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

TSC Category	Process Development/Manufacturing Science and Technology					
TSC	Pharmacovigilance Integration					
TSC Description	Integrate patient-outcome factors into the design of biopharmaceuticals manufacturing processes					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
				BPM-PST-4007-1.1	**BPM-PST-5007-1.1**	
				Review the impact of biopharmaceuticals manufacturing processes on treatment effectiveness and therapeutic compliance	Facilitate manufacturing of safe and reliable patient-centric biopharmaceuticals drugs and treatments by incorporating patient-outcome factors in manufacturing process designs	
Knowledge				• Pharmacovigilance procedures and documentation requirements • Characteristics and quality of Active Pharmaceutical Ingredients (API) • Biopharmaceuticals manufacturing processes • Drug and treatment dosing volume, delivery techniques and frequency	• Applications of pharmacovigilance regulations and procedures on manufacturing processes • Biopharmaceuticals contamination risks • Long-term drug stability risks • Types of biopharmaceuticals delivery systems and their safety features • Types of biopharmaceuticals containment and closure systems and associated risks	
Abilities				• Contribute to Good Pharmacovigilance Practices (GVP) compliance within one's area of responsibilities • Consolidate post-sales customer feedback • Analyse the impact of elemental impurities on treatment effectiveness • Analyse the impact of API degradation on drug effectiveness • Document manufacturing facilities, personnel, processes	• Identify manufacturing processes that could impact pharmacovigilance related safety and quality issues • Direct post-sales assessments of customer feedback • Review results of patient-outcome analyses • Incorporate factors that minimise the risks of treatment effectiveness and therapeutic	

				and operational changes that may impact the final products and patient welfare • Identify possible chemical reactions between biopharmaceuticals and containment materials • Review the impact of biopharmaceuticals' viscosity on delivery requirements • Assess the fitness-for-purpose of delivery systems given intended patient population • Report the overall effectiveness of biopharmaceuticals products	compliance into manufacturing process designs • Identify measures to control consistency, stability and yield when scaling up processes from development sites to manufacturing sites • Identify measures to control long-term drug stability risks • Develop flexible containment solutions and easy-to-deliver delivery systems to assure safe and reliable self-administration	