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

TSC Category	Quality Assurance					
TSC	Analytical Method Validation					
TSC Description	Verify analytical methods used to ensure accuracy, validity and reliability of methods					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-QUA-2001-1.1	**BPM-QUA-3001-1.1**	**BPM-QUA-4001-1.1**	**BPM-QUA-5001-1.1**	
		Collect data to support analytical method validation	Perform critical analytical method validation characteristics studies	Establish and oversee processes and activities for analytical method validation	Lead analytical method validation to ensure consistency of processes	
Knowledge		• Purpose of analytical test method validation • Types of data required for analytical method validation • Methods of data collection • Importance of following Standard Operating Procedures (SOPs) • Procedures for quality assurance and quality control in biopharmaceuticals manufacturing plants	• Principles of analytical test method validation • Importance of analytical test method validation • Types of quality control tests • Differences between pharmacopeial and non-pharmacopeial methods • Analytical method validation characteristics	• Timing and frequency requirements for conducting analytical method validation • Applications of different analytical methods • Impact of different analytical methods on the accuracy, validity and reliability of analytical results • Methods of troubleshooting analytical methods and results for inaccuracies, invalidities and unreliability • Quality control management procedures • Regulatory agency inspections and audit procedures	• Importance of analytical test method validation throughout various steps of the biopharmaceutical manufacturing process • Importance of cross-functional collaboration in validating quality control testing procedures and analyses	
Abilities		• Identify data collection methodologies to be applied based on critical method validation characteristics to be studied • Follow work plans and schedules to complete data collection work on time • Collect data on critical method validation	• Identify critical method validation characteristics to be studied for specific analytical methods • Prepare lead-time, resources and schedules based on specific analytical methods • Perform critical method validation characteristics studies according to Standard Operating Procedures (SOPs)	• Develop analytical method validation plans • Articulate objectives of and key indicators of successful analytical method validation • Specify the quality control test requirements to be validated • Evaluate the impact of quality control test process changes on analytical methods	• Advise on critical process steps requiring quality control testing and analysis • Collaborate with key stakeholders across functions to approve validations of analytical methodologies • Drive analytical method validation improvements	

		characteristics according to SOPs • Store data in appropriate formats • Clean up data to remove incomplete, duplicated or incorrect data • Support the identification of process deviations from data collected • Submit data for evaluation	• Analyse method validation results • Document method validation results as per organisational procedures • Implement training on new analytical methods	• Develop analytical method validation Standard Operating Procedures (SOPs) and documentation for the organisation's internal use • Review analytical method validation results • Evaluate validation reports to identify areas for improvement • Recommend changes to quality control testing procedures and analysis • Facilitate training on new analytical methods		