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

TSC Category	Quality Assurance					
TSC	Packaging Validation					
TSC Description	Validate the methodologies and processes applied to package biopharmaceutical products to maintain quality standards and regulatory compliance					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUA-3006-1.1	**BPM-QUA-4006-1.1**		
			Implement validation processes to review the quality of packaging processes	Develop validation processes for the approval of packaging methodologies and processes		
Knowledge			• Procedures for quality assurance and quality control in biopharmaceuticals manufacturing plants • Packaging requirements for different kinds of biopharmaceutical products • Purpose of packaging validation • Types of data required for packaging validation • Environmental conditions to which biopharmaceutical packaging will be exposed to and should withstand • Features and indicators of package integrity • Prospective and concurrent validation • Techniques to analyse packaging material safety, product performance, sterilisation compatibility, shelf-life stability, and suitability for the intended manufacturing processes	• Industry standards and best practices in packaging validation • Impact of different packaging materials on validation parameters • Minimum sterilisation exposure and tolerance level requirements for different product packaging • Applications of manual versus automated packaging validation • Interactions among manufacturing systems, manual handling, packaging, distribution, and storage environments within the biopharmaceutical manufacturing ecosystem • Regulatory agency inspection and audit procedures		

			• Current Good Manufacturing Practices (CGMPs)			
Abilities			• Collect data on critical validation characteristics according to Standard Operating Procedures (SOPs) • Check if packaging materials are kept under proven storage conditions or those specified by suppliers • Verify materials and packaging variables that affect the ability of biopharmaceutical products to meet acceptable requirements • Verify packaging equipment and calibration parameters against validation criteria • Review sampling methods for packaging qualifications • Verify the environment and conditions under which packaging is performed • Analyse measurable acceptance criteria for tests or checks being conducted • Verify that packaging is performed in line with CGMPs procedures and standard protocols • Report packaging validation activities and results	• Develop packaging validation plans to assure the quality of product packaging • Develop packaging validation Standard Operating Procedures (SOPs) • Introduce technologies to automate or facilitate packaging validation processes • Validate packaging processes against specified product and packaging requirements • Determine final acceptance criteria for all packaging validation exercises • Define acceptable conditions for carrying out packaging activities and storage of packaging materials • Evaluate the impact of equipment, product, or process changes on packaging effectiveness • Adapt packaging validation procedures to accommodate new equipment, products or manufacturing processes • Communicate key findings from packaging validation results to relevant stakeholders		