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

TSC Category	Production					
TSC	Good Manufacturing Practices Implementation					
TSC Description	Implement Current Good Manufacturing Practices in the design, monitoring, and control of manufacturing processes and facilities to ensure the potency, quality, and purity of biopharmaceuticals products					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-OPR-2009-1.1	**BPM-OPR-3009-1.1**	**BPM-OPR-4009-1.1**	**BPM-OPR-5009-1.1**	
		Apply Current Good Manufacturing Practices (CGMPs) when designing, monitoring, controlling and performing manufacturing activities	Implement the principles of Current Good Manufacturing Practices (CGMPs) through the application of industry best-practices and international standards	Develop protocols aligned with Current Good Manufacturing Practices (CGMPs) for a department	Synthesise Current Good Manufacturing Practices (CGMPs) with all design, monitoring, and control of biopharmaceuticals manufacturing processes across the organisation	
Knowledge		• Principles of CGMPs • Types of work processes occurring in biopharmaceuticals manufacturing facilities and how CGMPs apply • Production areas and cleanrooms Standard Operating Procedures (SOPs) • Uses of production equipment • Equipment cleaning frequency and maintenance log requirements • Responsibilities of job functions regarding compliance to CGMPs • Frontline reporting and recording procedures for non-compliance • Good documentation practices • Processes to prevent cross-contamination • Processes and locations for the preparation and staging of raw materials	• Risk management techniques • Specification, design, verification, qualification and commissioning standards • Verification and validation methods and requirements for equipment, facilities and processes	• Relationships of CGMPs with quality assurance and quality control, and its impact on patient safety • Operational workflows for manufacturing processes • Risk management international guidelines and standards • Organisation's regulatory and compliance requirements in relation to CGMPs • Biopharmaceuticals manufacturing process lifecycles • Methods of improving manufacturing processes designs and control quality • Methods of reviewing alignment of processes to CGMPs	• Global best practices in manufacturing standards • Global best practices in risk management • Change and culture management strategies • End-to-end biopharmaceuticals manufacturing processes across the organisation	

Abilities		• Apply SOPs when performing work activities in plants • Identify the type of controlled documents required in manufacturing facilities in compliance with CGMPs requirements • Record non-compliance of Good Manufacturing Practices (GMPs) or cleanroom protocols • Report and inform respective parties on any non-compliance with manufacturing or clean room protocols and practices • Explain the importance of abiding by CGMPs to external parties such as vendors	• Perform work processes in accordance with CGMPs • Check work processes for compliance with CGMPs • Take corrective actions against non-compliance of Good Manufacturing Practices (GMPs) or cleanroom protocols • Identify improvements that can be made to promote better alignment of processes with CGMPs	• Translate CGMPs standards into operating protocols for a department • Establish processes to monitor compliance with CGMPs in a department • Introduce risk control programmes and activities for a department in line with organisational policies • Develop validation strategies to demonstrate processes are fit for intended uses in accordance with CGMPs and other regulatory guidelines • Control and monitor operations in accordance with regulatory guidelines • Review CGMPs deviations • Establish systems and programmes for CGMPs training	• Synthesise processes across the design, monitoring, and control of manufacturing practices and align to CGMPs • Establish processes to monitor compliance with CGMPs across the organisation • Build a culture that promotes alignment to CGMPs across the organisation • Lead risk control programmes • Resolve significant deviations with senior quality review teams • Investigate root causes of serious breaches and deviations from CGMPs standards	