

SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP – PROCESS DEVELOPMENT/MS&T MANAGER		
Sector	Biopharmaceuticals Manufacturing	
Track	Process Development/Manufacturing Science and Technology (MS&T)	
Occupation	Manager	
Job Role	Process Development/MS&T Manager	
Job Role Description	<p>The Process Development/MS&T Manager reviews the operational and financial viability of developing, monitoring and improving biopharmaceuticals manufacturing processes within the facilities. He/She translates the department's objectives and priorities into actionable operating plans and Key Performance Indicators (KPIs) for Process Development/MS&T teams and tracks the progress. He is responsible for optimising internal processes while keeping in line with external guidelines and managing risks for the department. The Process Development/MS&T Manager is responsible for facilitating cross-departmental collaboration in order to successfully implement large-scale manufacturing processes for new biopharmaceuticals products or significant changes to equipment, systems and processes for existing products.</p> <p>The Process Development/MS&T Manager is expected to serve as a role model in the department and should be a personable and inspiring leader who can communicate well to influence internal and external stakeholders. He should be a champion for innovation and particularly enjoys leading efficiency and improvement initiatives across the organisation.</p>	
Critical Work Functions and Key Tasks	Critical Work Functions	Key Tasks
	Design biopharmaceuticals manufacturing processes	Implement Quality by Design (QbD) procedures within the department
		Determine the financial and operational viability of scaled-up manufacturing for new biopharmaceutical products
		Evaluate financial and operational viability of selected process control, sampling and monitoring systems and technologies
		Facilitate cross-departmental collaboration to ensure consistency in approaches for different manufacturing processes and facilities across the organisation
		Evaluate potential operational risks for proposed manufacturing processes and alter the designs as necessary
	Implement technology transfer	Manage financial and operational aspects of performing pilot tests and re-trials
		Review results of pilot tests and re-trials from a financial and operational perspective
		Determine resource and operational requirements for technology transfer implementation plans
		Facilitate training for new and revised Standard Operating Procedures (SOPs)

		Manage resources and costs for technology transfer implementation
	Innovate existing manufacturing processes	Review the feasibility, costs and potential business value of proposed technical innovations to manufacturing processes
		Review new automated technologies, flexible facilities and single-use systems from a financial and operational perspective
		Review proposals for alternative raw materials sources
		Devise operational solutions to address gaps and bottlenecks within existing manufacturing processes
		Lead the implementation of improvements to manufacturing processes from a financial and operational perspective
		Consult key internal stakeholders to assess effectiveness of manufacturing process improvements
		Manage department operations
	Coordinate team resources to ensure adequate staffing levels	
	Facilitate collaboration between Process Development/MS&T, Engineering and Maintenance and Production departments for the purposes of ongoing validation and monitoring of manufacturing processes	
	Develop periodic reports for senior management and regulatory authorities on ongoing process validation	
	Monitor the department's financial inflow and outflow against allocated budgets and forecasts	
	Initiate training programmes to build capabilities in the department	
	Assess feasibility of proposals to improve department workflows	
	Justify the resources required to support changes in resources, procedures, systems, equipment or technology within the department	
	Manage risk and regulatory compliance	
		Train teams on the Quality and Health, Safety and Environment (HSE) requirements of manufacturing processes that impact process designs
		Train teams on Current Good Manufacturing Practices (CGMPs) and the impact on process designs
		Develop contingency plans to minimise impact of unforeseen delays in process development activities on manufacturing operations
		Activate contingency plans when delays or lapses in process development activities arise

	Technical Skills & Competencies		Generic Skills & Competencies (Top 5)	
	Skills & Competencies	Automated Process Design	Level 5	Communication
Biological Product Introduction		Level 5	Decision Making	Intermediate
Budgeting		Level 4	Developing People	Intermediate
Business Continuity Management		Level 5	Leadership	Intermediate
Business Performance Management		Level 5	Resource Management	Advanced
Change Management		Level 5		
Conflict Resolution		Level 5		
Continuous Improvement		Level 5		
Good Manufacturing Practices Implementation		Level 5		
Green Manufacturing Design and Implementation		Level 5		
Innovation Management		Level 5		
Manufacturing Process Design		Level 5		
Pharmaceutical and Nutritional Product Introduction		Level 5		
Process Analytical Technology Implementation		Level 4		
Process Optimisation		Level 5		
Process Validation		Level 5		
Project Management		Level 5		
Risk Management		Level 5		
Strategy Development		Level 4		
Systems Thinking		Level 5		
Team Effectiveness Management	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/biopharmmfmg			

The information contained in this document serves as a guide.