

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

TSC Category	Quality Control					
TSC	Product Testing					
TSC Description	Test biopharmaceutical products to verify that they have been produced to the required quality and regulatory standards					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			BPM-QUC-3005-1.1	BPM-QUC-4005-1.1	BPM-QUC-5005-1.1	
			Implement testing procedures for biopharmaceutical products	Review product testing outcomes to identify quality lapses and required improvements	Establish plans and protocols for the quality control testing of biopharmaceutical products	
Knowledge			<ul style="list-style-type: none"> • Current Good Manufacturing Practices (CGMPs) and related industry protocols and regulations • Relevant regulations, safe work practices and procedures required when performing chemical or product tests • Details of sampling and testing plans • Units of measurement • Types and applications of tools, equipment and materials used for sampling • Types of measuring equipment and methods of calibration • Quality assurance and quality control procedures • Legislative requirements for the handling, labelling, transport, storage and retention of hazardous product samples and materials • Purpose and standard procedures and/or methods of conducting product tests 	<ul style="list-style-type: none"> • Types of online, inline and atline sampling equipment and tools • Methods of sampling and protecting sampling integrity • Principles of statistics for sampling plan development • Analytical and physical chemistry for product testing • Instrumental and laboratory techniques • Quantity and concentration considerations for product sampling and testing • Differences in testing processes and methodologies for biopharmaceutical products • Environmental factors and conditions for testing product quality • Links between product testing results and potential process gaps 	<ul style="list-style-type: none"> • Stages of product development in biopharmaceutical manufacturing • Product quality monitoring systems • Principles of pharmacology and toxicology • Medical technologies and associated Good Laboratory Practices (GLPs) in Quality Control • Parameters and attributes that are fundamental to each biopharmaceutical product • Range of analytical methods for testing product attributes • Potential sources of variation affecting product quality 	

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			<ul style="list-style-type: none"> Procedures for handling out-of-specification results 			
Abilities			<ul style="list-style-type: none"> Apply Health, Safety and Environment (HSE) regulations and practices in product testing Follow the organisation's procedures and sampling plans to prepare sampling tools and equipment Collect and transport product samples to testing areas, in accordance with Standard Operating Procedures (SOPs) Prepare and check materials and calibrate equipment needed for product testing, according to organisational procedures Perform routine quality tests on products against specified acceptance criteria, in accordance with SOPs Identify abnormal occurrences affecting sampling or product testing conditions Conduct re-tests where required Document testing activities and results according to documentation policies and procedures 	<ul style="list-style-type: none"> Develop sampling plans for products to be tested Outline the steps for testing different kinds of biopharmaceutical products Specify the quantities or concentrations of products to be tested Specify the optimal environmental factors and conditions to assess the quality of products Specify acceptance criteria for tests Perform non-standard quality tests on products where required Monitor the routine testing of products, ensuring the correct volumes, calibration of equipment, conditions and processes are employed Identify deviations or quality issues with products Review the frequency and severity of product defects or quality lapses Identify possible causes of defects and follow-up actions to achieve required product quality and specifications 	<ul style="list-style-type: none"> Define customised testing plans for different or new products, based on their stage of development Determine the analytical methods and procedures that are acceptable for testing a product's identity, purity, potency, concentration, inter-batch consistency, stability and other quality indicators Determine types of products to be tested and the frequency of testing Establish parameters and standard assay protocols for the conduct of product testing Oversee product testing procedures, ensuring alignment with process and product quality standards Evaluate product testing results over time, identifying trends and their implications Lead investigations of major or recurrent defects or quality variations that emerge from product testing Recommend process changes or additional steps to raise product quality to required standards 	