<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Quality Assurance</th>
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<tbody>
<tr>
<td>TSC</td>
<td>Audit Management</td>
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<tr>
<td>TSC Description</td>
<td>Review organisational objectives, policies, procedures, structure, controls and systems to verify that the organisation’s activities are efficiently managed</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-QUA-2002-1.1</td>
<td>BPM-QUA-3002-1.1</td>
<td>BPM-QUA-4002-1.1</td>
<td>BPM-QUA-5002-1.1</td>
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<tr>
<td>Collect data required for audits</td>
<td>Support audits of processes and standards and monitor the implementation of follow-up actions</td>
<td>Audit processes and standards and review findings for follow-up actions</td>
<td>Drive audit processes from planning and opening meetings, through to reporting and follow-up actions</td>
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### Knowledge
- Purpose of audits
- Types of audits conducted in the biopharmaceuticals manufacturing sector
- Importance of following Standard Operating Procedures (SOPs)
- Information required for the audit process
- Organisational documentation procedures
- Principles of audits and their applications
- Procedures for conducting audits
- Types of non-conformances
- Organisation’s internal audit objectives
- Organisation’s regulatory and compliance requirements for external audits
- Management systems standards requirements
- Procedures of external audits
- Quality Standards and Quality Management principles
- Types of audit methodologies
- Methods of preparing audit plans, audit checklists and corrective action forms
- Methods of overseeing the auditing process
- Analysis of audit findings and audit conclusions
- Methods of improving regulatory compliance

### Abilities
- Identify types of audits and their purposes
- Identify types of information required for audits
- Collect and submit data and other documents according to SOPs
- Record results of audits
- Coordinate with auditees to obtain documents and information relevant to audit scopes
- Review documents and information to identify non-conformances in processes and standards
- Prepare documentation to be reviewed for external audits
- Monitor the implementation of improvement recommendations
- Identify audit scopes according to organisational requirements
- Conduct internal audit programmes
- Validate audit findings in accordance with organisational requirements
- Review documentation prepared for external audits for adequacy
- Facilitate external audits to meet regulatory and compliance requirements
- Drive auditing processes across the organisation
- Determine the alignment of internal audit programmes with external regulatory and compliance audit requirements
- Review audit findings and draw conclusions
- Lead and conduct opening and closing meetings
- Present audit findings to stakeholders
- Recommend improvement measures to reconcile process and
| | | • Identify areas of improvement for process and standards compliance | • Document audit findings according to organisational procedures | standards compliance with internal and external audit requirements |