### TSC Category
Production

**TSC**
Good Manufacturing Practices Implementation

**TSC Description**
Implement Current Good Manufacturing Practices in the design, monitoring, and control of manufacturing processes and facilities to ensure the potency, quality, and purity of biopharmaceuticals products.

<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>
</tr>
</thead>
<tbody>
<tr>
<td>BPM-OPR-2009-1.1</td>
<td>BPM-OPR-3009-1.1</td>
<td>BPM-OPR-4009-1.1</td>
<td>BPM-OPR-5009-1.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TSC Proficiency Description</strong></td>
<td>Apply Current Good Manufacturing Practices (CGMPs) when designing, monitoring, controlling and performing manufacturing activities</td>
<td>Implement the principles of Current Good Manufacturing Practices (CGMPs) through the application of industry best-practices and international standards</td>
<td>Develop protocols aligned with Current Good Manufacturing Practices (CGMPs) for a department</td>
<td>Synthesise Current Good Manufacturing Practices (CGMPs) with all design, monitoring, and control of biopharmaceuticals manufacturing processes across the organisation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Knowledge**

- Principles of CGMPs
- Types of work processes occurring in biopharmaceuticals manufacturing facilities and how CGMPs apply
- Production areas and cleanrooms Standard Operating Procedures (SOPs)
- Uses of production equipment
- Equipment cleaning frequency and maintenance log requirements
- Responsibilities of job functions regarding compliance to CGMPs
- Frontline reporting and recording procedures for non-compliance
- Good documentation practices
- Processes to prevent cross-contamination
- Processes and locations for the preparation and staging of raw materials
- Risk management techniques
- Specification, design, verification, qualification and commissioning standards
- Verification and validation methods and requirements for equipment, facilities and processes
- Relationships of CGMPs with quality assurance and quality control, and its impact on patient safety
- Operational workflows for manufacturing processes
- Risk management international guidelines and standards
- Organisation’s regulatory and compliance requirements in relation to CGMPs
- Biopharmaceuticals manufacturing process lifecycles
- Methods of improving manufacturing processes designs and control quality
- Methods of reviewing alignment of processes to CGMPs
- Global best practices in manufacturing standards
- Global best practices in risk management
- Change and culture management strategies
- End-to-end biopharmaceuticals manufacturing processes across the organisation
### Abilities

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td><strong>Apply SOPs when performing work activities in plants</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Identify the type of controlled documents required in manufacturing facilities in compliance with CGMPs requirements</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Record non-compliance of Good Manufacturing Practices (GMPs) or cleanroom protocols</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Report and inform respective parties on any non-compliance with manufacturing or cleanroom protocols and practices</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Explain the importance of abiding by CGMPs to external parties such as vendors</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Perform work processes in accordance with CGMPs</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Check work processes for compliance with CGMPs</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Take corrective actions against non-compliance of Good Manufacturing Practices (GMPs) or cleanroom protocols</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Identify improvements that can be made to promote better alignment of processes with CGMPs</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Translate CGMPs standards into operating protocols for a department</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Establish processes to monitor compliance with CGMPs in a department</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Introduce risk control programmes and activities for a department in line with organisational policies</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Develop validation strategies to demonstrate processes are fit for intended uses in accordance with CGMPs and other regulatory guidelines</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Control and monitor operations in accordance with regulatory guidelines</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Review CGMPs deviations</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Establish systems and programmes for CGMPs training</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Synthesise processes across the design, monitoring, and control of manufacturing practices and align to CGMPs</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Establish processes to monitor compliance with CGMPs across the organisation</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Build a culture that promotes alignment to CGMPs across the organisation</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Lead risk control programmes</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Resolve significant deviations with senior quality review teams</strong></td>
</tr>
<tr>
<td>-</td>
<td><strong>Investigate root causes of serious breaches and deviations from CGMPs standards</strong></td>
</tr>
</tbody>
</table>