

**SKILLS FRAMEWORK FOR BIOPHARMACEUTICALS MANUFACTURING  
TECHNICAL SKILLS & COMPETENCIES (TSC) REFERENCE DOCUMENT**

<b>TSC Category</b>	Quality Assurance					
<b>TSC</b>	Audit Management					
<b>TSC Description</b>	Review organisational objectives, policies, procedures, structure, controls and systems to verify that the organisation's activities are efficiently managed					
<b>TSC Proficiency Description</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Level 4</b>	<b>Level 5</b>	<b>Level 6</b>
		<b>BPM-QUA-2002-1.1</b>	<b>BPM-QUA-3002-1.1</b>	<b>BPM-QUA-4002-1.1</b>	<b>BPM-QUA-5002-1.1</b>	
		Collect data required for audits	Support audits of processes and standards and monitor the implementation of follow-up actions	Audit processes and standards and review findings for follow-up actions	Drive audit processes from planning and opening meetings, through to reporting and follow-up actions	
<b>Knowledge</b>		<ul style="list-style-type: none"> <li>Purpose of audits</li> <li>Types of audits conducted in the biopharmaceuticals manufacturing sector</li> <li>Importance of following Standard Operating Procedures (SOPs)</li> <li>Information required for the audit process</li> <li>Organisational documentation procedures</li> </ul>	<ul style="list-style-type: none"> <li>Principles of audits and their applications</li> <li>Procedures for conducting audits</li> <li>Types of non-conformances</li> </ul>	<ul style="list-style-type: none"> <li>Organisation's internal audit objectives</li> <li>Organisation's regulatory and compliance requirements for external audits</li> <li>Management systems standards requirements</li> <li>Procedures of external audits</li> </ul>	<ul style="list-style-type: none"> <li>Quality Standards and Quality Management principles</li> <li>Types of audit methodologies</li> <li>Methods of preparing audit plans, audit checklists and corrective action forms</li> <li>Methods of overseeing the auditing process</li> <li>Analysis of audit findings and audit conclusions</li> <li>Methods of improving regulatory compliance</li> </ul>	
<b>Abilities</b>		<ul style="list-style-type: none"> <li>Identify types of audits and their purposes</li> <li>Identify types of information required for audits</li> <li>Collect and submit data and other documents according to SOPs</li> <li>Record results of audits</li> </ul>	<ul style="list-style-type: none"> <li>Coordinate with auditees to obtain documents and information relevant to audit scopes</li> <li>Review documents and information to identify non-conformances in processes and standards</li> <li>Prepare documentation to be reviewed for external audits</li> <li>Monitor the implementation of improvement recommendations</li> </ul>	<ul style="list-style-type: none"> <li>Identify audit scopes according to organisational requirements</li> <li>Conduct internal audit programmes</li> <li>Validate audit findings in accordance with organisational requirements</li> <li>Review documentation prepared for external audits for adequacy</li> <li>Facilitate external audits to meet regulatory and compliance requirements</li> </ul>	<ul style="list-style-type: none"> <li>Drive auditing processes across the organisation</li> <li>Determine the alignment of internal audit programmes with external regulatory and compliance audit requirements</li> <li>Review audit findings and draw conclusions</li> <li>Lead and conduct opening and closing meetings</li> <li>Present audit findings to stakeholders</li> <li>Recommend improvement measures to reconcile process and</li> </ul>	

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				<ul style="list-style-type: none"><li>• Identify areas of improvement for process and standards compliance</li><li>• Document audit findings according to organisational procedures</li></ul>	standards compliance with internal and external audit requirements	
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