SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING SKILLS MAP - PROCESS DEVELOPMENT/MS&T DIRECTOR		
Sector	Biopharmaceuticals Manufacturing	
Track	Process Development/Manufacturing Science and Technology (MS&T)	
Occupation	Director	
Job Role	Process Development/MS&T Director	
Job Role Description	The Process Development/MS&T Director approves and guides the development of new or improved processes in the biopharmaceuticals manufacturing facilities and leads subsequent change management initiatives. He/She endorses all major decisions regarding piloting new technology, implementing process scale-up as well as monitoring and optimising existing processes. In addition, he is accountable for the Process Development/MS&T department meeting its operational and financial targets. The Process Development/MS&T Director holds ultimate responsibility for the development, monitoring and improvement of biopharmaceuticals manufacturing processes within the facilities. The Process Development/MS&T Director is required to maintain a broad, strategic perspective, applying transdisciplinary thinking and a global mindset, to consider issues within the wider context and make effective decisions that will impact the biopharmaceuticals manufacturing facilities. He should be passionate in driving a culture of innovation within and beyond the department to enhance the overall reliability and efficiency of biopharmaceutical manufacturing facilities. He is a strong leader who applies his interpersonal skills to engage with internal and external stakeholders to drive the department's activities.	
Critical Work Functions and Key Tasks	**Critical Work Functions**	**Key Tasks**
	Design biopharmaceuticals manufacturing processes	Formulate Quality by Design (QbD) principles for the organisation
		Define the target products quality profiles and strategic business priorities to guide the design of new biopharmaceuticals manufacturing processes
		Approve methods and technologies for transfer and scale-up of the manufacturing processes
		Endorse performance parameters for new manufacturing processes
		Approve selected process control, sampling and monitoring systems and technologies
		Approve facility layout designs
	Implement technology transfer	Endorse protocols for pilot tests
		Approve refinements to the process designs following piloting activities
		Approve technology transfer implementation plans
		Endorse new and revised Standard Operating Procedures (SOPs) for manufacturing processes

		Establish channels for cross-departmental collaboration to drive successful transition to full scale production
	Innovate existing manufacturing processes	Synthesise the impact of emerging technological changes on the types of technology, facilities and systems used in manufacturing processes to guide process development activities
		Approve recommended innovations to manufacturing processes
		Approve changes to raw material sourcing
		Approve manufacturing process enhancements that align with business requirements
		Facilitate cross-departmental collaboration to implement improvements to manufacturing processes
	Manage department operations	Establish long-term objectives for the department that align with the strategies of the manufacturing facilities
		Establish robust operating and resourcing structures for the department to support business objectives
		Synergise regulatory and business requirements to provide guidance for ongoing process validation
		Facilitate periodic cross-departmental reviews of ongoing process validation as per regulatory requirements
		Source budgets for the department's activities at a corporate level and allocate to different teams and projects
		Define the required capabilities for the department to support business objectives
		Approve workflow improvement solutions and initiatives for the department
		Approve recommendations on significant changes to department's operations and the required resources
	Manage risk and regulatory compliance	Approve the risk management plans for the department
		Keep abreast of changes to local and international Quality and Health, Safety and Environment (HSE) regulations
		Collaborate with the Quality and Production departments to ensure overall compliance of manufacturing processes with required Current Good Manufacturing Practices (CGMPs)
		Approve business continuity policies, strategies and plans
		Lead the activation of contingency plans in the event of significant delays, lapses or emergencies in process development activities

Skills & Competencies	**Technical Skills & Competencies**		**Generic Skills & Competencies (Top 5)**	
	Automated Process Design	Level 6	Communication	Advanced
	Big Data Analysis	Level 5	Decision Making	Advanced
	Biological Product Introduction	Level 6	Developing People	Advanced

	Budgeting	Level 5	Global Mindset	Advanced
	Business Continuity Management	Level 5	Leadership	Advanced
	Business Networking	Level 5		
	Business Performance Management	Level 5		
	Business Planning	Level 5		
	Change Management	Level 5		
	Conflict Resolution	Level 5		
	Continuous Improvement	Level 5		
	Good Manufacturing Practices Implementation	Level 5		
	Green Manufacturing Design and Implementation	Level 6		
	Innovation Management	Level 6		
	Manufacturing Process Design	Level 6		
	Pharmaceutical and Nutritional Product Introduction	Level 6		
	Process Optimisation	Level 5		
	Product Improvement	Level 5		
	Project Management	Level 6		
	Risk Management	Level 5		
	Strategy Development	Level 5		
	Systems Thinking	Level 5		
	Technical Presentation	Level 6		
Programme Listing	For a list of Training Programmes available for the Biopharmaceuticals Manufacturing sector, please visit: www.skillsfuture.sg/skills-framework/biopharmmfg			

The information contained in this document serves as a guide.