

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY CONTROL MANAGER		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Manager	
Job Role	Quality Control Manager	
Job Role Description	<p>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 Practice (GLP) 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.</p> <p>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.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Monitor product quality compliance	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
	Manage laboratory operations	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
	Manage conformance to cleanliness standards	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		

	Optimise quality and efficiency of department workflows and activities	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		
	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		
Skills and Competencies	Technical Skills and Competencies		Generic Skills and Competencies (Top 5)	
	Biorisk Management	Level 5	Decision Making	Advanced
	Budgeting	Level 4	Developing People	Advanced
	Business Continuity Management	Level 5	Leadership	Advanced
	Business Performance Management	Level 5	Problem Solving	Advanced
	Change Management	Level 5	Transdisciplinary Thinking	Advanced
	Chemical Risk Management	Level 5		
	Cleanliness Testing	Level 5		
	Conflict Resolution	Level 5		
	Continuous Improvement	Level 5		
	Good Manufacturing Practices Implementation	Level 5		

	Hazards 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 Utilities Testing	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/biopharmmmfg		

The information contained in this document serves as a guide.