

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

TSC Category	Engineering and Maintenance					
TSC	Equipment and Systems Testing					
TSC Description	Execute equipment and systems testing procedures to ensure continuity of operations and meet standards of performance					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-ENM-2006-1.1	BPM-ENM-3006-1.1			
		Conduct equipment and system tests	Implement equipment and system testing procedures			
Knowledge		<ul style="list-style-type: none"> Mechanical, structural and electrical testing techniques Types of testing and measuring instruments and their applications Testing procedures Methods of calibrating, and testing measuring instruments Equipment cleaning, maintenance and decontamination procedures Testing and calibration documentation procedures Hazards and safety precautions associated with testing 	<ul style="list-style-type: none"> Methods of determining testing criteria Equipment manuals, systems diagrams, plans and drawings Techniques for identifying malfunctions and defects Guidelines for calibration and testing of measuring instruments Techniques of interpreting testing results Techniques of digital data analysis, comparisons and representations Follow-up measures according to testing results 			
Abilities		<ul style="list-style-type: none"> Identify areas for testing using appropriate procedures and tools Prepare areas for testing in accordance with the relevant legal and safety requirements Prepare reagents, additives and materials to be used during testing Check measuring instruments for functionality, damage and/or missing parts 	<ul style="list-style-type: none"> Implement testing procedures according to manufacturers' instructions and specifications Implement measuring equipment calibration procedures Perform challenge tests according to established testing procedures Review accuracy of testing equipment calibration 			

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		<ul style="list-style-type: none"> • Calibrate measuring instruments according to organisational procedures • Apply testing procedures to conduct tests on equipment and systems • Escalate test failures in accordance with organisational procedures • Maintain test equipment • Adhere to relevant Health, Safety and Environment (HSE) risk control measures when conducting structural tests • Maintain complete and accurate records of testing and instrument calibrations 	<ul style="list-style-type: none"> • Oversee testing work and check that it is executed according to work schedules • Implement risk control measures to mitigate possible issues in executing work • Analyse testing results and suggest follow-up measures • Monitor testing works conducted and ensure compliance with Health, Safety and Environment (HSE) policies, procedures and regulations 			
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