

| SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY ASSURANCE ASSISTANT | | |
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| Sector | Biopharmaceuticals Manufacturing | |
| Track | Quality Assurance and Quality Control (QA&QC) | |
| Occupation | Technician | |
| Job Role | Quality Assurance Assistant | |
| Job Role Description | <p>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.</p> <p>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.</p> | |
| Critical Work Functions and Key Tasks | Critical Work Functions | Key Tasks |
| | Validate manufacturing methods and processes | Collect information and data required for validation activities in line with Standard Operating Procedures (SOPs) |
| | | Assist with the monitoring of manufacturing processes, according to validation plans and schedules |
| | | Collate information for product and process quality metric management reports |
| | Facilitate achievement of quality expectations and standards | Collect information on quality records and follow-up actions to support internal and external audits |
| | | Record results of internal and external audits |
| | Manage document control procedures | File electronic and hardcopy documents according to standard procedures and requirements |
| | | Organise information in the document management system, ensuring its accuracy and accessibility by appropriate stakeholders |
| | | Track document updates and distribution |
| | | Prepare information needed for audits of the documentation management system |

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| | 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 | | |
| Skills and Competencies | Technical Skills and Competencies | | Generic Skills and Competencies (Top 5) | |
| | Analytical Method Validation | Level 2 | Computational Thinking | Basic |
| | Audit Management | Level 3 | Digital Literacy | Basic |
| | Change Management | Level 3 | Problem Solving | Intermediate |
| | Cleaning Validation | Level 3 | Service Orientation | Intermediate |
| | Continuous Improvement | Level 3 | Teamwork | Basic |
| | Document Control | Level 2 | | |
| | Good Manufacturing Practices Implementation | Level 3 | | |
| | Health, Safety and Environment Procedures Implementation | Level 2 | | |
| | Innovation Management | Level 3 | | |
| | Packaging Validation | Level 3 | | |
| | Process Monitoring | Level 3 | | |
| | Process Validation | Level 2 | | |
| | Project Management | Level 3 | | |
| | Systems Thinking | Level 3 | | |
| Technical Report Writing | Level 3 | | | |
| Programme Listing | For a list of Training Programmes available for the Biopharmaceuticals Manufacturing sector, please visit: www.skillsfuture.sg/skills-framework/biopharmmgf | | | |

The information contained in this document serves as a guide.