

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

TSC Category	Quality Control					
TSC	Laboratory Management					
TSC Description	Implement Good Laboratory Practice procedures to ensure that performance, quality, health, and safety standards are met					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-QUC-2003-1.1	BPM-QUC-3003-1.1	BPM-QUC-4003-1.1	BPM-QUC-5003-1.1	
		Apply laboratory Standard Operating Procedures (SOPs) within own work area	Implement Good Laboratory Practice (GLP) to ensure organisational standards are met	Develop Good Laboratory Practice (GLP) procedures and oversee their implementation	Drive the application of Good Laboratory Practice (GLP) policies in the organisation and conduct laboratory commissioning, certification and accreditation assessments	
Knowledge		<ul style="list-style-type: none"> Health, Safety and Environment (HSE) regulations and procedures related to working in laboratories Laboratory SOPs Laboratory activity documentation requirements Typical processes for laboratory audits and inspections Types of measuring equipment and methods of calibration Types of chemicals and materials used for testing in laboratories Inventory management procedures for bulk materials, samples and consumables Legislative requirements for the handling, labelling, transport, storage and retention of hazardous products, samples and materials Good Laboratory Practice (GLP) procedures 	<ul style="list-style-type: none"> Types of laboratory accreditations and certifications Types of laboratory inspections and audits, and their processes Procedures for preparing laboratories for audits and inspections Applications of chemicals, reagents, additives and materials to different laboratory tests Shelf lives of different chemicals and materials used for testing in laboratories Optimal times to procure different chemicals and materials for the laboratory 	<ul style="list-style-type: none"> Laboratory commissioning, certification and accreditation requirements Types of Standard Operating Procedures (SOPs) for different laboratory activities Methods of reviewing work conducted in laboratories Methods of identifying non-compliance to Good Laboratory Practice (GLP) Implications of non-compliance to GLP Inventory management strategies and techniques Decommissioning plans 	<ul style="list-style-type: none"> Procedures for conducting pre-commissioning inspections Requirements for commissioning Procedures for conducting pre-certification and pre-accreditation audits and inspections Prescribed standards for specific certificates Prescribed standards for specific accreditations Methods of addressing gaps against prescribed standards for specific certificates or accreditations Operations and maintenance programmes Principles of decommissioning 	

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<p>Abilities</p>		<ul style="list-style-type: none"> • Apply the organisation's SOPs within own work area • Apply HSE regulations and practices in laboratory work • Perform routine equipment maintenance and calibration • Service and replace test equipment and materials used for testing • Document laboratory activities in accordance with organisational policies • Report areas of non-compliance • Participate in laboratory audits and inspections 	<ul style="list-style-type: none"> • Implement Standard Operating Procedures (SOPs) in a laboratory setting • Prepare laboratories for inspections or audits • Verify materials and equipment are prepared and calibrated • Review laboratory documentation and amend as necessary • Suggest improvements to laboratory practices to enhance quality, health, and safety standards • Assess need to supplement laboratory inventory • Manage inventory in laboratories 	<ul style="list-style-type: none"> • Identify commissioning, certification and accreditation requirements for laboratories • Develop SOPs for laboratory work that align with GLP policies and commissioning, certification and accreditation requirements • Communicate information on the responsibilities of individuals to maintain the laboratory's compliance with GLP • Verify that all technical work is performed in accordance with relevant SOPs and schedules • Identify actual and potential problems with GLP policy compliance • Review the preparation of laboratories for inspections or audits • Oversee activities for improving laboratory practices • Approve laboratory documentation • Develop inventory management plans for product testing in laboratories • Implement laboratory decommissioning activities according to set plans 	<ul style="list-style-type: none"> • Devise Good Laboratory Practice (GLP) policies to ensure optimal laboratory performance and integrity of containment • Establish procedures and guidelines for equipment calibration • Coach others in implementing GLP • Conduct pre-commissioning inspections to assess the readiness of laboratory facilities to meet requirements for commissioning • Conduct pre-certification and pre-accreditation audits and inspections to identify gaps against prescribed standards for specific certificates or accreditations • Select appropriate improvement recommendations to rectify non-compliance to GLP • Monitor the implementation of improvement activities • Plan the decommissioning of laboratory facilities in compliance with standard decommissioning principles 	
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