<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Production</th>
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<tbody>
<tr>
<td>TSC Description</td>
<td>Operate technical systems in the manufacturing of biopharmaceuticals</td>
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<tr>
<td>TSC Proficiency Description</td>
<td>Level 1</td>
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<tr>
<td>Description</td>
<td>BPM-OPR-3011-1.1</td>
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<td>Implement procedures to operate, monitor and control the status of manufacturing systems</td>
<td>Verify systems and controller operations and calibrate systems to perform the configured functions</td>
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**Knowledge**
- 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
- 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
- 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
### Operational State Conditions
- 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

### Abilities
- 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
- Troubleshooting and reconfiguration methods to restore optimal operating conditions
- Risk assessment and mitigation techniques
- 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 issues

### Start-up, Operational Duration, and Shut-down of Manufacturing Systems
- Industry standards of risk management in biopharmaceuticals manufacturing
- 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

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| Complete and update relevant documentation and records in accordance with current organisational standards and GDP | Manufacturing system operations | or complex system faults or breakdowns | Establish plant-wide processes to manage risks and hazards associated with manufacturing system and process control equipment operations |