SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY CONTROL LABORATORY ANALYST/CHEMIST/MICROBIOLOGIST		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Analyst	
Job Role	Quality Control Laboratory Analyst/Chemist/Microbiologist	
Job Role Description	The Quality Control Laboratory Analyst/Chemist/Microbiologist monitors sampling, cleanliness and product quality testing activities, performs non-standard quality tests, and manages associated documentation and data. He/She identifies the operating criteria for the tools, equipment and materials to be used, and collaborates with the Engineering and Maintenance department to ensure that laboratory equipment and infrastructure function as required. In addition, he/ implements Standard Operating Procedures (SOPs) and workflow improvements in the laboratory. The Quality Control Laboratory Analyst/Chemist/Microbiologist works in a laboratory setting, primarily in a cleanroom environment, and may be required to work on a shift. He has to exercise critical and analytical thinking to review data and identify discrepancies against set criteria. He requires strong communication and teamwork to collaborate effectively with others in order to fulfil work objectives.	
Critical Work Functions and Key Tasks	**Critical Work Functions**	**Key Tasks**
	Perform sampling	Identify sampling tools, equipment and materials needed for sampling
		Perform appropriate actions for any abnormal occurrences affecting sampling conditions
		Guide sample collection activities in compliance with specified procedures
		Oversee the handling, storage and preservation of samples in accordance with Standard Operating Procedures (SOPs)
		Verify sampling conditions and related information are accurately documented
	Monitor product quality compliance	Implement processes for testing the quality of products and associated materials and packaging
		Check testing tools, equipment and materials for alignment with regulatory guidelines and protocols
		Perform routine and non-standard tests on materials and products
		Guide testing activities to ensure correct testing volumes, conditions and processes are used
		Analyse testing results and the frequency and severity of product defects and quality lapses

		Check Quality Control (QC) testing activities for compliance with Quality and Health, Safety and Environment (HSE) procedures
	Manage laboratory operations	Implement the organisation's operational excellence model for laboratory work
		Perform inspections and tests on laboratory infrastructure, equipment and utilities
		Collaborate with the Engineering and Maintenance department and vendors to ensure functionality of infrastructure and equipment
		Verify that calibration requirements for laboratory equipment are met
		Verify data integrity and records and perform data analysis
	Manage conformance to cleanliness standards	Verify that the correct materials, chemicals and equipment required to test cleanliness have been prepared
		Implement testing procedures and acceptance criteria for cleaned and sterilised items and equipment
		Verify that checks for particulates and contaminants have been completed
		Investigate cleanliness or hygiene lapses to trace sources of contamination
		Implement guidelines and indicators for testing of disposed waste
		Verify the safety of waste for disposal and testing
	Optimise quality and efficiency of department workflows and activities	Implement SOPs in the laboratory
		Compile data to support business and performance metrics reporting
		Prepare for and participate in laboratory inspections and audits
		Propose solutions to improve QC procedures, activities and workflows
		Gather information to support feasibility assessments of introducing new QC procedures, systems and equipment
		Implement workflow improvements to improve efficiency of workflow and activities
		Record improvement activities implemented and reductions and improvements achieved

Skills and Competencies	**Technical Skills and Competencies**		**Generic Skills and Competencies (Top 5)**	
	Biorisk Management	Level 3	Communication	Intermediate
	Change Management	Level 4	Computational Thinking	Intermediate
	Chemical Risk Management	Level 3	Decision Making	Intermediate
	Cleanliness Testing	Level 4	Problem Solving	Intermediate
	Conflict Resolution	Level 4	Sense Making	Intermediate
	Continuous Improvement	Level 4		

	Good Manufacturing Practices Implementation	Level 4	
	Hazards and Risk Identification and Management	Level 3	
	Health, Safety and Environment Procedures Implementation	Level 3	
	Innovation Management	Level 4	
	Laboratory Data Analysis	Level 3	
	Laboratory Management	Level 3	
	Packaging Testing	Level 4	
	Product Testing	Level 4	
	Project Management	Level 4	
	Raw Materials and Utilities Testing	Level 4	
	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.