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

TSC Category	Quality Control					
TSC	Packaging Testing					
TSC Description	Verify that biopharmaceuticals packaging materials maintain the desired level of compliance					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUC-3004-1.1	**BPM-QUC-4004-1.1**	**BPM-QUC-5004-1.1**	
			Perform tests to verify the quality of biopharmaceutical product packaging	Oversee the implementation of packaging tests according to established processes	Lead development of packaging testing plans and processes	
Knowledge			• Packaging processes for biopharmaceutical products • Sample handling and processing for packaging testing • Equipment required for packaging testing • Indicators of substandard product packaging or defect • Current Good Manufacturing Practices (CGMPs) • Environmental conditions for testing biopharmaceuticals packaging materials • Features and indicators of package integrity • Microbial barrier, immersion, peeling ability, sealing strength, and accelerated aging tests	• Principles of packaging engineering • Principles of biochemical and food sciences that impact on packaging of biopharmaceutical products • Optimal packaging materials and conditions for meeting product requirements • Packaging requirements for different kinds of biopharmaceutical products • Types of packaging materials • Significant parameters or features for each step in the packaging process • Sealing temperature, time, pressure and other parameters for packaging testing • Techniques to analyse packaging material safety, product performance, sterilisation compatibility, and shelf-life stability for the intended manufacturing process	• Optimal timings and frequencies for the conduct of packaging testing • Impact of different packaging materials and processes on biopharmaceutical product quality • Inherent variabilities in the characteristics of primary package materials • Maximum sterilisation exposure and tolerance levels for biopharmaceutical products • Applications of manual packaging validation versus automated verification • Interactions among manufacturing systems, manual handling, packaging, distribution, and storage environments within the biopharmaceutical manufacturing ecosystem • Regulatory agency inspection and audit procedures	

Abilities			• Prepare equipment and materials used for packaging quality testing • Prepare environment and conditions to simulate actual use for conducting package performance testing • Gather samples of product packaging in accordance with specified plans • Conduct visual inspection tests to identify unsealed areas, non-homogeneous areas, and other defects • Conduct routine tests to assess sealing tightness, strength and peeling ability of packaging • Conduct tests to assess microbial barriers of packaging systems • Conduct accelerated aging tests to simulate the aging up to the expiry date of the packaging • Examine variations or deviations of a package and between packages • Report completed packaging testing activities, results and key findings	• Develop Standard Operating Procedures (SOPs) and documentation for internal packaging testing • Implement packaging testing activities according to set plans and Current Good Manufacturing Practices (CGMPs) • Identify the materials and packaging variables that affect the ability of biopharmaceutical products to meet acceptable requirements • Specify the packaging equipment and process parameters to be monitored, inspected and controlled • Determine the equipment and calibration needed to inspect the quality of packaging • Determine sampling methods for packaging qualifications • Determine the appropriate environment and conditions under which package testing should be performed • Specify measurable acceptance criteria for the conduct of tests or checks • Check that the conduct of tests on packaging is in line with CGMPs and standard protocols • Investigate packaging deviations encountered	• Develop packaging testing plans to ensure materials maintain the desired level of compliance with packaging requirements over time • Specify package requirements and characteristics to be tested • Introduce new methods and equipment to perform packaging tests • Lead investigation reporting of non-conformance to packaging requirements and standards • Deliver updates to key stakeholders on overall results and key findings from packaging tests and their implications on final product quality • Evaluate testing reports to identify areas for improvement	

				during the execution of testing activities		