

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

TSC Category	General Management					
TSC	Risk Management					
TSC Description	Implement risk management strategies to support business operations					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-GMT-4011-1.1	BPM-GMT-5011-1.1	BPM-GMT-6011-1.1
				Review operational risks and implement risk controls within a department	Drive organisation's risk management framework, policy and processes	Influence organisation's risk management philosophies and strategies to align to organisational objectives
Knowledge				<ul style="list-style-type: none"> Relevant operational risk regulatory requirements Roles in operational risk governance structure Techniques to investigate operational risks Methods of developing key risk indicators (KRIs) 	<ul style="list-style-type: none"> Organisation's products, policies and processes Organisational risk management policies Methods of evaluating operational risk management process and controls Internal and external risk events Inherent risks and residual risks Target risks of the organisation such as key risk indicators or metrics 	<ul style="list-style-type: none"> Risk management philosophies Criteria for reasonable assurance on achievement of organisational objectives
Abilities				<ul style="list-style-type: none"> Develop a range of KRIs to be monitored regularly by senior team members Implement operational risk assessment initiatives within a department Develop communication plans to ensure all operational risk regulatory requirements are understood and adhered to 	<ul style="list-style-type: none"> Identify and define the boundaries of operational risks for the organisation Implement the operational risk management policies and processes Identify and assess key operational risks to the organisation Guide departments to define and express operational risk appetite Provide tools or mechanisms to manage risks 	<ul style="list-style-type: none"> Establish organisation's internal and external context for managing risks Establish risk management philosophies and strategies with reasonable assurance Integrate risk management philosophies and strategies with organisational strategic objectives Refine risk management philosophies and strategies in accordance with organisational guidelines and policies

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					<ul style="list-style-type: none">• Evaluate and select appropriate risk response activities to manage operational risks across business units• Refine operational risk management processes for business units to achieve appropriate return on investment	
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