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

TSC Category	Quality Assurance					
TSC	Process Validation					
TSC Description	Verify that processes are reproducible and consistent in delivering quality products according to specifications, and in line with international regulations					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-QUA-2007-1.1	**BPM-QUA-3007-1.1**	**BPM-QUA-4007-1.1**	**BPM-QUA-5007-1.1**	
		Collect data required for process validation activities	Evaluate data to establish whether processes are reproducible and capable of consistently delivering quality products	Develop process validation procedures and evaluate validation results	Formulate process validation strategies to ensure quality integrated systems across the manufacturing process chain	
Knowledge		• Purpose of process validation • Definitions of process variables, parameters and conditions • Types of data required for process validation • Methods of data collection • Procedures for quality assurance and quality control in biopharmaceutical manufacturing plants • Types, causes and consequences of process deviations • Importance of following Standard Operating Procedures (SOPs) • Current Good Manufacturing Practices (CGMPs)	• Design of experiment studies • Laboratory-scale, pilot-scale and commercial models of production • Quality, product and raw material attributes • Process, operating and equipment parameters • Functionalities and limitations of commercial manufacturing equipment • Predictors of and contributors to production variability • Risk and impact analysis procedures and tools for screening variables • Principles of statistical control, including but not limited to deviation analysis and process control limits • Procedures for quality control in biopharmaceutical manufacturing plants • Methods of documenting investigations and reporting out-of-specification attributes and parameters	• Approaches to process control • Effects of scale on commercial processes • Application of statistical metrics • Purpose and applications of various process validation tests and procedures • Types of Process Analytical Technology (PAT) tools and their applications • Potential risks of process deviations • Production efficiency and quality metrics	• End-to-end processes in biopharmaceutical manufacturing • Procedures of biopharmaceutical manufacturing processes • Parameters for testing the viability of biopharmaceutical manufacturing processes • Principles of process development • Principles of integrating Process Analytical Technology (PAT) into process validation procedures • Techniques to project the long-term impact of process deviations • Local and global industry standards and best practices in process validation	

Abilities		• Identify data collection methodologies to apply based on critical validation characteristics to be studied • Follow work plans and schedules to complete data collection within schedule • Collect data on critical validation characteristics according to SOPs • Store data in appropriate formats • Support in the identification of process deviations • Submit data for evaluation	• Evaluate data on the performance of manufacturing processes and production outputs • Detect and evaluate deviations of process variables from process plants' steady state condition to determine root causes • Identify and record deviations in production attributes and parameters • Identify possible sources of variability in product and process quality • Perform impact analysis for identified root causes • Evaluate the re-usability of materials to establish usable lifetimes of materials • Document investigations and data analyses performed as per organisational procedures	• Plan process validation tests, procedures and schedules in accordance with regulations and Current Good Manufacturing Practices (CGMPs) • Establish procedures for production attributes and parameters deviation detection, control, and mitigation • Evaluate the analytical methods used in process validation analysis • Describe the statistical methods to be used process validation to analyse data collected • Facilitate the integration of PAT into process validation procedures • Assess the impact of changes in processes on production efficiency and validation requirements • Evaluate key results and findings from process validation tests and analyses • Confirm the uniformity of product and process quality • Draft Process Performance Qualification (PPQ) reports	• Liaise with relevant departments to develop organisation-wide process validation plans, which incorporate Process Performance Qualification (PPQ) protocols • Determine optimal manufacturing conditions for required operating parameters, processing limits and raw material inputs • Determine data collection and evaluation requirements • Determine acceptance criteria for each process step • Develop sampling plans, assuring statistical confidence of quality within and between batches • Develop strategies for addressing deviations from expected conditions and managing non-conforming data • Direct the implementation of process controls during the process design and qualification phases • Communicate key insights from process validation analyses to relevant stakeholders • Review PPQ reports to conclude whether processes meet validation criteria • Provide detailed justification in cases where validation	

					approval is denied, outlining specific aspects of the design stage through the process qualification stage to meet approval requirements	