td>Quality Control Laboratory Analyst/Chemist/ Microbiologist</td>
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<tr>
<td>Quality Control Senior Laboratory Analyst/ Senior Chemist/ Senior Microbiologist</td>
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<tr>
<td>Quality Control Manager</td>
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<tr>
<td>Quality Assurance and Quality Control Director</td>
<td>40</td>
</tr>
</tbody>
</table>

**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 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

- **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

<table>
<thead>
<tr>
<th>TECHNICAL SKILLS AND COMPETENCIES</th>
<th>GENERIC SKILLS AND COMPETENCIES (TOP 5)</th>
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<td>Analytical Method Validation Level 2</td>
<td>Computational Thinking Basic</td>
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<tr>
<td>Audit Management Level 3</td>
<td>Digital Literacy Basic</td>
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<td>Change Management Level 3</td>
<td>Problem Solving Intermediate</td>
</tr>
<tr>
<td>Cleaning Validation Level 3</td>
<td>Service Orientation Intermediate</td>
</tr>
<tr>
<td>Continuous Improvement Level 3</td>
<td>Teamwork Basic</td>
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<td>Document Control Level 2</td>
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<tr>
<td>Good Manufacturing Practices Implementation Level 3</td>
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<tr>
<td>Health, Safety and Environment Procedures Implementation Level 2</td>
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<td>Innovation Management Level 3</td>
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<td>Packaging Validation Level 3</td>
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<td>Process Monitoring Level 3</td>
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<td>Process Validation Level 2</td>
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<td>Project Management Level 3</td>
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<tr>
<td>Systems Thinking Level 3</td>
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<tr>
<td>Technical Report Writing Level 3</td>
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</tbody>
</table>

## 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

#### 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
- Oversees 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
Optimise quality and efficiency of department workflows and activities

KEY TASKS
- 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

GENERAL 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 enable him to interact effectively with diverse groups of internal and external stakeholders.

CRITICAL WORK FUNCTIONS
Validate manufacturing methods and processes

KEY TASKS
- 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
- Overseas Corrective and Preventive Actions (CAPAs) implementation and documentation in collaboration with other departments
- Develop product and process quality metric reports

CRITICAL WORK FUNCTIONS AND KEY TASKS
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

- Manage customer feedback and assess need for escalation
- 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

CRITICAL WORK FUNCTIONS
Manage document control procedures

KEY TASKS
- 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**

- 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**

- 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

**TECHNICAL SKILLS AND COMPETENCIES 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 registration applications 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**

- Review and endorse validation Standard Operating Procedures (SOPs) and plans, ensuring alignment with regulatory requirements, Current Good Manufacturing Practices (CGMPs) 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

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- Validate manufacturing methods and processes
- Approve improvements to address identified product quality issues
- 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
- Review audit results and the proposed changes to procedures
- Develop training programmes for CGMPs, regulatory and other requirements in line with the training strategy
- Approve batches for forward processing
- Approve changes to resources, procedures, systems, equipment, and technology within the QA department
- Monitor effectiveness of improvements and changes made to QA activities and workflows

- Facilitate registration and release of biopharmaceutical products
- Endorse Certificates of Analysis
- Approve batches for forward processing
- Review product and process quality metric reports
- 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
- 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

- Facilitate achievement of quality expectations and standards
- Optimize 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
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- 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

**COMPETENCIES**

**SKILLS AND KEY TASKS**

**CRITICAL WORK FUNCTIONS**

- Manage Quality department operations

**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

**TECHNICAL SKILLS AND COMPETENCIES GENERIC SKILLS AND COMPETENCIES (TOP 5)**

- Decision Making
  - Advanced
- Interpersonal Skills
  - Advanced
- Leadership
  - Intermediate
- Problem Solving
  - Advanced
- Resource Management
  - Advanced

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

**SKILLS AND COMPETENCIES**

- Manage conformance to cleanliness standards

**CRITICAL WORK FUNCTIONS**

- Perform sampling

**KEY TASKS**

- Prepare sampling tools, equipment and materials
- Collect samples from identified points
- Preserve sample integrity using appropriate measures and procedures

- Monitor product quality compliance

**KEY TASKS**

- 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

**CRITICAL WORK FUNCTIONS**

- Manage laboratory operations

**KEY TASKS**

- Ensure operation and maintenance of laboratory equipment and utilities
- Document sampling conditions and activities
- Preserv sample integrity using appropriate measures and procedures
- Collect samples from identified points
- Check suitability of sampling conditions according to guidelines

**CRITICAL WORK FUNCTIONS**

- Manage conformance to cleanliness standards

**KEY TASKS**

- 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, materials and areas with cleanliness or hygiene lapses
- Perform tests and checks on disposed waste

**CRITICAL WORK FUNCTIONS**

- Optimise quality and efficiency of department workflows and activities

**KEY TASKS**

- 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

**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.
Quality Control Laboratory Analyst

**JOB ROLE DESCRIPTION**

The Quality Control Laboratory Analyst 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 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 fulfill work objectives.

### CRITICAL WORK FUNCTIONS AND KEY TASKS

#### CRITICAL WORK FUNCTIONS

- **Perform sampling**
  - Identify sampling tools, equipment and materials needed for sampling
  - Select sampling locations and 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**
  - Implement guidelines and indicators for testing of disposed waste
  - Verify that the correct materials, chemicals and equipment required to test cleanliness have been prepared
  - Identify sampling tools, equipment and materials needed for sampling
  - Select sampling locations and 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

### 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 ASSISTANT LABORATORY ANALYST
Quality Control Laboratory Analyst/Chemist/Microbiologist

**SKILLS AND COMPETENCIES**

<table>
<thead>
<tr>
<th>TECHNICAL SKILLS AND COMPETENCIES</th>
<th>GENERIC SKILLS AND COMPETENCIES (TOP 5)</th>
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<tbody>
<tr>
<td>Biorisk Management Level 3</td>
<td>Communication Intermediate</td>
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<tr>
<td>Change Management Level 4</td>
<td>Computational Thinking Intermediate</td>
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<tr>
<td>Chemical Risk Management Level 3</td>
<td>Decision Making Intermediate</td>
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<tr>
<td>Cleanliness Testing Level 4</td>
<td>Problem Solving Intermediate</td>
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<td>Conflict Resolution Level 6</td>
<td>Sense Making Intermediate</td>
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<td>Continuous Improvement Level 4</td>
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<td>Technical Presentation Level 4</td>
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<tr>
<td>Technical Report Writing Level 4</td>
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**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- Optimize 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

**JOB ROLE DESCRIPTION**

The Quality Control Laboratory Analyst/Chemist/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/Chemist/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/Chemist/Microbiologist should have strong teamwork and communication skills.
Quality Control Senior Laboratory Analyst/ Senior Chemist/Senior Microbiologist

**CRITICAL WORK FUNCTIONS**

- 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**

- Big Data Analysis Level 3
- Biorisk Management Level 4
- Change Management Level 4
- Chemical Risk Management Level 4
- 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 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

**TECHNICAL SKILLS AND COMPETENCIES GENERIC SKILLS AND COMPETENCIES (TOP 5)**

- Communication Level 3 Advanced
- Decision Making Level 4 Advanced
- Interpersonal Skills Level 4 Intermediate
- Leadership Level 4
- Problem Solving Level 4 Advanced

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

- Optimise quality and efficiency of department workflows and activities
- Monitor the effectiveness of improvements and changes made to QC procedures, activities and workflows
- 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
- 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
- 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
- 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

**FUNCTIONS AND CRITICAL WORK**

- Optimise quality and efficiency of department workflows and activities
- Review results from improvement activities
- Implement initiatives to encourage improvement of QC procedures, systems, and equipment
- Oversee the introduction of new workflow improvements to improve procedures, systems, and equipment
- Assess the feasibility and viability of introducing new and improved QC procedures, systems and equipment
- Implement initiatives to encourage improvement of QC procedures, activities, and workflows
- Review results from improvement activities

**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.
Quality Control Manager

CRITICAL WORK FUNCTIONS AND 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

SOFTWARE SKILLS AND COMPETENCIES

- Bioreactor Management Level 5
- Bioprocess Management Level 5
- Business Continuity Management Level 5
- Business Performance Management Level 5
- Change Management Level 5
- Chemist Risk Management Level 5
- Chemical Risk Management Level 5
- Cleanliness Testing Level 5
- Conflict Resolution Level 5
- Continuous Improvement Level 5
- Good Manufacturing Practices Implementation Level 5
- Hazard 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 Utility Testing 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
- Developing People Advanced
- Leadership Advanced
- Problem Solving Advanced
- Transdisciplinary Thinking Advanced

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.
## Quality Assurance and Quality Control Director

### CRITICAL WORK FUNCTIONS AND 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

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## SKILLS AND COMPETENCIES

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<td>Business Continuity</td>
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<td>Business Networking</td>
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<td>Business Performance</td>
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### GENERIC SKILLS AND COMPETENCIES (TOP 5)

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## CRITICAL WORK FUNCTIONS

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- Approve the development of training programmes

### KEY TASKS

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- Lead external communications in response to product quality deviations and product recalls
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## JOB ROLES

- **Production Senior Technician/ Production Technician/Assistant Biotechnologist**
  - Page 44
- **Production Engineer/Biotechnologist**
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- **Production Executive**
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- **Production Team Supervisor**
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- **Production Manager**
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- **Production Director**
  - Page 54
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 the 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.”

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.

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**Critical Work Functions and 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 automatic 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

**COMPETENCIES**

**TECHNICAL SKILLS AND COMPETENCIES**

- Automated Operation Monitoring Level 3
- Automated Process Control Level 3
- Bioreactor Operation and Control Level 3
- Bioprocess Management Level 2
- Call 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**

**Key Tasks**

- Develop Standard Operating Procedures (SOPs) for materials management in the manufacturing facilities.
- Ensure 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.
- Ensure batches have been dispensed appropriately.

- 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.
- Ensure that, 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.

- Identify daily productivity, efficiency and volume targets that align with the master production plan.
- 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.

- 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.

- Analyse inventory levels against plans, escalating any potential supply gaps.
- Implement disposal procedures for degraded and contaminated materials.
- Ensure batches have been dispensed appropriately.
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- 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.

- 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.

- Track daily productivity, efficiency and volume targets that align with the master production plan.
- 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.
Production Engineer/Biotechnologist

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

**CRITICAL WORK FUNCTIONS**
- Improve production operations

**KEY TASKS**
- 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

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

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

**SKILLS AND COMPETENCIES**
- Automated Operation Monitoring: Level 3
- Automated Process Control: Level 3
- Bio reactor 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

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**
- Implement materials management procedures
- Clean equipment and facilities
- Produce pharmaceutical and nutritional products
- Produce biologics
- Improve production operations

**KEY TASKS**
- 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
- Approve lines for production after intra-product cleaning
- 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
- 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 bioreactor’s 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
- 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 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**

- **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
  - 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

- **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

**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 6
- 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 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

- Implement materials management procedures
- Manage production operations
- Improve production operations
- Manage risk and regulatory compliance

KEY TASKS

- 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
- 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
- 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
- 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**

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**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**

- Manage production operations
- Improve production operations
- Manage risk and regulatory compliance

**KEY TASKS**

- 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
- Foster a culture of cross-departmental collaboration and continuous improvement to drive operational excellence
- Approve improvement solutions and initiatives for the Production department
- 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
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**Production Director**

**Engineering and Maintenance**

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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.

For future entrants in the sector, he advises: “Working for a biopharmaceuticals manufacturing company gives me a high level of personal satisfaction because what we do matters.”
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

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**

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**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**

- Install equipment and systems
- Maintain equipment and systems
- Manage energy resources and utilities
- Manage the department

**KEY TASKS**

- 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
- 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 (CGMP) 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
- Oversee day-to-day operations of CGMP utility equipment and systems
- Monitor resolution of disruptions to energy resources and utilities supplies
- 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

### TECHNICAL SKILLS AND COMPETENCIES

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### GENERIC SKILLS AND COMPETENCIES (TOP 5)

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## 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

- **Manage the department**
- **Maintain equipment and systems**
- **Manage energy resources and utilities**
- **Validate equipment**

#### 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**
- Manage risk and regulatory compliance

**KEY TASKS**
- 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

**TECHNICAL SKILLS AND COMPETENCIES**

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**GENERAL SKILLS AND COMPETENCIES (TOP 5)**
- Automated Process Design Level 5
- Communication Advanced
- Business Continuity Management Level 5
- Interpersonal Skills Advanced
- Change Management Level 5

**SKILLS AND COMPETENCIES**

**CRITICAL WORK FUNCTIONS AND KEY TASKS**

**CRITICAL WORK FUNCTIONS**
- Manage energy resources and utilities

**KEY TASKS**
- 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

**CRITICAL WORK FUNCTIONS**
- Install equipment and systems

**KEY TASKS**
- 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

**CRITICAL WORK FUNCTIONS**
- Maintain equipment and systems

**KEY TASKS**
- 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
- 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

**CRITICAL WORK FUNCTIONS**
- Manage energy resources and utilities

**KEY TASKS**
- 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

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.
Engineering and Maintenance Engineer

CRITICAL WORK FUNCTIONS AND 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

CRITICAL WORK FUNCTIONS KEY TASKS

- Innovate equipment, systems and controls
- Validate equipment

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

SKILLS AND COMPETENCIES

Engineering and Maintenance Engineer
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.

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**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 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

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

SKILLS AND COMPETENCIES

TECHNICAL SKILLS AND COMPETENCIES

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

GENERIC SKILLS AND COMPETENCIES (TOP 5)

Communication
Decision Making
Interpersonal Skills
Problem Solving
Teamwork
### 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

**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

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### Critical Work Functions and 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
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<td>Continuous Improvement</td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Good Manufacturing</td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Practices Implementation</td>
<td>Level 5</td>
<td></td>
</tr>
<tr>
<td>Innovation Management</td>
<td>Level 6</td>
<td></td>
</tr>
<tr>
<td>Risk Management</td>
<td>Level 6</td>
<td></td>
</tr>
<tr>
<td>Strategy Development</td>
<td>Level 6</td>
<td></td>
</tr>
<tr>
<td>Technical Presentation</td>
<td>Level 6</td>
<td></td>
</tr>
</tbody>
</table>
Develop testing plans and procedures by determining...

Resolve conflicts by evaluating and implementing...

Develop business plans by reviewing existing resources...

Implement risk management strategies to support...

Integrate understanding of biopharmaceuticals...
Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

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

Overview of Technical Skills and Competencies

Technical Skills and Competencies (TSCs)

<table>
<thead>
<tr>
<th>TSC Category</th>
<th>TSC Title</th>
<th>TSC Description</th>
<th>Proficiency Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production</td>
<td>Automated Process Control</td>
<td>Use automated process control to reduce process variations and detect process deviations</td>
<td><img src="image" alt="Proficiency Levels" /></td>
</tr>
<tr>
<td>Bioreactor Operation and Control</td>
<td>Operate bioreactors in biopharmaceuticals manufacturing facilities</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Cell Culture</td>
<td>Maintain both microbial and mammalian cell cultures as pure cultures during the upstream stages of production</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Chromatography Equipment Operation and Control</td>
<td>Operate chromatography systems in biopharmaceuticals manufacturing facilities</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Cleaning and Sterilising</td>
<td>Clean and sterilise equipment, systems and materials for biopharmaceuticals production</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Emergency Shutdown and Restart</td>
<td>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</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Filtration Equipment Operation and Control</td>
<td>Operate filtration equipment in biopharmaceuticals manufacturing facilities</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Flexible Facilities Implementation</td>
<td>Facilitate implementation and changeover of flexible facilities, integrating single-use technologies with flexible manufacturing operations</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Good Manufacturing Practices Implementation</td>
<td>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</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Equipment Operation and Control</td>
<td>Operate production equipment ensuring optimal conditions for biopharmaceuticals manufacturing production</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Manufacturing Systems Operation and Control</td>
<td>Operate technical systems in the manufacturing of biopharmaceuticals</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Materials Management</td>
<td>Manage biopharmaceuticals materials and materials flow according to established procedures for meeting batch requirements</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Production Optimisation</td>
<td>Manage production processes and resources to maximise performance</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Production Planning</td>
<td>Execute the production plans to meet production targets and cycle time indices</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
<tr>
<td>Production Resource Management</td>
<td>Define productivity targets and allocate resources to support and synchronise production processes</td>
<td><img src="image" alt="Proficiency Levels" /></td>
<td></td>
</tr>
</tbody>
</table>
Review organisational objectives, policies, procedures, and standards of cleanliness.

Verify that processes are reproducible and consistent in testing biopharmaceutical products to ensure validation and regulatory compliance.

Implement documentation policies to facilitate the referencing of information for processes, systems and equipment, and to comply with regulatory requirements.

Validate processes and methods for achieving required standards of cleanliness.

Implement quality assurance procedures and conduct audits to ensure compliance.

Ensure that performance, quality, health, and safety standards are met.

Give leadership to achieve desired work results; Manage resources, set milestones and drive work.

Provide leadership, adapt and influence performance of self and others.

Accountable for achieving assigned objectives, decisions made by self and others.

Perform tasks to verify that residues and contaminants are at risk-free levels during the manufacture of subsequent products.

Ensure that performance, quality, health, and safety standards are met.

Maintain the desired level of compliance.

Perform tests to verify that biopharmaceutical packaging materials meet the desired quality standards.

Maintain the desired level of compliance.

Use discretion in identifying and responding to issues, work with others and contribute to work performance.

Use discretion in resolving issues or enquiries. Work without frequently looking to other for guidance.

Establish quality control procedures for biopharmaceuticals manufacturing processes, products, equipment and systems, to ensure the desired level of compliance at all stages.

Test raw materials and utilities before the start of biopharmaceuticals manufacturing processes to verify that they meet the desired quality standards.

Establish quality control procedures for biopharmaceuticals manufacturing processes, products, equipment and systems, to ensure the desired level of compliance at all stages.

Test raw materials and utilities before the start of biopharmaceuticals manufacturing processes to verify that they meet the desired quality standards.

Verify that processes are reproducible and consistent in testing biopharmaceutical products to ensure validation and regulatory compliance.

Implement quality assurance procedures and conduct audits to ensure compliance.

Accountable for achieving assigned objectives, decisions made by self and others.

Accountable for a broader set of tasks assigned.

Minimal discretion required. Expected to seek guidance.

Minimal discretion required. Expected to seek guidance.

May hold some accountability for performance of others, in addition to self.

Hold accountability for performances of self and others.

Hold accountability for performances of self and others.

Hold accountability for performances of self and others.

Perform tests to verify that residues and contaminants are at risk-free levels during the manufacture of subsequent products.

Ensure that performance, quality, health, and safety standards are met.

Maintain the desired level of compliance.

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### Overview of Generic Skills and Competencies

<table>
<thead>
<tr>
<th>GSC</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Communication</strong></td>
<td>Convey and exchange thoughts, ideas and information effectively through various mediums and approaches.</td>
</tr>
<tr>
<td><strong>Competencies</strong></td>
<td>Thinking, Computational, Developing, Decision Making</td>
</tr>
<tr>
<td><strong>Proficiency Levels</strong></td>
<td>Basic, Intermediate, Advanced</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Articulate and discuss ideas; engage in discussions; negotiate; consider and respond to different perspectives.</td>
</tr>
<tr>
<td><strong>Computational Thinking</strong></td>
<td>Develop and use computational models, tools and techniques to interpret and share ideas and applications.</td>
</tr>
<tr>
<td><strong>Creative Thinking</strong></td>
<td>Design new ideas or information in new ways and make connections between seemingly unrelated fields to create new ideas and applications.</td>
</tr>
<tr>
<td><strong>Decision Making</strong></td>
<td>Choose a course of action from various alternatives using a reasoned process to achieve intended goals.</td>
</tr>
<tr>
<td><strong>Developing People</strong></td>
<td>Help others to learn and develop their capabilities to enhance their performance and achieve personal and professional goals.</td>
</tr>
<tr>
<td><strong>Digital Literacy</strong></td>
<td>Use ICT tools, equipment and software to create, access and communicate information digitally with others.</td>
</tr>
<tr>
<td><strong>Global Mindset</strong></td>
<td>Awareness of diversity across global cultures and markets. Seek opportunities to adopt successful practices and ideas.</td>
</tr>
</tbody>
</table>

#### Proficiency Levels
- **Basic**: Understand the key concepts and apply them in straightforward situations.
- **Intermediate**: Analyse and evaluate information, applying the concepts in a variety of contexts.
- **Advanced**: Synthesize information, applying the concepts in complex and novel situations.

### Overview of Generic Skills and Competencies

<table>
<thead>
<tr>
<th>GSC</th>
<th>GSC Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interpersonal Skills</strong></td>
<td>Manage relationships efficiently and communicate with others effectively to achieve mutual consensus and outcomes.</td>
</tr>
<tr>
<td><strong>Leadership</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Lifelong Learning</strong></td>
<td>Seek out opportunities to enhance one’s knowledge and skills. Access and acquire new knowledge and skills actively for continual learning.</td>
</tr>
<tr>
<td><strong>Managing Diversity</strong></td>
<td>Work well with people from different ethnic, social, cultural and educational backgrounds and understand the concerns and interests of diverse work groups.</td>
</tr>
<tr>
<td><strong>Problem Solving</strong></td>
<td>Generate feasible and efficient solutions to solve problems and capitalise on new opportunities.</td>
</tr>
<tr>
<td><strong>Resource Management</strong></td>
<td>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 managing machines, money and materials.</td>
</tr>
</tbody>
</table>

#### Proficiency Levels
- **Basic**: Understand the key concepts and apply them in straightforward situations.
- **Intermediate**: Analyse and evaluate information, applying the concepts in a variety of contexts.
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Overview of Generic Skills and Competencies

Generic Skills and Competencies (GSCs)

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<thead>
<tr>
<th>GSC</th>
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<th>Proficiency Levels</th>
<th>Proficiency Levels</th>
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<th>Proficiency Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sense Making</td>
<td>Organise and analyse data and information accurately to identify relationships and hand service challenges with a positive mindset. Demonstrate an understanding of the organisation’s service vision, mission and values.</td>
<td>Beginner</td>
<td>Intermediate</td>
<td>Advanced</td>
<td></td>
</tr>
<tr>
<td>Service Orientation</td>
<td>Commit to exceeding both internal and external customer needs. Proactively identify customer needs and sustain a culture of service excellence within the organisation.</td>
<td>Beginner</td>
<td>Intermediate</td>
<td>Advanced</td>
<td></td>
</tr>
<tr>
<td>Teamwork</td>
<td>Work collaboratively and effectively with others to contribute to group efforts to achieve identified objectives.</td>
<td>Beginner</td>
<td>Intermediate</td>
<td>Advanced</td>
<td></td>
</tr>
<tr>
<td>Transdisciplinary Thinking</td>
<td>Understanding of concepts across multiple disciplines, with the capacity to synthesise the knowledge and insights to guide decisions and foster cooperation.</td>
<td>Beginner</td>
<td>Intermediate</td>
<td>Advanced</td>
<td></td>
</tr>
<tr>
<td>Virtual Collaboration</td>
<td>Use online collaborative communication tools to work as teams to accomplish tasks or projects.</td>
<td>Beginner</td>
<td>Intermediate</td>
<td>Advanced</td>
<td></td>
</tr>
</tbody>
</table>

We would like to thank the following organisations and partners for their support and contributions in the development and validation of the Skills Framework for Biopharmaceuticals Manufacturing:

- Abbott Manufacturing (Singapore) Pte Ltd
- AbbVie Pte Ltd
- Alcon Manufacturing and Logistics Pte Ltd
- Amgen Singapore Manufacturing Pte Ltd
- GlaxoSmithKline Biologicals Pte Ltd
- Glaxo Wellcome Manufacturing Pte Ltd
- Kaneka Singapore Co Pte Ltd
- Lanza Biologics Tuas Pte Ltd
- Mead Johnson (SI) Pte Ltd
- MSD International GmBH (Singapore)
- Novartis Singapore Pharmaceutical Manufacturing Pte Ltd
- Pfizer Asia Pacific Pte Ltd
- Roche Singapore Technical Operations Pte Ltd
- Sanofi Aventis Singapore Pte Ltd
- Shire Singapore Pte Ltd
- Wyeth Nutritional (SI) Pte Ltd

In addition, we would like to express our gratitude to the following stakeholders and partners for their contribution to the development of the Skills Framework for Biopharmaceuticals Manufacturing:

- Organisations that have provided the necessary information and assisted in the validation
- Individuals who have agreed to share their personal career stories
- The Unions who have provided their views and support on behalf of their members
- The Industry Association and Professional Bodies for sharing their business and members’ perspectives
- Various Government and Government-Linked Agencies for their assistance
- Education and Training Providers for the inputs on skills and competencies development
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

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

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

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.

Legend:
- Denotes vertical career progression
- Denotes lateral (cross-functional) career progression

...