

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

TSC Category	Quality Control					
TSC	Quality Control Management					
TSC Description	Establish quality control procedures for biopharmaceutical manufacturing processes, products, equipment and systems, to ensure the desired level of compliance at all stages					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-QUC-4006-1.1	BPM-QUC-5006-1.1	BPM-QUC-6006-1.1
				Develop quality control procedures to test and validate biopharmaceutical manufacturing products	Devise the organisation's quality control policies and objectives to establish organisation-wide validation systems and procedures	Advocate the organisation's quality control systems and benchmark existing processes against global and local practices for improvement
Knowledge				<ul style="list-style-type: none"> Types of biopharmaceutical manufacturing inputs, outputs and processes The organisation's quality control requirements Methods of developing quality performance criteria Methods of evaluating the effectiveness of quality control procedures Key stakeholders to be consulted during the development and improvement of quality control procedures Current Good Manufacturing Practices (CGMPs) 	<ul style="list-style-type: none"> Methods of developing quality control policies Types of quality control performance metrics and parameters Quality control regulations Principles of biopharmaceutical manufacturing validation and testing requirements Methods of measuring and monitoring quality standards for biopharmaceutical manufacturing processes and products 	<ul style="list-style-type: none"> Global and local benchmarks for best practice in quality control Industry trends and technologies used in quality control Strategic planning processes Techniques to encourage quality control change and innovation Methods of cascading organisational quality control policies to managers and other key stakeholders Factors that may influence the organisation's quality control policies and objectives Methods of reviewing quality control policy scope, criteria and objectives
Abilities				<ul style="list-style-type: none"> Review the organisation's quality control policies and biopharmaceutical manufacturing processes 	<ul style="list-style-type: none"> Formulate the organisation's quality control policies and objectives in alignment with regulatory standards and requirements 	<ul style="list-style-type: none"> Devise quality control strategies for the organisation to achieve its objectives, based on industry best practices and regulatory requirements

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				<ul style="list-style-type: none"> • Develop quality control procedures based on organisational and regulatory requirements • Review quality control performance and effectiveness metrics to develop procedural improvements • Communicate changes in quality control requirements to relevant stakeholders to ensure compliance with new procedures 	<ul style="list-style-type: none"> • Define quality parameters in collaboration with external suppliers and clients • Establish organisation-wide processes and systems to implement quality control tests and validation procedures • Endorse changes to processes or infrastructure resulting from validation findings 	<ul style="list-style-type: none"> • Keep abreast of industry trends and technology developments in quality control • Deliver organisation-wide updates on new or amended legislative or regulatory requirements and their impact on quality control strategies • Develop processes for the effective review of quality control policies and objectives according to organisational requirements • Determine the organisation's Quality Control performance against relevant industry benchmarks • Drive a quality culture across the organisation • Spearhead incentive or reward schemes to encourage the adoption of quality control policies and procedures
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