

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – QUALITY CONTROL SENIOR LABORATORY ANALYST/SENIOR CHEMIST/SENIOR MICROBIOLOGIST		
Sector	Biopharmaceuticals Manufacturing	
Track	Quality Assurance and Quality Control (QA&QC)	
Occupation	Analyst	
Job Role	Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist	
Job Role Description	<p>The Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist develops sampling plans and procedures for testing product quality and cleanliness. He/She determines the optimal operating conditions for laboratory infrastructure and equipment, and investigates underlying causes, technical faults or practices that impact laboratory equipment operation. In addition, he develops Standard Operating Procedures (SOPs) for laboratories in line with Good Laboratory Practices (GLPs), and assesses the viability of introducing new or improved Quality Control procedures.</p> <p>The Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist oversees operations and activities in one or multiple laboratories within the manufacturing facility, and often in a cleanroom environment. He may be expected to work on a shift. He should possess excellent analytical skills and sound judgement in order to establish and communicate critical guidelines, parameters and procedures for laboratory operations, make key decisions and resolve any complex problems that emerge. Often working in a team and having to supervise and guide others, the Quality Control Senior Laboratory Analyst/Senior Chemist/Senior Microbiologist should have strong teamwork and communication skills.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Perform sampling	Develop sampling plans for Quality Control (QC) purposes
		Cascade guidelines for optimal sampling conditions to laboratory personnel
		Determine sample points and sample collection procedures
		Establish Standard Operating Procedures (SOPs) and conditions for the handling, storage and preservation of samples
		Review sampling documentation to identify anomalies and issues
	Monitor product quality compliance	Develop methods and indicators of success for the testing the quality of materials, products and packaging
Develop inspection and testing protocols for materials, products and packaging		
Verify alignment of testing activities and procedures with established protocols		
Conduct root cause analyses for product defects and quality lapses		

		Outline Health, Safety and Environment (HSE) procedures to adhere to during testing and validation			
	Manage laboratory operations	Facilitate the application of the organisation's operational excellence model in laboratory work			
		Specify the protocols for laboratory infrastructure, equipment and utilities to be inspected and tested			
		Investigate underlying causes, technical faults and practices that impact laboratory equipment operation and infrastructure functionality			
		Determine optimal calibration standards for laboratory equipment operation			
		Review reports and develop guidelines and standard practices for data documentation and analysis			
		Develop SOPs and conduct training for performing cleanliness tests, identification and removal of contamination sources			
	Manage conformance to cleanliness standards	Establish objectives and indicators for tests of cleanliness			
		Develop schedules for tests and inspections of cleaned and sterilised items and equipment			
		Outline processes and accountabilities for checking of particulates and contaminants			
		Develop SOPs for testing of disposed waste			
		Conduct training on waste disposal and testing procedures			
		Optimise quality and efficiency of department workflows and activities	Develop SOPs and infrastructure requirements for laboratories in line with Good Laboratory Practices (GLPs) requirements		
	Conduct training on SOP for laboratories				
	Review data to support business and performance metrics reporting				
	Articulate commissioning, certification and accreditation requirements for laboratories				
	Assess the feasibility and viability of introducing new and improved QC procedures, systems and equipment				
	Oversee the introduction of new workflow improvements to improve efficiency				
	Implement initiatives to encourage improvement of QC procedures, activities and workflows				
	Review results from improvement activities				
	Skills and Competencies	Technical Skills and Competencies		Generic Skills and Competencies (Top 5)	
		Big Data Analysis	Level 3	Communication	Advanced
		Biorisk Management	Level 4	Decision Making	Advanced
		Change Management	Level 4	Interpersonal Skills	Advanced
Chemical Risk Management		Level 4	Leadership	Intermediate	
Cleanliness Testing		Level 4	Problem Solving	Advanced	
Conflict Resolution		Level 4			

	Continuous Improvement	Level 4	
	Good Manufacturing Practices Implementation	Level 4	
	Hazards and Risk Identification and Management	Level 4	
	Health, Safety and Environment Procedures Implementation	Level 4	
	Innovation Management	Level 4	
	Laboratory Data Analysis	Level 4	
	Laboratory Management	Level 4	
	Packaging Testing	Level 4	
	Product Testing	Level 4	
	Project Management	Level 4	
	Quality Control 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.