SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY ASSURANCE MANAGER		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Manager	
Job Role	Quality Assurance Manager	
Job Role Description	The Quality Assurance Manager translates the long-term goals for Quality Assurance (QA) into tactical plans while maintaining oversight of the department's operational and financial status. He/She endorses the Standard Operating Procedures (SOPs) for plants and reviews validation plans and procedures, ensuring alignment with Current Good Manufacturing Practices (CGMPs) and regulatory requirements, respectively. He defines the information required for new product registrations and facilitates registration applications to obtain approval for the release of biopharmaceutical products. He is responsible for building department personnel capability by initiating training programmes, and developing strategies to facilitate operational improvements for the department. The Quality Assurance Manager is responsible for all QA activities within the organisation. He is therefore required to have deep knowledge of regulatory requirements and expertise pertaining to verification of product and process quality for product release. The Quality Assurance Manager is a leader who provides clear guidance on critical work activities and deliverables, and has the foresight to develop skills and capabilities within and beyond the department to optimise resources, talent and overall performance. He also has the ability to develop creative solutions to resolve problems.	
Critical Work Functions and Key Tasks	**Critical Work Functions**	**Key Tasks**
	Validate manufacturing methods and processes	Review and endorse validation Standard Operating Procedures (SOPs) and plans, ensuring alignment with regulatory requirements, Current Good Manufacturing Practices (CGMPs) requirements and the organisation's policies
		Devise an operational excellence model for validation of manufacturing methods and processes
		Oversee investigations into major process deviations to determine root causes
		Evaluate the impact of process deviations on production operations and the need for Corrective and Preventative Actions (CAPAs)
		Review product and process quality metric reports
	Facilitate registration and release of biopharmaceutical products	Define the information required and data integrity standards for new product registrations
		Review and monitor product registration applications, ensuring alignment with regulatory requirements and other changes that may impact a product's registration status

		Endorse Certificates of Analysis
		Approve batches for forward processing
	Facilitate achievement of quality expectations and standards	Liaise with customers in the event of major product quality deviations and product recalls
		Determine the extent of the plant's control over quality deviation
		Initiate product recall procedures and determine responsibilities and accountabilities of impacted organisational personnel
		Approve improvements to address identified product quality issues
		Translate internal and external audit policies into procedures and checks to be followed
		Review audit results and the proposed changes to procedures
		Develop training programmes for CGMPs, regulatory and other requirements in line with the training strategy
		Introduce additional training programmes to address gaps identified from audits and checks
	Optimise quality and efficiency of department workflows and activities	Design Quality Assurance (QA) policies to prevent issues that could lead to sub-optimal product quality
		Develop strategies for the QA department to encourage continuous improvement of QA procedures, activities and workflow management
		Recommend changes to resources, procedures, systems, equipment, and technology within the QA department
		Monitor effectiveness of improvements and changes made to QA activities and workflows
	Manage Quality department operations	Communicate and implement QA strategies, objectives, policies and processes
		Translate long-term goals for the QA department into tactical plans
		Set and communicate individual objectives and review and assess the performance of direct reports
		Direct capability development roadmaps and programmes for the QA department
		Coordinate department resources to ensure adequate staffing and capability levels
		Maintain oversight of the completion of all QA tasks, ensuring proper documentation, progress tracking and reporting
		Monitor the QA department's financial inflows and outflows against allocated budgets and forecasts

	Technical Skills and Competencies		Generic Skills and Competencies (Top 5)	
Skills and Competencies	Analytical Method Validation	Level 5	Decision Making	Advanced
	Audit Management	Level 5	Interpersonal Skills	Advanced
	Budgeting	Level 4	Leadership	Intermediate
	Business Continuity Management	Level 5	Problem Solving	Advanced
	Business Performance Management	Level 5	Resource Management	Advanced
	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		
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.