

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – PROCESS DEVELOPMENT/MS&T ENGINEER		
Sector	Biopharmaceuticals Manufacturing	
Track	Process Development/Manufacturing Science and Technology (MS&T)	
Occupation	Engineer	
Job Role	Process Development/MS&T Engineer	
Job Role Description	<p>The Process Development/MS&T Engineer supports process development, monitoring and improvement activities for the biopharmaceuticals manufacturing facilities. He/She will analyse the critical material attributes of biopharmaceutical products, prepare Process Flow Diagrams (PFD), perform pilot tests and support technology transfer activities. He also assists in developing and updating Standard Operating Procedures (SOPs) for the manufacturing facility and supporting the delivery of associated training. The Process Development/MS&T Engineer should have deep understanding of the engineering and scientific concepts underlying the manufacture of the biopharmaceutical product and equipment involved in order to make significant contributions in determining how the product is made within the manufacturing facilities.</p> <p>The Process Development/MS&T Engineer should have a passion for innovation and continuous improvement and he applies this to his work, driving efficiency and improvement in new and existing manufacturing processes. He must be able work independently and exercise analytical and innovative thinking to analyse information, solve problems and improve existing methods and processes.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Design biopharmaceuticals manufacturing processes	Use Quality by Design (QbD) principles and procedures to guide process design work
		Define the critical material attributes of the final products that must be controlled to meet the target products quality profiles
		Develop a Process Flow Diagram (PFD)
		Review technologies for transfer and scale-up of the manufacturing processes
		Propose possible process control, sampling and monitoring points and related performance parameters to achieve the critical material attributes of the final products
		Analyse the functionality of different process control, sampling and monitoring systems and technologies
		Design the layouts of equipment and systems for the manufacturing facilities in collaboration with the Engineering and Maintenance department
		Conduct process modelling to identify risks in the proposed manufacturing processes and propose mitigation actions

	Implement technology transfer	Prepare protocols for pilot tests		
		Conduct pilot tests and re-trials as necessary		
		Analyse results of pilot tests and re-trials to verify the new or improved manufacturing processes are robust and repeatable		
		Maintain records of manufacturing process pilot tests performed		
		Support the development of implementation plans for technology transfer		
		Prepare Standard Operating Procedures (SOPs) for new or improved manufacturing processes in line with Current Good Manufacturing Practices (CGMPs)		
		Support delivery of training on approved SOPs		
		Support the transfer of scaled-up manufacturing processes to new facilities		
	Conduct ongoing validation of existing manufacturing processes	Monitor manufacturing process performance using Process Analytical Technology (PAT) and other methods		
		Perform statistical analysis and modelling using manufacturing performance data		
		Identify gaps, problems or sub-optimal performance in existing processes and their potential causes		
		Identify Corrective and Preventive Actions (CAPA) to address out-of-control processes		
	Innovate existing manufacturing processes	Research ways to innovate and optimise manufacturing processes and equipment		
		Assess the functionality of new automated technologies, flexible facilities, single-use systems and other manufacturing equipment		
		Propose alternative sources for raw materials that will reduce costs or improve reliability and quality of the final products		
		Use process modelling to identify gaps and bottlenecks within existing manufacturing processes		
		Support implementation of improvements to manufacturing processes		
		Analyse manufacturing performance indicators such as production time, yield and defective rates after manufacturing process improvements have been implemented		
Skills & Competencies	Technical Skills & Competencies		Generic Skills & Competencies (Top 5)	
	Automated Process Design	Level 4	Communication	Basic
	Big Data Analysis	Level 3	Interpersonal Skills	Basic
	Biological Product Introduction	Level 4	Problem Solving	Basic
	Cell Culture	Level 4	Sense Making	Basic
	Change Management	Level 4	Teamwork	Basic

	Conflict Resolution	Level 4	
	Continuous Improvement	Level 4	
	Facility Design	Level 4	
	Flexible Facilities Implementation	Level 4	
	Good Manufacturing Practices Implementation	Level 4	
	Green Manufacturing Design and Implementation	Level 4	
	Innovation Management	Level 4	
	Laboratory Data Analysis	Level 3	
	Manufacturing Process Design	Level 4	
	Pharmaceutical and Nutritional Product Introduction	Level 4	
	Pharmacovigilance Integration	Level 4	
	Process Analytical Technology Implementation	Level 3	
	Process Modelling	Level 4	
	Process Monitoring	Level 4	
	Process Optimisation	Level 4	
	Process Validation	Level 3	
	Product Improvement	Level 3	
	Project Management	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/biopharmmmfg		

The information contained in this document serves as a guide.