

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

TSC Category	Production					
TSC	Manufacturing Equipment Operation and Control					
TSC Description	Operate production equipment ensuring optimal conditions for biopharmaceuticals manufacturing production					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			BPM-OPR-3010-1.1	BPM-OPR-4010-1.1	BPM-OPR-5010-1.1	
			Implement procedures to operate manufacturing equipment	Verify conditions and operations of equipment and implement changes to optimise their functioning from pre-commissioning to shut-down	Establish guidelines for the commissioning, operations and integration of manufacturing equipment vis-à-vis broader systems and processes in the plants	
Knowledge			<ul style="list-style-type: none"> Types of equipment, their purposes and functions Standard Operating Procedures (SOPs) of various manufacturing equipment Current Good Documentation Practice (GDP), Current Good Manufacturing Practices (CGMPs) and other regulations and safe working practices Equipment cleaning, sanitisation, preparation and maintenance procedures Range of equipment tests and checking procedures, and their impact on operations Common faults, hazards and potential deviations in equipment operations and their indicators Equipment parameters and impact of adjustments on operations and processes 	<ul style="list-style-type: none"> Interpretation of equipment blueprints, drawings and diagrams and their links to other plants and systems Principles and theories of manufacturing equipment and functions of their components Critical and standard limits, parameters and alarms of equipment operating conditions Optimal operating conditions for biopharmaceuticals manufacturing equipment Procedures to verify safety and quality conditions during equipment use and manufacturing operations Details of instructions and guidelines for equipment operations Types and indicators of hazards or abnormal conditions involving processes, equipment 	<ul style="list-style-type: none"> End-to-end processes, systems and equipment in biopharmaceuticals manufacturing plants Lifecycles of manufacturing equipment Impact of adjusting equipment parameters on other machines, processes and biopharmaceutical products Equipment providers' or manufacturers' guidelines Pros, cons and key considerations of commissioning new manufacturing systems Industry best practices and optimal timings for the start-up, operational duration, and shut-down of manufacturing equipment and units Technical and environmental factors that impact the performance of manufacturing equipment 	

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

			<ul style="list-style-type: none"> • Corrective actions and equipment troubleshooting methods • Features and quality characteristics of biopharmaceuticals products and production materials 	<ul style="list-style-type: none"> • and materials during operations • Troubleshooting methods and equipment- or process-adjustment principles to restore optimal operating conditions • Risk assessment and mitigation techniques 	<ul style="list-style-type: none"> • Techniques in resolving multifaceted technical equipment faults • Techniques to minimise impact of equipment defects or breakdowns on broader manufacturing processes • Industry standards of risk management in biopharmaceuticals manufacturing 	
Abilities			<ul style="list-style-type: none"> • Calibrate the manufacturing equipment • Operate the equipment in accordance with SOPs • Perform routine checks on the operations of equipment to verify the processes and products acceptability in accordance with SOPs and quality standards • Monitor critical parameters • Take corrective actions to adjust equipment and other affected machinery operations • Report variations, faults or hazards in equipment operations to authorised personnel • Perform cleaning and maintenance of manufacturing equipment after use • Dispose waste and rejected by-products appropriately • Update documentation at key stages following the completion of the 	<ul style="list-style-type: none"> • Develop Standard Operating Procedures (SOPs) for equipment operations • Verify the conditions and operations of manufacturing equipment components • Oversee equipment preparation and start-up • Perform procedural and safety checks on manufacturing and emergency response equipment prior to starting, during normal operations, during shut-down and during upset conditions • Verify that waste and rejected by-products are disposed of appropriately • Direct changes to critical parameters to adjust or restore equipment to optimal functioning • Resolve identified defects or faults in equipment parts or operations 	<ul style="list-style-type: none"> • Maintain oversight of manufacturing equipment conditions and performance • Evaluate viability of commissioning new manufacturing equipment • Determine suitable timings and conditions for shut-down of manufacturing equipment and units • Establish guidelines and performance indicators of optimal equipment functioning, as well as the parameters and conditions which influence them • Write programming codes for computerised or automated manufacturing equipment • Train team members on equipment parameters and conditions to be adjusted for optimisation of performance 	

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

			<p>manufacturing processes</p>	<ul style="list-style-type: none"> • Identify needs for and completion of equipment maintenance works • Mitigate risks associated with identified hazards relating to manufacturing equipment operations 	<ul style="list-style-type: none"> • Provide advice to resolve highly technical or complex defects, faults or breakdowns in equipment parts or overall operations • Establish processes and mechanisms to manage risks and hazards associated with manufacturing equipment operations 	
--	--	--	--------------------------------	--	---	--