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

TSC Category	Production					
TSC	Flexible Facilities Implementation					
TSC Description	Facilitate implementation and changeover of flexible facilities, integrating single-use technologies with flexible manufacturing operations					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-OPR-2008-1.1	**BPM-OPR-3008-1.1**	**BPM-OPR-4008-1.1**	**BPM-OPR-5008-1.1**	
		Operate and use flexible facilities in biopharmaceuticals manufacturing	Implement single-use equipment and other flexible facilities in biopharmaceuticals manufacturing plants	Develop guidelines and procedures for the changeover and implementation of flexible facilities	Establish organisational directions for the use of flexible facilities and single-use equipment	
Knowledge		• Concept of flexible facilities and their purposes • Types of single-use manufacturing technologies and their purposes • Protocols to handle and transport portable manufacturing equipment, machinery and materials • Fluid transfer procedures • Processes for rinsing single-use assembly surfaces • Standard Operating Procedures (SOPs) for flexible or single-use facilities in biopharmaceuticals manufacturing • Current Good Manufacturing Practices (CGMPs) and other regulations and safe working practices • Decontamination and disposal procedures • Properties and personal protection procedures for handling hazardous products and materials	• Various types of flexible facilities and equipment, and configuration methods • Importance of single-use technologies in producing sterile products and protecting critical process equipment • Tests to check compatibility of flexible or single-use facilities with existing fixed process equipment • Correct operations of single-use assemblies • Components of single-use technologies and their materials of construction • Preparation of single-use equipment for product contact • Potential impact of poor fluid transfer procedures on product quality or purity • Importance of safe and effective decontamination and disposal procedures	• Industry standards and best practices in managing flexible facilities changeovers • Pros and cons of implementing flexible facilities and single-use technologies • Single-use assembly cleanliness requirements • Optimal flexible facilities changeover timings and conditions	• Facility and equipment requirements for various biopharmaceuticals products • Optimal uses and configurations of flexible facilities and equipment • Manufacturing processes and systems connected to and affected by single-use equipment and other flexible facilities • Return on Investment (ROI) analysis for flexible facilities implementation • Compatibility of chemicals used in flexible facilities	

		• Procedures to clear and flush the lines	• Occupational health, safety and environmental impact of poor fluid handling and equipment disposal			
Abilities		• Prepare portable or single-use manufacturing technologies and other flexible facilities • Move portable manufacturing equipment, machinery and materials as instructed • Rinse single-use assembly surfaces as instructed • Connect flexible facilities equipment and parts according to instructions • Start up single-use equipment according to SOPs • Operate single-use technologies during biopharmaceuticals production • Dispose single-use equipment safely and in accordance to standard protocols • Locate and interpret information in Safety Data Sheets (SDSs) • Document flexible facilities set-up activities performed	• Oversee preparation of portable or single-use manufacturing technologies • Install single-use facilities with fixed process equipment • Check integrity of flexible facilities equipment and parts set-up • Prepare filters and rinsing fluids for integration into single-use assemblies • Monitor usage of single-use assemblies and associated rinsing processes for alignment with cleanliness and quality standards • Disconnect single-use assemblies and facilities from process equipment to allow for changeovers • Reconfigure flexible facilities and equipment as directed to accommodate scaling up of production	• Oversee product and facility changeovers for multiple product lines • Add or remove unit operations based on biopharmaceuticals products manufacturing needs • Set targets and guidelines for facilities changeover time • Establish flexible facilities or single-use equipment cleaning and rinsing requirements within flexible facilities • Lead teams to facilitate changeovers of facilities	• Advise on flexible facilities feasibility assessments from biopharmaceuticals products and processes perspectives • Direct suitable placements of flexible facilities and equipment for manufacturing of different products • Establish organisational processes and Standard Operating Procedures (SOPs) to set up, operate, clear out and change over flexible facilities and single-use technologies • Guide use of flexible facilities with the scaling up of production from clinical trial material runs to commercial manufacturing scales • Review evaluations of flexible facilities success and determine if they should be continued • Troubleshoot multi-disciplinary issues with flexible systems	