

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

TSC Category	Engineering and Maintenance					
TSC	Test Planning					
TSC Description	Develop testing plans and procedures by determining scope and risks, identifying the objects of testing, selecting test methods and tools, and controlling test implementation					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-ENM-4012-1.1	BPM-ENM-5012-1.1	
				Formulate procedures and parameters for the testing of biopharmaceutical manufacturing equipment and systems	Establish testing objectives and plans based on manufacturing requirements	
Knowledge				<ul style="list-style-type: none"> • International standards, codes, legislation pertaining to manufacturing equipment testing • Equipment and machinery testing and validation processes • Methods of deploying testing procedures according to overall testing plans • Limitations of machines • Testing documentation, reporting and close out requirements 	<ul style="list-style-type: none"> • Methods of developing testing plans and objectives • Health, Safety and Environment (HSE) requirements related to testing of biopharmaceutical manufacturing equipment and systems • Business risks of obsolete equipment and systems • Emerging trends and industry developments in testing • Resource requirements for equipment and systems testing 	
Abilities				<ul style="list-style-type: none"> • Develop testing procedures based on established plans and product specification requirements • Define testing boundaries and parameters for equipment and systems • Develop challenge test protocols 	<ul style="list-style-type: none"> • Articulate objectives of testing procedures • Develop testing plans based on organisation wide strategies and objectives • Synthesise emerging industry trends, techniques and developments in testing • Develop test plans for assessing need and 	

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				<ul style="list-style-type: none"> • Prioritise work to maximise efficiency and effectiveness of testing • Determine equipment, tools and personal protective equipment to be used for testing • Allocate testing tasks according to requirements • Oversee final review of testing to ensure compliance with all requirements and specifications • Verify the functions and capabilities of machinery and equipment • Direct responses to failures of challenge tests 	<p>optimal timelines for equipment upgrades</p> <ul style="list-style-type: none"> • Integrate relevant HSE practices and procedures into the design of testing plans • Ensure equipment and systems are tested within an acceptable timeframe • Liaise with stakeholders to communicate and resolve issues 	
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