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

TSC Category	Production					
TSC	Chromatography Equipment Operation and Control					
TSC Description	Operate chromatography systems in biopharmaceuticals manufacturing facilities					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-OPR-3004-1.1	**BPM-OPR-4004-1.1**		
			Implement procedures to operate chromatography equipment	Verify conditions and operations of chromatography equipment and perform troubleshooting		
Knowledge			• Chromatography equipment designs and their applications • Principles of chromatography • Types of chromatography techniques used in downstream purification processes • Sterilisation of chromatography equipment • Critical process parameters in chromatography operations • Types of column packing and unpacking procedures and their suitability for various column sizes and media types • Importance of correct media unpacking procedures in ensuring robust media life • Safety precautions with chromatography equipment operations and waste disposal	• Optimal operating conditions for chromatography equipment • Procedures to verify safety and quality conditions during equipment use and manufacturing operations • Importance of loading conditions, dynamic binding capacity, linear velocity, residence time and elution conditions on process performance • Appropriate safety factors for the resin volume and its impact on chromatography process performance • Types and indicators of hazards or abnormal conditions involving processes, equipment and materials during operations • Troubleshooting methods and equipment- or process-adjustment principles to restore optimal operating conditions		

				• Risk assessment and mitigation techniques		
Abilities			• Implement pre-checks on the chromatography equipment status, performance and safety • Prepare chromatography equipment and media in accordance with Standard Operating Procedures (SOPs) • Perform packing and operations of process scale chromatography columns • Measure performance of packed chromatography columns • Unpack media from chromatography process equipment • Verify media and assembly integrity • Perform qualitative and quantitative analyses using chromatography and spectroscopy techniques • Calculate the required resin volume with safety factors for chromatography processes based on lab-based process development data • Complete log and batch sheets • Sterilise equipment after use and dispose biohazard waste	• Identify the critical chromatography process parameters for the chosen resin type • Prepare protocols or flow charts detailing the various steps in the chromatography operations • Implement Standard Operating Procedures (SOPs) for chromatography operations • Oversee and direct changes to critical parameters to adjust or restore chromatography equipment to optimal functioning • Analyse column packing results • Identify defects or faults in equipment parts or operations • Conduct root cause analysis • Mitigate risks associated with identified hazards relating to chromatography operations • Review batch sample testing outcomes to verify product quality		