

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP –ENGINEERING AND MAINTENANCE ENGINEER		
Sector	Biopharmaceuticals Manufacturing	
Track	Engineering and Maintenance	
Occupation	Engineer	
Job Role	Engineering and Maintenance Engineer	
Job Role Description	<p>The Engineering and Maintenance Engineer applies engineering principles and techniques to optimise the equipment and systems within the manufacturing facility. He/She provides technical guidance and direction for the installation of equipment and systems. He develops plans for the maintenance of equipment and systems, and recommends engineering solutions to troubleshoot faults. The Engineering and Maintenance Engineer innovates equipment and systems, and contributes to manufacturing equipment and systems improvement projects by conducting feasibility assessments and tests on new technologies. He is also expected to manage energy resources and utilities by developing solutions to optimise machine availability and energy efficiency. The Engineering and Maintenance Engineer must ensure compliance with Standard Operating Procedures (SOPs), Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) within his purview. He develops guidelines and conducts equipment qualification and validation in line with biopharmaceuticals manufacturing regulatory requirements.</p> <p>The Engineering and Maintenance Engineer should possess an enquiring and analytical mind and have a knack for investigating issues, analysing multifaceted engineering problems and developing solutions. He must also be a strong team player who can guide and mentor others, and communicate technical advices and solutions to colleagues beyond the team.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Install equipment and systems	Perform feasibility studies and cost-benefit analysis on the introduction of new equipment
		Recommend equipment to be installed
		Develop technical installation, assembly, integration and engineering plans for equipment and systems
		Provide technical guidance and directions on the installations and assembly of new equipment
		Verify that all installations and assembly works conform to technical specifications
		Check that installations and assembly documentations and records are aligned with engineering plans
	Maintain equipment and systems	Review equipment conditions and non-destructive testing data to support schedule for maintenance activities
Facilitate the Maintenance Excellence Programme (MEP) for the manufacturing facility		
Develop maintenance and spare parts plans and Standard Operating Procedures (SOPs) for all equipment and systems		

		Establish plans, guiding procedures, and parameters for equipment and systems testing and repair			
		Recommend repair works and solutions to address equipment and system failures			
		Conduct root cause analysis of equipment and system failures and malfunctions			
		Analyse testing, maintenance and repair records to identify trends, potential malfunctions and solutions applied			
		Outline cleaning procedures and cleanliness standards to be adhered to following maintenance and repair works			
	Manage energy resources and utilities	Evaluate energy resources and utilities usage requirements for the plant			
		Establish requirements for energy resources and utilities supply and operational standards			
		Develop technical guidelines to resolve disruptions to energy resources and utilities supply			
		Analyse data to identify areas where energy efficiency can be optimised			
		Develop solutions to optimise machine availability while managing energy resources and utilities			
	Innovate equipment, systems and controls	Conduct feasibility assessments for new automated equipment, systems and controls			
		Install and calibrate automated equipment and system components			
		Troubleshoot system bugs or malfunctions of automated equipment and systems			
		Review performance of automated equipment and systems to identify modifications required			
	Validate equipment	Keep abreast of regulatory changes and their implications on equipment usage			
		Develop protocols and parameters for equipment qualifications and validations			
		Perform equipment qualifications and validations to verify their conditions and performances			
		Develop equipment qualifications and validations reports			
	Skills & Competencies	Technical Skills & Competencies		Generic Skills & Competencies (Top 5)	
		Automated Equipment and Control Systems Configuration	Level 4	Communication	Intermediate
Automated Process Control		Level 4	Decision Making	Intermediate	
Automated Process Design		Level 4	Interpersonal Skills	Intermediate	
Big Data Analysis		Level 3	Problem Solving	Intermediate	
Change Management		Level 4	Teamwork	Intermediate	
Cleaning and Sterilising		Level 3			
Computer Systems Validation		Level 4			
Conflict Resolution		Level 4			

	Continuous Improvement	Level 4	
	Engineering Drawing	Level 3	
	Equipment and Systems Repair	Level 4	
	Equipment Qualification	Level 3	
	Facility Maintenance	Level 4	
	Flexible Facilities Implementation	Level 4	
	Good Manufacturing Practices Implementation	Level 4	
	Green Manufacturing Design and Implementation	Level 3	
	Health, Safety and Environment Procedures Implementation	Level 3	
	Innovation Management	Level 4	
	Manufacturing Equipment Operation and Control	Level 4	
	Manufacturing Systems Operation and Control	Level 4	
	Preventive Maintenance	Level 4	
	Process Analytical Technology Implementation	Level 3	
	Process Optimisation	Level 3	
	Systems Thinking	Level 4	
	Technical Presentation	Level 4	
	Technical Report Writing	Level 4	
	Test Planning	Level 4	
	Utilities Management	Level 4	
	Vendor Management	Level 4	
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.