

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP - PRODUCTION ENGINEER/BIOTECHNOLOGIST		
Sector	Biopharmaceuticals Manufacturing	
Track	Production	
Occupation	Engineer	
Job Role	Production Engineer/Biotechnologist	
Job Role Description	<p>The Production Engineer/Biotechnologist oversees the operations and monitoring of manufacturing equipment on a section of a production line. He/She develops Standard Operating Procedures (SOPs) for handling materials and operating equipment in the facilities and inspects production anomalies or lapses. He independently performs and ensures the proper handling of biopharmaceutical materials and cleaning and sterilisation activities within the facilities whilst guiding junior staff in their support roles. The Production Engineer/Biotechnologist must adhere to Health, Safety and Environment (HSE) regulations and Current Good Manufacturing Practices (CGMPs) to ensure employee safety and product quality. He should have the technical expertise to work with both automated as well as manual systems in the production line and be able to propose improvements for the systems.</p> <p>The Production Engineer/Biotechnologist works on a rotating shift and oversees day-to-day manufacturing operations. He is methodical in approaching his tasks and enjoys solving problems independently. He is a proactive and collaborative team player, with strong communication and interpersonal skills.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Implement materials management procedures	Develop Standard Operating Procedures (SOPs) for materials management in the manufacturing facilities
		Verify materials are stored and transported according to SOPs
		Implement disposal procedures for degraded and contaminated materials
		Analyse inventory levels against plans, escalating any potential supply gaps
		Implement plans to reduce unnecessary scrapping of materials within the manufacturing facilities
		Verify batches have been dispensed appropriately
	Clean equipment and facilities	Develop SOPs for cleaning and sterilising
		Oversee preparation of materials, equipment and solvents required for cleaning and sterilisation
Verify that equipment, containers, cleanrooms and facilities are cleaned and sterilised to acceptable standards		
Verify Clean-in-Place (CIP) and Sterilise-in-Place (SIP) procedures are carried out according to SOPs		

		Collaborate with the Engineering and Maintenance department to complete cleaning and sterilisation for product changeovers
		Identify instances where cleaning and sterilisation must be repeated
	Produce pharmaceutical and nutritional products	Set daily productivity, efficiency and volume targets that align with the master production plans
		Approve calibration and pre-start-up checks of manufacturing equipment
		Oversee equipment monitoring across a production line ensuring compliance with Health, Safety and Environment (HSE) procedures and Current Good Manufacturing Practices (CGMPs)
		Investigate major system breakdowns, deviations and suboptimal performance
		Document production yields
		Conduct inspections on final packaged products to ensure quality standards are being met
		Confirm that waste and rejected by-products are disposed appropriately
		Check equipment parameter records and batch and log sheets
	Produce biologics	Prepare media, materials and equipment for cell culture processes
		Approve calibration and pre-start-up checks of bioreactors, purification and final filling equipment
		Monitor bioreactors, purification and final filling equipment following HSE procedures and CGMPs
		Harvest culture and record quality, speed and yields of cell propagation
		Conduct inspections on final filled products to ensure quality standards are being met
		Confirm that waste and rejected by-products are disposed appropriately
		Check equipment parameter records and batch and log sheets
	Improve production operations	Analyse causes of performance problems and process deviations that may impact achievement production objectives and targets
		Propose ideas to improve production operations
		Gather information to support a feasibility assessment of improving production workflows, equipment and systems
Assist with the implementation of workflows, systems and equipment improvements		

	Technical Skills & Competencies		Generic Skills & Competencies (Top 5)	
	Skills & Competencies	Automated Operation Monitoring	Level 3	Communication
Automated Process Control		Level 3	Decision Making	Intermediate
Bioreactor Operation and Control		Level 4	Interpersonal Skills	Intermediate
Biorisk Management		Level 3	Problem Solving	Intermediate
Cell Culture		Level 4	Teamwork	Intermediate
Change Management		Level 4		
Chemical Risk Management		Level 3		
Chromatography Equipment Operation and Control		Level 4		
Cleaning and Sterilising		Level 3		
Conflict Resolution		Level 4		
Continuous Improvement		Level 4		
Emergency Shut-down and Restart		Level 3		
Engineering Drawing		Level 2		
Equipment and Systems Repair		Level 3		
Filtration Equipment Operation and Control		Level 4		
Flexible Facilities Implementation		Level 3		
Good Manufacturing Practices Implementation		Level 4		
Green Manufacturing Design and Implementation		Level 3		
Hazards and Risk Identification and Management		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		
Materials Management		Level 3		
Process Monitoring		Level 4		
Production Optimisation		Level 3		
Project Management	Level 4			
Systems Thinking	Level 4			

	Technical Presentation	Level 4	
	Technical Report Writing	Level 4	
	Vendor Management	Level 3	
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.