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

TSC Category	Quality Assurance					
TSC	Document Control					
TSC Description	Implement documentation policies to facilitate the referencing of information for processes, systems and equipment, and to comply with regulatory requirements					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-QUA-2005-1.1	**BPM-QUA-3005-1.1**	**BPM-QUA-4005-1.1**		
		Apply document processing and formatting procedures	Implement document control procedures and operate document management systems	Develop documentation policies and evaluate new and existing documentation practices based on identified requirements		
Knowledge		• Methods of processing documents for biopharmaceuticals manufacturing processes, systems and equipment • Document formatting standards • Types of document filling systems • Types of document approval processes • Methods of assuring version control • Methods of tracking document distribution	• Methods of managing documentation for biopharmaceuticals manufacturing processes, systems and equipment • Types of document management systems • Organisation's document management policies and document filling and review procedures • Organisation's document distribution system • Principles of conducting documentation audits	• Types of documentation for biopharmaceuticals manufacturing processes, systems and equipment • Organisation's documentation objectives and requirements • Biopharmaceuticals manufacturing documentation best practices • Types of information to include in documents for processes, systems and maintenance • Types of knowledge management tools • Methods of formulating policies and procedures • Key stakeholders to be consulted for documentation development and review • Methods of ensuring documentation accuracy and usefulness • Types of regulatory audits and related documentation requirements		

				• Methods of conducting document management reviews		
Abilities		• Organise information in document management systems, ensuring the accuracy of information and its accessibility by appropriate stakeholders • Apply document formatting and version control procedures • Track document distribution • File electronic and hardcopy documents according to standard procedures • Prepare documents required for documentation audits	• Review the maintenance of document management systems • Document and update personal certifications and licenses for employees • Verify the correct distribution of documents • Perform document management audits to ensure documentation requirements are met • Record results of audits • Implement new and revised documentation policies and procedures to ensure compliance with the organisation's and regulatory requirements	• Evaluate documentation requirements for biopharmaceuticals manufacturing processes, systems and equipment • Develop documentation policies and procedures based on the organisation's requirements • Revise existing documentation policies and procedures based on industry best practices • Develop templates for technical documents • Communicate changes in documentation requirements to relevant stakeholders to ensure compliance with new procedures • Evaluate the implementation of documentation procedures in the organisation • Facilitate documentation audits • Evaluate audit findings and results and highlight areas of improvement		