SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING
TECHNICAL SKILLS & COMPETENCIES (TSC) REFERENCE DOCUMENT

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Process Monitoring					
TSC Description	Verify that routine manufacturing processes are consistently within a state of control					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-PST-3010-1.1	**BPM-PST-4010-1.1**	**BPM-PST-5010-1.1**	
			Monitor manufacturing processes and identify deviations	Oversee process monitoring procedures and systems and determine follow-up actions to rectify deviations	Lead process monitoring to provide ongoing assurance that the process remains in a state of control	
Knowledge			• Current Good Manufacturing Practices (CGMPs) • Different process variables, parameters and conditions • Standard Operating Procedures (SOPs) for performing, monitoring and controlling biopharmaceuticals manufacturing activities • Importance of proper calibration of field control instruments • Process control limits • Types, causes and consequences of process deviations • Hazards and critical situations during process deviations • Procedures for process control in biopharmaceuticals manufacturing plants • Procedures for reporting and recording out-of-specification process performance	• Methods of monitoring processes and identifying deviations • Root cause analysis procedures • Statistical techniques used to monitor process deviation trends • Types of process alerts and associated responses • Principles of statistical process control charts • Risk and impact analysis procedures • Key requirements and processes of implementing Corrective and Preventive Actions (CAPA) • Documentation standards for CAPA implementation	• Principles of process development • Types of data collection systems • Technologies that facilitate process monitoring • Impact of different process parameters and metrics on overall process performance • Statistical procedures to measure process performance • Types of Process Analytical Technology (PAT) tools and their applications • Potential risks of process deviations • Production efficiency and quality metrics • Procedures for managing Corrective and Preventive Actions (CAPA) for manufacturing processes	
Abilities			• Set up process monitoring systems and equipment according to instructions • Interpret manufacturing processes data • Detect deviations of process variables from	• Oversee monitoring of manufacturing processes • Evaluate patterns and trends in manufacturing processes performance data	• Develop data collection plans and statistical procedures used in measuring process stability and capability • Identify technical systems and technologies that	

©SkillsFuture Singapore

			the steady state condition of process plants • Identify potential causes of deviations • Record details of readings on deviations, actions and activities in accordance to standard procedures • Perform Corrective and Preventive Actions (CAPA) under guidance • Restore processes to within specifications using the correct procedures	• Perform analyses to determine causes of process deviations • Determine appropriate actions to correct, anticipate or prevent undesired process variability • Identify CAPA to restore processes to desired state • Implement CAPA to ensure routine manufacturing processes are within a state of control • Document CAPA performed	facilitate process monitoring • Plan procedures and schedules to monitor manufacturing processes • Establish processes and mechanisms to trigger appropriate alerts upon detection of process deviations • Facilitate integration of technologies and systems into process monitoring procedures • Determine product and process performance parameters and metrics to be monitored • Review key findings from analyses of manufacturing processes performance data • Review viability and effectiveness of CAPA	

©SkillsFuture Singapore