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

TSC Category	Quality Assurance					
TSC	Computerised Systems Validation					
TSC Description	Commission computerised systems for use in biopharmaceuticals manufacturing facilities					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUA-3004-1.1	**BPM-QUA-4004-1.1**	**BPM-QUA-5004-1.1**	
			Perform validation tests for computerised systems according to established procedures	Develop validation procedures for computerised systems and evaluate validation results	Formulate validation strategies to ensure quality of integrated systems across the manufacturing process chain	
Knowledge			• Current Good Manufacturing Practices (CGMPs), Good Automated Manufacturing Procedures (GAMPs) and other regulations relevant to computerised systems • Principles of computer-aided manufacturing • Principles of data integration • Purpose and applications of various computerised systems' validation tests and procedures • Impact of computerised systems on quality and safety in biopharmaceuticals manufacturing • Impact analysis and risk assessment methodologies • Types and applications of computerised systems used in the biopharmaceutical manufacturing sector • Processes controlled by computerised systems	• Principles of automated control systems • Computer system programmes used in the biopharmaceuticals manufacturing sector • Potential risks and principles of risk management in computer system implementation • Concepts of computerised system integration • Production efficiency and quality metrics • Procedures for managing fixes, updates and retirement for computerised systems • Design philosophies applicable to manufacturing and industry standards relating to batch process control	• End-to-end processes in biopharmaceutical manufacturing • Principles of computerised systems • Principles of computerised systems integration and system integration lifecycles • Parameters for testing the viability of computerised systems in manufacturing processes • Techniques to project the long-term impact of automation or computerised systems on manufacturing processes • Local and international industry standards and best practices in computerised systems implementation	

			• Types of data collected by computerised systems • Basic terms in programming and coding language			
Abilities			• Schedule validation tests for computerised systems • Carry out validation procedures and controls for computerised systems in accordance with GAMPs regulations • Conduct impact analyses of computerised systems on quality and safety • Perform suitability testing for computerised systems • Conduct risk assessments of computerised systems • Identify the immediate impact of computerised system programming changes on manufacturing processes • Conduct assessment of computerised systems for compliance with GAMPs • Report results from computerised system validation tests • Implement improvements to current computerised systems and processes	• Plan computerised systems validation procedures in accordance with regulations and principles of Good Automated Manufacturing Procedures (GAMPs) • Map out tests and procedures required to validate computerised systems • Evaluate impact analyses and determine the overall effect of computerised systems on quality and safety • Evaluate potential risks associated with implementing computerised systems • Assess the impact of changes in computerised systems on production efficiency or quality • Recommend suitable computerised systems for biopharmaceutical manufacturing plant operations • Evaluate the compliance of computerised systems with GAMPs and regulatory guidelines • Evaluate results from computerised systems validation testing and identify gaps that affect	• Formulate strategies to validate computerised systems • Establish appropriate types and sequence of tests that can be employed to validate computerised systems • Articulate quality requirements and validation parameters for computerised systems • Oversee computerised systems validation procedures and controls in accordance with regulations and principles of Good Automated Manufacturing Procedures (GAMPs) • Anticipate the impact of changes in computerised systems to overall manufacturing operations • Determine applicable regulations for compliance for the organisation's computerised systems • Evaluate methods to mitigate potential risks of computerised systems that impact on manufacturing operations • Evaluate suitability of improvements made to the organisation's	

				manufacturing operations	computerised systems and processes	