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

TSC Category	Quality Assurance					
TSC	Cleaning Validation					
TSC Description	Validate processes and methods for achieving required standards of cleanliness					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUA-3003-1.1	**BPM-QUA-4003-1.1**		
			Implement validation processes to review the quality of cleaning procedures	Develop validation processes to ensure the effectiveness and consistency of cleaning methodologies		
Knowledge			• Purpose of cleaning validation • Types of data required for cleaning validation • Procedures for Quality Assurance and Quality Control in biopharmaceuticals manufacturing plants • Indicators of acceptable cleanliness levels • Types of contaminants and their effects • Optimal environmental conditions to maintain cleanliness standards • Cleaning, sanitation and disinfection procedures • Types and applications of cleaning devices, solutions and testing equipment • Current Good Manufacturing Practices (CGMPs) • Biopharmaceutical product and equipment cleanliness requirements and parameters	• Cleaning standards for various biopharmaceutical products and equipment • Industry standards and best practices in cleaning validation • Implications of contaminant type, facility and risks on acceptance criteria • Current Good Manufacturing Practices (CGMPs) • Emerging technologies and methods for cleaning validation		
Abilities			• Collect data on critical validation characteristics • Check that cleaning procedures are	• Develop cleaning validation plans customised to different		

			performed in line with Standard Operating Procedures (SOPs) and CGMPs • Identify deviations or potential risks in processes used to clean equipment and surfaces • Verify the environmental conditions under which cleaning is carried out • Verify the equipment used to clean or remove contaminants • Verify the quality and quantity of disinfectants, detergents, solvents and other agents used for cleaning • Determine the specificity and sensitivity of methods used to detect residuals or contaminants • Report cleaning validation results • Investigate significant trends or findings from cleaning validation results	biopharmaceutical product requirements • Articulate objectives and indicators of successful cleaning validation • Determine the cleaning methods and processes that require validation • Develop cleaning validation processes for biopharmaceutical manufacturing plants • Establish quality standards and desired outcomes of cleaning validation activities • Determine final acceptance criteria for all cleaning validation exercises • Define the acceptable range of environmental conditions for cleanrooms and general facilities • Define key accountabilities for the performance of cleaning validation • Present key findings from cleaning validation results to relevant stakeholders		