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

TSC Category	Quality Assurance					
TSC	Quality Assurance Management					
TSC Description	Implement quality assurance procedures and conduct audits to ensure compliance					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-QUA-3008-1.1	**BPM-QUA-4008-1.1**	**BPM-QUA-5008-1.1**	**BPM-QUA-6008-1.1**
			Implement quality assurance procedures	Develop quality assurance procedures and facilitate external quality audits	Devise the organisation's quality assurance policies and objectives and establish procedures for monitoring and measuring compliance with quality assurance requirements	Advocate the organisation's quality assurance strategies and benchmark existing processes against global and local practices for improvement
Knowledge			• Quality assurance practices and procedures • Types of biopharmaceutical manufacturing equipment, systems and processes • Current Good Manufacturing Practices (CGMPs) • Regulatory requirements for product registration and batch release • Requirements of internal and external quality audits • Types of quality data, statistical collection tools and methodologies • Methods to identify quality gaps	• Organisation's quality assurance objectives • Organisation's regulatory and compliance requirements for quality assurance • Biopharmaceutical manufacturing process lifecycles • Methods of improving manufacturing processes and product quality • Procedures for facilitating external audits • Methods of analysing customer complaints • Structure of a product registration report • Batch release requirements	• Methods of developing quality assurance policies • Methods of measuring and monitoring quality standards • Procedures of product recall • Legal and other requirements relevant to product recall • Procedures and regulations for product registration • Confidentiality and non-disclosure requirements of audit information	• Global and local benchmarks for best practices in quality assurance • Regulatory requirements and their impact on quality assurance strategies • Methods in Strategic Planning Process • Methods of cascading organisational quality assurance policies to managers and other key stakeholders • Factors influencing the organisation's quality assurance policies and objectives • Product recall precedents
Abilities			• Present information required during audits according to Standard Operating Procedures (SOPs) • Develop audit checklists and forms for respective manufacturing	• Develop quality assurance procedures in compliance with the organisation's policies and regulatory requirements • Scope and plan internal audits in accordance	• Formulate the organisation's quality assurance policies and objectives in accordance with regulatory standards • Oversee the completion and proper documentation of all	• Devise quality assurance strategies for the organisation to achieve its objectives, based on industry best-practices and regulatory requirements

			processes and related departments • Consolidate audit findings and prepare reports on quality performance • Assist to identify potential quality issues with manufacturing processes and products from audit results • Analyse audit reports to highlight gaps in quality assurance and training needs • Implement improvement initiatives and support training activities to address gaps in quality procedures • Record details of customer complaints and assist with investigations • Support product registration and batch release activities by collecting and organising the information required	with internal and external requirements • Facilitate external quality audits and review findings • Analyse trends in the quality performance of manufacturing facilities to identify gaps • Analyse customer complaints to identify contributing factors and escalate issues accordingly to appropriate staff for follow-up action • Prepare product registration reports • Review completed batch reports and checklists • Recommend interventions and initiate or refine training programmes to close quality gaps and address non-compliances • Present and explain relevant quality records and audit reports to stakeholders as required	quality assurance activities • Review the alignment of Standard Operating Procedures (SOPs) with Current Good Manufacturing Practices (CGMPs) • Liaise with external suppliers and clients to ensure quality parameters are clearly defined • Lead preparations for external audits and conduct opening and closing meetings • Review results of external audits and determine critical changes to processes and procedures required • Obtain approval from stakeholders to disclose information required by external auditors • Oversee product registration and batch release activities and delegate responsibilities to staff accordingly • Lead investigations into major customer complaints • Manage biopharmaceutical product recalls	• Direct product registration and batch release activities • Identify implications of changes to regulatory requirements on the organisation's Standard Operating Procedures (SOPs) • Deliver organisation-wide updates on new or amended legislative or regulatory requirements and their impact on quality assurance strategies • Establish processes for the effective review of quality assurance policies and objectives • Inspire a quality culture across the organisation and direct training activities across manufacturing facilities • Spearhead incentives or reward schemes to encourage the adoption of quality assurance policies and procedures • Manage major customer complaints and associated product recall activities