| SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING<br>SKILLS MAP – QUALITY ASSURANCE AND QUALITY CONTROL DIRECTOR | | |
|---|---|---|
| **Sector** | Biopharmaceuticals Manufacturing | |
| **Track** | Quality Assurance and Quality Control (QA&QC) | |
| **Occupation** | Director | |
| **Job Role** | Quality Assurance and Quality Control Director | |
| | 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.<br><br>The Quality Assurance and Quality Control Director possesses excellent leadership skills and is able develop capabilities, build strong teams and engage internal and external stakeholders. He is adept at inspiring and driving a culture of innovation and continuous improvement within and beyond the department to enhance the overall quality of the organisation's products. He possesses the competitive drive to bring the organisation's quality standards to global recognition. | |
| **Critical Work Functions and Key Tasks** | **Critical Work Functions** | **Key Tasks** |
| | Manage quality assurance and quality control operations | Establish department strategies and operating structures to support business objectives and priorities |
| | | Establish long-term goals for the Quality Assurance and Quality Control (QA&QC) departments that align with the vision and strategy of the organisation |
| | | Work with teams to translate business strategies into annual performance goals and departmental objectives |
| | | Review and approve final QA&QC procedures, and associated department capabilities, ensuring alignment with organisational strategies and priorities |
| | | Deliver timely and accurate reports on Quality activities and Key Performance Indicators (KPIs) to senior management and leadership teams |
| | | Allocate budgets to the QA&QC departments , and monitor cost-effectiveness to optimise resources and prioritise spending |
| | | Establish the organisation's external reputation with regulatory agencies and industry groups |

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| | Optimise quality and efficiency of department workflows and activities | Review and approve all quality policies and procedures, ensuring alignment with organisational strategy and priorities |
| | | Foster a plant-wide culture that embraces concepts of Quality Risk Management and Quality by Design |
| | | Establish cross-department strategies and mechanisms to drive continuous improvement of QA&QC activities |
| | | Build a culture of innovation within the QA&QC departments to encourage continuous improvement |
| | | Review and approve recommendations on significant changes that need to be made to resources, procedures, systems, equipment, and technology |
| | | Maintain business accountability for overall workflow improvements in the QA&QC departments |
| | Facilitate registration and release of biopharmaceutical products | Approve final product registration documentation |
| | | Liaise with internal and external stakeholders to obtain product registration and approval |
| | | Endorse batches for release |
| | Facilitate achievement of quality expectations and standards | Approve product recalls |
| | | Lead external communications in response to product quality deviations and product recalls |
| | | Monitor the implementation of improvements to address identified product quality issues |
| | | Develop policies for internal and external audits in line with the organisation's guidelines and regulatory requirements |
| | | Approve revisions to procedures and processes based on audit results |
| | | Determine training strategies for QA&QC for personnel in manufacturing facilities |
| | | Approve the development of training programmes |

| **Skills and Competencies** | **Technical Skills and Competencies** | | **Generic Skills and Competencies (Top 5)** | |
|---|---|---|---|---|
| | Big Data Analysis | Level 5 | Decision Making | Advanced |
| | Biorisk Management | Level 5 | Developing People | Advanced |
| | Budgeting | Level 5 | Leadership | Advanced |
| | Business Continuity Management | Level 5 | Resource Management | Advanced |
| | Business Networking | Level 5 | Transdisciplinary Thinking | Advanced |
| | Business Performance Management | Level 5 | | |
| | Business Planning | Level 5 | | |
| | Change Management | Level 5 | | |
| | Chemical Risk Management | Level 5 | | |
| | Conflict Resolution | Level 5 | | |

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| | Continuous Improvement | Level 5 | |
| | Good Manufacturing Practices Implementation | Level 5 | |
| | Innovation Management | Level 6 | |
| | Project Management | Level 6 | |
| | Quality Assurance Management | Level 6 | |
| | Quality Control Management | Level 6 | |
| | Risk Management | Level 5 | |
| | Strategy Development | Level 5 | |
| | Systems Thinking | Level 5 | |
| | Technical Presentation | Level 6 | |
| **Programme Listing** | For a list of Training Programmes available for the Biopharmaceuticals Manufacturing sector, please visit: www.skillsfuture.sg/skills-framework/biopharmmfg | | |

The information contained in this document serves as a guide.