

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

TSC Category	Production					
TSC	Manufacturing Systems Operation and Control					
TSC Description	Operate technical systems in the manufacturing of biopharmaceuticals					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			BPM-OPR-3011-1.1	BPM-OPR-4011-1.1	BPM-OPR-5011-1.1	
			Implement procedures to operate, monitor and control the status of manufacturing systems	Verify systems and controller operations and calibrate systems to perform the configured functions	Establish guidelines for manufacturing systems operations and control, ensuring integration and optimisation of system and process control operations across the plants	
Knowledge			<ul style="list-style-type: none"> Types and applications of system controllers, control modes, schemas and control points Types and components of process control, display and manufacturing systems, and their different functions Fundamental operating procedures and requirements for various technical systems Current Good Documentation Practices (GDP), Current Good Manufacturing Practices (CGMPs) and other regulations and safe working practices Types, interpretations and implications of different process alarms System maintenance tools, methods and procedures Types of system faults, methods and procedures of restoring system parameters to 	<ul style="list-style-type: none"> Proper set-up and applications of system controllers and their features Configuration techniques for manufacturing and process control systems and displays Appropriate settings to capture and provide required historical data Principles of process dynamics Appropriate responses to different process alarms Optimal operating conditions for biopharmaceuticals manufacturing systems Optimal conditions and timings for commissioning or shutting down of manufacturing and process control systems Procedures to verify safety and quality conditions during system preparation and operations 	<ul style="list-style-type: none"> End-to-end processes and systems in biopharmaceuticals manufacturing plants Impact of adjusting system parameters on other machines, processes and the biopharmaceutical products Critical historical data and optimal settings and processes to obtain it Principles and guidelines of appropriate responses to different process alarms Technical and wider environmental factors that impact the performance of manufacturing systems Techniques in resolving multifaceted system breakdowns or faults Viability, costs and benefits of commissioning new manufacturing systems Industry best practices and optimal timings for 	

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

			<p>operational state conditions</p> <ul style="list-style-type: none"> • Housekeeping, waste disposal, work area restoration procedures and other proper post-shutdown protocols • Hazards associated with systems and necessary safety precautions • Organisational structures and procedures for reporting system faults 	<ul style="list-style-type: none"> • Troubleshooting and reconfiguration methods to restore optimal operating conditions • Risk assessment and mitigation techniques 	<p>the start-up, operational duration, and shut-down of manufacturing systems</p> <ul style="list-style-type: none"> • Industry standards of risk management in biopharmaceuticals manufacturing 	
Abilities			<ul style="list-style-type: none"> • Monitor conditions of technical systems in process plants by calling up the relevant process displays • Operate controllers to control different process variables of manufacturing systems • Analyse system data to identify factors influencing manufacturing operations • Prepare the technical systems for manufacturing processes • Check the safety, quality and accurate calibration of materials, tools and equipment in manufacturing systems • Maintain manufacturing systems in their optimal conditions, highlighting deviations to relevant personnel • Rectify system faults and restore system parameters to operational steady state conditions 	<ul style="list-style-type: none"> • Outline physical and operational interconnections among different manufacturing and process control systems • Develop guidelines and instructions for system and controller operations • Configure manufacturing and control systems to capture required data • Oversee system start-up and operations, ensuring proper protocols and Current Good Manufacturing Practices (CGMPs) are followed • Check and verify that system preparations have been performed in line with quality and safety standards • Communicate the proper calibration of materials, tools and equipment • Investigate and resolve system breakdowns, deviations or suboptimal performance • Assess and communicate risks and hazards associated with 	<ul style="list-style-type: none"> • Integrate manufacturing plant-wide systems and process control operations • Maintain oversight of manufacturing systems performance • Establish internal Standard Operating Procedures (SOPs) for system monitoring and control • Translate system data analysis and insights into reconfiguration of manufacturing systems to optimise operations • Direct the commissioning and shut-down of manufacturing and process control systems, considering optimal timings and impact on products and processes • Formulate instructions and guidelines on how system parameters and conditions can be calibrated or adjusted to optimise performance • Provide advice to resolve highly technical 	

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

			<ul style="list-style-type: none"> • Complete and update relevant documentation and records in accordance with current organisational standards and GDP 	<p>manufacturing system operations</p>	<p>or complex system faults or breakdowns</p> <ul style="list-style-type: none"> • Establish plant-wide processes to manage risks and hazards associated with manufacturing system and process control equipment operations 	
--	--	--	--	--	--	--