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

TSC Category	Quality Control					
TSC	Cleanliness Testing					
TSC Description	Perform tests to verify that residue and contaminants are at risk-free levels during the manufacture of subsequent products					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUC-3001-1.1	**BPM-QUC-4001-1.1**	**BPM-QUC-5001-1.1**	
			Perform tests to verify the cleanliness of biopharmaceutical manufacturing equipment and surfaces	Develop and monitor the implementation of Standard Operating Procedures (SOPs) for cleanliness tests	Establish cleanliness testing processes and activities	
Knowledge			• Cleaning, sanitation and disinfection procedures • Sampling procedures • Procedures for conducting cleanliness tests • Indicators of acceptable cleanliness levels • Importance of cleanliness tests and their limitations • Types and applications of disinfectants, detergents and other cleaning solutions • Processes for reviewing and approving cleanliness test results • Regulations on cleaning in the biopharmaceutical manufacturing sector • Current Good Manufacturing Practices (CGMPs)	• Types of contaminants and their effects on biopharmaceutical products, the environment and the human body • Optimal environmental conditions for cleanliness testing • Cleanliness requirements for biopharmaceutical manufacturing equipment • Cleanliness parameters for biopharmaceutical products and equipment • Indicators of cleaning solutions' efficacy	• Cleaning standards for various biopharmaceutical products and equipment • Industry standards and best practices in cleanliness testing • Implications of contaminant type, facility and risks on acceptance criteria • Emerging technologies and methods for cleanliness testing	
Abilities			• Prepare equipment for cleanliness testing in accordance with Standard Operating Procedures (SOPs) • Collect microbiological samples prior to and throughout cleaning procedures	• Develop SOPs for cleanliness testing • Specify suitable environmental conditions for performing of cleanliness tests • Identify appropriate cleanliness tests and procedures to be applied	• Establish cleanliness testing plans customised to different biopharmaceutical product requirements • Develop organisational guidelines for testing the cleanliness of equipment and surfaces	

			• Check that environmental conditions for conducting cleanliness tests are in the acceptable range • Check that the preparation of isolators or cleanroom environment are in accordance with SOPs • Perform routine cleanliness tests • Check for particulates and contaminants left behind by manufacturing processes • Record cleanliness test results in accordance with SOPs • Report cleanliness test findings and trends	on various equipment and surfaces • Specify measurable acceptance criteria for cleanliness tests or checks • Review cleanliness test results to assess efficacy of cleaning solutions • Investigate lapses in cleanliness identified • Identify contaminants affecting products or equipment • Analyse the impact of particulates and contaminants left behind by the manufacturing process	• Introduce new methods to test for cleanliness and identify contaminants • Determine final acceptance criteria for equipment cleanliness levels • Lead investigations on non-conformities to cleanliness standards • Report overall results and key findings from cleanliness tests and their implications on product quality and business operations • Recommend process changes to minimise contamination within biopharmaceutical manufacturing facilities	