<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Production</th>
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<tbody>
<tr>
<td>TSC</td>
<td>Bioreactor Operation and Control</td>
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<tr>
<td>TSC Description</td>
<td>Operate bioreactors in biopharmaceuticals manufacturing facilities</td>
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<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-OPR-3002-1.1</td>
<td>Implement procedures for operating bioreactors</td>
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<tr>
<td>BPM-OPR-4002-1.1</td>
<td>Verify conditions and operations of bioreactors and perform troubleshooting</td>
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**Knowledge**

- Bioreactor designs and applications
- Principles of microbiology and biochemistry
- Principles of fluid flow, heat transfer and mass transfer
- Critical process parameters for operating bioreactors
- Methods of monitoring and controlling cell culture conditions in bioreactors
- Sterilisation requirements for cell culture media and bioreactor systems
- Requirements of inocula for cell culture processes
- Fundamentals of batch, continuous and fed-batch cell culture processes
- Safety precautions associated with bioreactor operations and waste disposal
- Methods for product recovery from cell culture processes
- Optimal operating conditions for bioreactors
- Procedures to verify safety and quality conditions during equipment use and manufacturing operations
- Types and indicators of hazards or abnormal conditions involving processes, equipment and materials during operations
- Troubleshooting methods and equipment- or process-adjustment principles to restore optimal operating conditions
- Risk assessment and mitigation techniques

**Abilities**

- Set up bioreactors and single-use bioreactor bags by calibrating and
- Identify the cell culture process requirements and objectives
<table>
<thead>
<tr>
<th>Activity</th>
<th>Technical Skills &amp; Competencies</th>
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</table>
| Installing pH probe, Dissolved Oxygen (DO) probe, and inlet and exit gas filters | • Load culture medium into bioreactors  
• Test agitation and aeration, temperature controller and pH controller  
• Sterilise bioreactors, equipment, feed containers and reagent solutions before and after use  
• Perform bioreactor inoculation  
• Notify the authorised personnel where bioreactor operations cannot be carried out  
• Extract samples from bioreactors to measure cell density, viability and concentration  
• Carry out culture harvesting and dispose sterilised biohazard wasters  
• Prepare bioreactors for next culture operations  
• Complete log and batch sheets |
| | • Implement Standard Operating Procedures (SOPs) for bioreactor operations  
• Inspect and verify the conditions and operations of bioreactor components  
• Oversee bioreactor preparation and start-up  
• Oversee and direct changes to critical parameters to adjust or restore bioreactors to optimal functioning  
• Review batch sample testing outcomes to verify product quality  
• Identify defects or faults in equipment parts or operations  
• Conduct root cause analysis  
• Mitigate risks associated with identified hazards relating to bioreactor operations |