

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – PROCESS DEVELOPMENT/MS&T SENIOR ENGINEER		
Sector	Biopharmaceuticals Manufacturing	
Track	Process Development/Manufacturing Science and Technology (MS&T)	
Occupation	Engineer	
Job Role	Process Development/MS&T Senior Engineer	
Job Role Description	<p>The Process Development/MS&T Senior Engineer leads the technical development, monitoring and improvement activities for biopharmaceuticals manufacturing processes within the facilities. He/She oversees the design and piloting of new processes and associated manufacturing facility layouts. The Process Development/MS&T Senior Engineer is the go-to technical expert for manufacturing processes across the facilities. He reviews the Standard Operating Procedures (SOPs) for manufacturing processes, collaborates with other departments to deliver training and implements technology transfer.</p> <p>The Process Development/MS&T Senior Engineer works primarily in production lines within the manufacturing facilities. He has a passion for innovation and continuous improvement and thoroughly enjoys critically analysing existing manufacturing processes in order to identify improvements or rectify deviations. He has strong communication and teamwork skills in order to successfully implement new and improved manufacturing processes in consultation and collaboration with other stakeholders.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Design biopharmaceuticals manufacturing processes	Lead Quality by Design (QbD) initiatives and coach others on incorporating principles into design activities
		Determine the processes required to manufacture new biopharmaceutical products from the critical material attributes
		Review Process Flow Diagrams (PFD)
		Determine methods and technologies for transfer and scale-up of the manufacturing processes
		Determine process control, sampling and monitoring points and related performance parameters required to achieve the critical material attributes of the final products
		Determine the functionality needed from process control, sampling and monitoring systems and technologies and collaborate with the Engineering and Maintenance department to select equipment
		Review facility layout designs
		Review process modelling results to detect risks of the proposed manufacturing processes and alter the design as necessary
	Implement technology transfer	Review protocols for pilot tests
Oversee conduct of pilot tests and re-trials		

		Review results of pilot tests and re-trials against target products quality profiles and regulatory requirements			
		Refine process designs as needed following piloting activities			
		Develop implementation plans for technology transfer			
		Review Standard Operating Procedures (SOPs) for new improved manufacturing processes and ensure alignment with Current Good Manufacturing Practices (CGMPs)			
		Deliver training on approved SOPs in collaboration with the Production department			
		Facilitate technology transfer and scale-up activities and provide technical troubleshooting expertise as required			
	Conduct ongoing validation of existing manufacturing processes	Define process performance parameters for monitoring using Process Analytical Technology (PAT) and other methods			
		Develop advanced statistical models and parameters for analysis of manufacturing performance data			
		Review key findings from analyses of manufacturing process performance data and their implications			
		Review implementation of Corrective and Preventive Actions (CAPA) to address out-of-control processes, ensuring objectives have been achieved			
	Innovate existing manufacturing processes	Design technical innovations to optimise manufacturing processes and equipment			
		Set guidelines for assessing the technical viability of new automated technologies, flexible facilities, single-use systems and other manufacturing equipment			
		Select alternative sources of raw materials for manufacturing processes			
		Devise technical solutions to address gaps and bottlenecks within existing manufacturing processes			
		Lead the implementation of improvements to manufacturing processes from a technical and product quality perspective			
		Monitor the impact of manufacturing process improvements			
	Skills & Competencies	Technical Skills & Competencies		Generic Skills & Competencies (Top 5)	
		Automated Process Design	Level 5	Communication	Intermediate
Big Data Analysis		Level 4	Decision Making	Intermediate	
Biological Product Introduction		Level 5	Problem Solving	Intermediate	
Cell Culture		Level 5	Sense Making	Intermediate	
Change Management		Level 4	Teamwork	Intermediate	
Conflict Resolution		Level 4			
Continuous Improvement		Level 5			
Facility Design		Level 5			

	Flexible Facilities Implementation	Level 5	
	Good Manufacturing Practices Implementation	Level 5	
	Green Manufacturing Design and Implementation	Level 5	
	Innovation Management	Level 5	
	Laboratory Data Analysis	Level 4	
	Manufacturing Process Design	Level 5	
	Pharmaceutical and Nutritional Product Introduction	Level 5	
	Pharmacovigilance Integration	Level 5	
	Process Analytical Technology Implementation	Level 5	
	Process Modelling	Level 5	
	Process Monitoring	Level 5	
	Process Optimisation	Level 5	
	Process Validation	Level 5	
	Product Improvement	Level 4	
	Systems Thinking	Level 5	
	Technical Presentation	Level 5	
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.