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

TSC Category	Production					
TSC	Cleaning and Sterilising					
TSC Description	Clean and sterilise equipment, systems and materials for biopharmaceuticals production					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-OPR-2005-1.1	**BPM-OPR-3005-1.1**	**BPM-OPR-4005-1.1**		
		Prepare for and perform cleaning and sterilisation of equipment in biopharmaceuticals manufacturing plants	Implement cleaning and sterilisation procedures and verify alignment with cleaning quality and process standards	Optimise cleaning and sterilisation procedures to maximise cleanliness standards		
Knowledge		• Current Good Manufacturing Practices (CGMPs) and other standards or regulations governing cleaning and sterilisation in the biopharmaceuticals manufacturing industry • Cleaning and sterilisation Standard Operating Procedures (SOPs) • Objectives of cleanliness and cleaning in biopharmaceuticals manufacturing environments • Types of equipment used for cleaning and sterilising • Types of equipment and containers in biopharmaceuticals manufacturing facilities that require repeated cleaning and sterilisation • Cleaning and sterilising parameters • Cleaning agent options and their preparation and verification procedures	• Types of contaminants and the effects on the environments and human body • Required standards of cleanliness and sterility in biopharmaceuticals manufacturing plants • Indicators of cleaning solutions and sterilisation methods efficacy • Methods to retain level of cleanliness and sterility post-cleaning and post-sterilisation • Principles of contamination and cross contamination	• International regulations for cleaning and sterilising in biopharmaceuticals manufacturing context • Impact of cleaning and sterilising activities on the end-to-end biopharmaceuticals manufacturing value chain • Optimal methods of cleaning and sterilising whilst retaining product quality and integrity • New and emerging cleaning and sterilising methods		

		• Air, surface and cleaning agents sampling and testing techniques • Principles and features of cleanroom environments, and associated cleanroom procedures • Post-cleaning and post-sterilisation maintenance or restoration procedures				
Abilities		• Verify quality of cleaning and sterilisation fluids • Prepare materials, equipment and solvents required for cleaning and sterilisation • Configure equipment systems for cleaning operations • Perform cleaning and clean-in-place operations for production equipment and materials in accordance to SOPs and CGMPs • Conduct sterilisation, and sterilise-in-place activities for relevant production equipment and materials in accordance to SOPs and CGMPs • Perform tests to verify cleaning and sterilising has been performed to the required standards • Document completion of cleaning and sterilising according to organisational procedures	• Develop cleaning and sterilisation Standard Operating Procedures (SOPs) • Set timings and schedules for the cleaning and sterilising of production line components • Conduct training on requirements for cleaning and sterilisation of equipment and containers • Conduct inspections on cleaning and sterilisation procedures to ensure compliance • Review records of cleaning and sterilisation activities • Work with Quality Control department to ensure cleaning and sterilising is conducted to the required standards	• Review cleaning and sterilisation Standard Operating Procedures (SOPs) • Integrate cleaning and sterilising activities with other systems and processes in the biopharmaceuticals manufacturing facilities • Review cleaning and sterilising activities • Identify improvements that can be made to cleaning and sterilising procedures and equipment • Perform root-cause analysis on contamination issues resulting from inadequate cleaning and sterilising • Develop follow-up actions to maintain cleanliness and sterility standards across product lines following lapses		