<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Process Development/Manufacturing Science and Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSC</td>
<td>Process Monitoring</td>
</tr>
<tr>
<td>TSC Description</td>
<td>Verify that routine manufacturing processes are consistently within a state of control</td>
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<table>
<thead>
<tr>
<th>TSC Proficiency Description</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
<th>Level 6</th>
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<tbody>
<tr>
<td>BPM-PST-3010-1.1</td>
<td>Monitor manufacturing processes and identify deviations</td>
<td>BPM-PST-4010-1.1</td>
<td>Oversee process monitoring procedures and systems and determine follow-up actions to rectify deviations</td>
<td>BPM-PST-5010-1.1</td>
<td>Lead process monitoring to provide ongoing assurance that the process remains in a state of control</td>
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**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

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

- 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
- 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