SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY ASSURANCE SPECIALIST		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Analyst	
Job Role	Quality Assurance Specialist	
Job Role Description	The Quality Assurance Specialist implements validation processes to identify deviations and potential risks in the manufacturing processes. He/She is responsible for first-line verification of quality standards in the organisation and supports the product release and registration process by collaborating with other departments to gather relevant information. In addition, he assists in audits, handles quality queries, delivers quality-related training, and is responsible for ensuring that documents are organised and managed according to standard procedures and requirements. The Quality Assurance Specialist communicates with customers on product enquiries and develops practical solutions to implement workflow improvements and enhance department operations. The Quality Assurance Specialist is meticulous and systematic in carrying out his tasks, and exercises critical and analytical thinking to identify discrepancies in processes and resolve problems. He applies communication and teamwork skills to interact effectively with others to achieve organisational objectives.	
Critical Work Functions and Key Tasks	**Critical Work Functions**	**Key Tasks**
	Validate manufacturing methods and processes	Implement validation processes to review systems, methods and processes utilised in manufacturing facilities
		Verify that manufacturing processes are performed in line with established standards and in accordance with validation plans
		Implement the organisation's operational excellence model for validation of manufacturing methods and processes
		Identify deviations and potential risks in manufacturing systems, processes and methods, and their possible causes
		Communicate results of Corrective and Preventative Actions (CAPAs) to relevant stakeholders
		Compile quality metric data required for management reporting and prepare sections of quality metric reports
	Facilitate registration and release of biopharmaceutical products	Consolidate and ensure data integrity of information and materials for product registration reports
		Assist in the generation of Certificates of Analysis
		Collaborate with other departments to collect and organise information required for batch releases
	Facilitate achievement of quality	Record details of customer complaints and the organisation's responses
		Support traceability investigations of customer complaints

	expectations and standards	Present quality records and follow-up actions during internal and external audits
		Identify areas of improvement from audit results
		Assist in the delivery of training
		Collect data on training outcomes and effectiveness
	Manage document control procedures	Check that electronic and hardcopy documents are organised and managed according to Standard Operating Procedures (SOPs) and requirements
		Oversee the update and distribution of documents
		Review the formatting and editing of documents according to guidelines and templates
		Perform document control audits to analyse adequacy and alignment with requirements
		Record results of document control audits
	Optimise quality and efficiency of department workflows and activities	Implement Quality Assurance (QA) policies and procedures
		Assess the quality and efficiency of QA procedures to identify areas for improvement
		Translate improvement ideas and proposals into practical solutions
		Gather information to support feasibility assessments of introducing new procedures and improvements for QA activities
		Implement workflow improvements to improve efficiency
		Record improvement activities taken and reductions and improvements achieved

Skills and Competencies	**Technical Skills and Competencies**		**Generic Skills and Competencies (Top 5)**	
	Analytical Method Validation	Level 3	Communication	Basic
	Audit Management	Level 3	Interpersonal Skills	Basic
	Change Management	Level 4	Problem Solving	Basic
	Cleaning Validation	Level 3	Sense Making	Intermediate
	Computer Systems Validation	Level 3	Teamwork	Basic
	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	
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.