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

TSC Category	Production					
TSC	Filtration Equipment Operation and Control					
TSC Description	Operate filtration equipment in biopharmaceuticals manufacturing facilities					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
			BPM-OPR-3007-1.1	**BPM-OPR-4007-1.1**		
			Implement procedures to operate filtration equipment	Verify conditions and operations of filtration equipment and perform troubleshooting		
Knowledge			• Filtration equipment designs and their applications • Principles of filtration • Types of tangential and normal filtration processes • Methods of operating tangential, normal and other types of filtration equipment • Sterilisation requirements for filtration equipment • Critical process parameters for operating filtration equipment • Measures to keep the filtration operations within the required parameters • Safety precautions associated with filtration equipment operations and waste disposal • Importance of crossflow and transmembrane pressure optimisation on process performance	• Optimal operating conditions for filtration equipment • Types and characteristics of membranes and filters • Types of filter fouling mechanisms • Filter sizing and scaling models and techniques • Methods of conducting V_{max} sizing experiments for membrane filters • Methods of conducting P_{max} sizing experiment for pre-filter and clarification filters • 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 • Procedures to verify safety and quality conditions during filtration equipment use		

				and manufacturing operations • Risk assessment and mitigation techniques		
Abilities			• Set-up filtration equipment and configurations in accordance with equipment set-up procedures • Prepare for filter integrity tests and conduct other pre-checks of equipment and configurations to verify suitability for use • Monitor the filtration process parameters to verify the products acceptability in accordance with Standard Operating Procedures (SOPs) • Adjust the process parameters to ensure constant optimal performance • Notify the authorised personnel when the filtration processes cannot be carried out • Complete log and batch sheets • Change over filters and conduct leak tests to verify integrity • Sterilise equipment after use and dispose biohazard waste	• Determine the filtration process requirements and objectives • Conduct constant pressure and constant flow filtration tests • Use the V_{max} and A_{min} equations to calculate the minimum required filter areas for processes • Create resistance versus throughput curves and fit data to polynomial functions • Calculate the minimum required filter areas for process steps using the P_{max} algorithm • Recommend the proper filter configurations for the processes with appropriate safety factors • Lead implementation of Standard Operating Procedures (SOPs) for filtration operations • Review batch sample testing outcomes to verify product quality and identify defects • Conduct root cause analysis • Mitigate risks associated with identified hazards relating to filtration equipment operations		