

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY CONTROL ASSISTANT LABORATORY ANALYST		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Technician	
Job Role	Quality Control Assistant Laboratory Analyst	
Job Role Description	<p>The Quality Control Assistant Laboratory Analyst supports sampling, cleanliness and product quality testing activities by preparing tools, equipment and materials, as well as assisting in the execution of tests to identify products that do not meet specified quality requirements. He/She conducts laboratory tests to identify lapses in the plant's conformance to cleanliness or hygiene standards. He assists in the management of the quality control laboratory by performing routine monitoring and maintenance of laboratory infrastructure and equipment, recording laboratory data, and assisting in preparing the laboratory for audits.</p> <p>The Quality Control Assistant Laboratory Analyst works on a shift, in a cleanroom environment within a laboratory setting. He is structured and systematic, performing checks on materials at hand and verifying protocols to be used before executing quality control tasks in strict accordance to procedures. The QC Assistant Laboratory Analyst should have quick learning abilities to identify and apply areas of improvement within his own area of work. He is a good team player and applies basic analysis to identify issues and solve routine problems.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Perform sampling	Prepare sampling tools, equipment and materials
		Check suitability of sampling conditions according to guidelines
		Collect samples from identified points
		Preserve sample integrity using appropriate measures and procedures
		Document sampling conditions and activities
	Monitor product quality compliance	Prepare testing tools, equipment and materials
		Conduct chemical and microbiological tests on materials, products, and packaging
		Identify Out-of-Specification (OOS), deviations and quality problems of products, materials, packaging and utilities
		Report testing activities and results
Manage laboratory operations	Comply with Quality and Health, Safety and Environment (HSE) procedures when carrying out Quality Control (QC) tests	
	Follow the organisation's operational excellence model for laboratory work	
	Assist in monitoring and inspecting laboratory infrastructure, equipment and utilities	

		Raise equipment OOS issues and equipment purchase requests		
		Perform routine calibration and maintenance of laboratory equipment		
		Maintain integrity, accuracy and completeness of QC data and records		
	Manage conformance to cleanliness standards		Prepare materials, chemicals and equipment required to test cleanliness	
			Perform chemical testing for contamination of cleaned and sterilised items and equipment	
			Check for particulates and contaminants on equipment and surfaces in the production plant	
			Identify equipment, products and areas with cleanliness or hygiene lapses	
			Perform tests and checks on disposed waste	
	Optimise quality and efficiency of department workflows and activities		Assist in preparing for, and participate in laboratory inspections and audits	
			Identify opportunities to improve QC procedures and activities 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)
Biorisk Management		Level 2	Communication	Basic
Change Management		Level 3	Lifelong Learning	Basic
Chemical Risk Management		Level 2	Problem Solving	Basic
Cleanliness Testing		Level 3	Sense-Making	Basic
Continuous Improvement		Level 3	Teamwork	Basic
Good Manufacturing Practices Implementation		Level 3		
Hazards and Risk Identification and Management		Level 3		
Health, Safety and Environment Procedures Implementation		Level 2		
Innovation Management		Level 3		
Laboratory Data Analysis		Level 2		
Laboratory Management		Level 2		
Packaging Testing		Level 3		
Product Testing		Level 3		
Project Management		Level 3		
Raw Materials and Utilities Testing		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/biopharmfmg		

The information contained in this document serves as a guide.