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

TSC Category	Production					
TSC	Materials Management					
TSC Description	Manage biopharmaceuticals materials and materials flow according to established procedures for meeting batch requirements					
TSC Proficiency Description	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
		BPM-OPR-2012-1.1	**BPM-OPR-3012-1.1**	**BPM-OPR-4012-1.1**	**BPM-OPR-5012-1.1**	
		Apply materials management procedures to safely handle, prepare, and dispense materials	Implement materials management procedures to transport, prepare and dispense materials	Inspect materials management plans and provide expertise on optimum methods	Develop plans, schedules and controls to manage flow of materials	
Knowledge		• Risks of handling hazardous chemicals and materials • Methods of materials handling, storage, dispensing and disposal • Distinctions between non-bulk raw materials, Active Pharmaceutical Ingredients (API) and finished products • Types and functions of materials handling and transporting equipment, conveyors and pallets used in batch processes • Materials control documentation for batching • Basic requirements of Current Good Manufacturing Practices (CGMPs)	• Principles of physical chemistry • Materials handling process flow procedures • Classification of materials and the respective handling procedures • Proper methods of disposing different types of hazardous and non-hazardous materials • Current Good Manufacturing Practices (CGMPs)	• Principles of physical chemistry • Structures and properties of polymers, metals and alloys, ceramics, composites, nanomaterials, biomaterials and other materials used in biopharmaceuticals manufacturing • Degradation of biopharmaceuticals materials	• International regulations relating to the safe handling of hazardous materials in biopharmaceuticals manufacturing • Techniques to plan, schedule and control the flow of materials • Inventory management techniques and tools	
Abilities		• Identify safety hazards and apply adequate risk controls for handling raw materials • Process documents on receiving and delivering of materials in batches according to organisational practices • Load, transport and unload materials	• Implement materials flow procedures • Implement safety hazard and risk control procedures for handling biopharmaceuticals materials • Develop materials flow schedules and storage capacity plans	• Develop materials management procedures • Provide technical expertise on handling requirements for all types of materials in biopharmaceuticals manufacturing facilities • Advise on optimal time norms, conditions and locations for storage of	• Review materials identification, handling and disposal procedures • Determine appropriate inventory systems for materials management • Ensure alignment of materials management plans with international regulations relating to the safe handling of	

		following safe methods and organisational procedures • Sample raw materials and send for quality inspections • Handle batch materials in cleanrooms • Carry out batch and materials dispensing operations according to organisational procedures, reporting specifications and any abnormalities to authorised personnel • Record dispensed materials in batches according to CGMPs • Dispose materials according to established procedures	• Develop batch and materials dispensing procedures • Monitor compliance with materials management procedures • Implement inventory management systems • Manage inventory levels, ensuring availability of raw materials needed for production lines • Identify issues and concerns in materials issues and receipts • Communicate criteria and guidelines for raw materials inspections • Verify that degraded or contaminated materials are disposed of safely and in accordance with appropriate procedures	raw materials given the intended end products • Provide recommendations on materials compatibility • Define the critical testing parameters and criteria for materials inspections • Coach others on industry best practices and environmental standards in disposal of degraded or contaminated materials • Establish guidelines on recovery and reprocessing of materials • Set up manufacturing bills of materials • Recommend new equipment and technology transfer to support new materials handling processes	hazardous materials in biopharmaceuticals manufacturing • Review materials management procedures and identify improvements • Develop training curriculum for materials management • Oversee compliance with materials transfer procedures and policies	