

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

TSC Category	Health, Safety and Environment					
TSC	Biorisk Management					
TSC Description	Identify and implement biosafety and biosecurity practices to ensure a safe work environment					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-HSE-2001-1.1	BPM-HSE-3001-1.1	BPM-HSE-4001-1.1	BPM-HSE-5001-1.1	
		Follow biosafety procedures to conduct work safely within own work area	Deploy biosafety procedures to maintain a safe working environment	Develop and monitor the implementation of biosafety plans, and manage bio-incident responses	Formulate strategies and systems for ensuring biosafety and managing biorisks	
Knowledge		<ul style="list-style-type: none"> Organisational biosafety and biosecurity codes and practices Current Good Manufacturing Practices (CGMPs) Infection control, decontamination and waste management procedures Principles of handling biological materials Types and properties of upstream and downstream materials, equipment and processes, subject animals, agents, plants, and related biological materials Types of biological hazards and risks Types of preventive and protective measures for biological hazards and risks Types and functions of Personal Protective Equipment (PPE) Emergency Response Plans (ERPs) 	<ul style="list-style-type: none"> Organisational biosafety and biosecurity codes and practices Current Good Manufacturing Practices (CGMPs) National and international biosafety and biosecurity standards, guidelines and legislations Types and components of laboratory programmes Principles of biosafety and biosecurity audits, inspections and certifications Components of an Emergency Response Plan (ERP) 	<ul style="list-style-type: none"> Current Good Manufacturing Practices (CGMPs) Components of a biosafety plan Key considerations in designing biosafety plans Methods of reviewing the effectiveness of biosafety procedures Methods of conducting biorisk assessments Plans for addressing biorisks Methods of managing emergency responses to bio-incidents Types and content of biosafety training programmes for staff 	<ul style="list-style-type: none"> Industry best practices in biosafety Components of a biorisk management system Possible conflicts between biosafety, biosecurity and Current Good Manufacturing Practices (CGMPs) Types and features of laboratories of different containment levels Types of hazards and risks associated with new technologies, upstream materials, equipment and processes, subject animals, agents, plants, and related materials Methods of formulating programmes for addressing biohazardous waste management Methods of formulating biorisk training programmes Methods of formulating bio-incident Emergency Response Plans (ERPs) 	

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		<ul style="list-style-type: none"> Personnel to be notified of incidents and accidents 			<ul style="list-style-type: none"> Requirements of a biorisk management review programme 	
Abilities		<ul style="list-style-type: none"> Follow biosafety and biosecurity codes and practices in the workplace Apply safe microbiological practices and techniques when handling infected and non-infected organisms, microbes, biological materials and their derivatives Respond to incidents and accidents in biomedical facilities according to ERPs and notify appropriate personnel 	<ul style="list-style-type: none"> Apply national and international biosafety and biosecurity standards, guidelines and legislations in the workplace Implement biorisk control measures Participate in biosafety and biosecurity audits and inspections Report bio-incidents and accidents Conduct biorisk assessments Implement measures to reduce or eliminate potential biorisks and threats, and restore biosafety and biosecurity in the workplace Devise ERPs for biohazard incidents to ensure personnel safety in the workplace and to minimise environmental impact 	<ul style="list-style-type: none"> Develop appropriate plans for addressing biorisks, decontamination, and waste management Review the implementation of biorisk controls Facilitate the conduct of biorisk assessments Manage emergency responses to bio-incidents Develop training and communication programmes to enhance staff readiness in biosafety and biosecurity Conduct biorisk management review programmes Implement improvements to biorisk management systems 	<ul style="list-style-type: none"> Establish organisation-wide biosafety guidelines and strategies Formulate biorisk management strategies and systems for hazards and risks within laboratories of different containment levels Formulate decontamination and waste management programmes Integrate biosafety, biosecurity and CGMPs into Standard Operating Procedures (SOPs) to maintain safe working environments Drive the implementation of biorisk assessments Determine laboratory containment levels by reviewing hazards and risks associated with upstream and downstream processes Devise measures to reduce risks relating to newly introduced technologies Articulate the direction and objectives for biosafety training and biorisk management programmes Formulate biorisk management review programmes 	