

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

TSC Category	Engineering and Maintenance					
TSC	Maintenance Strategy Development					
TSC Description	Develop a corrective and preventive maintenance strategy					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
				BPM-ENM-4010-1.1	BPM-ENM-5010-1.1	BPM-ENM-6010-1.1
				Support development and facilitate implementation of corrective and preventive maintenance plans	Design corrective and preventive maintenance plans	Establish maintenance strategies for the organisation to improve reliability of equipment
Knowledge				<ul style="list-style-type: none"> Principles of maintenance planning Methods of interpreting production schedules Methods for monitoring actual to planned maintenance completion Recording systems and requirements Methods and techniques for dealing with maintenance difficulties 	<ul style="list-style-type: none"> Components of corrective and preventive maintenance plans Resources required for maintenance in a biopharmaceuticals manufacturing facility Factors that influence equipment reliability Responsibilities of the engineering and maintenance team Types of data and analysis used in proactive maintenance and performance monitoring Methods used to measure maintenance effectiveness Methods of developing response plans for equipment breakdowns Methods of managing the purchase and inventory control for parts and tools required for maintenance Strategies to reduce costs for spare parts 	<ul style="list-style-type: none"> Organisational strategies for maintenance planning Key manufacturing priorities and objectives Strategic thinking and its application to corrective and preventive maintenance Methods of formulating maintenance strategies Strengths and limitations of strategies, techniques and tools used in maintenance planning Methods of assessing a return on investment on the cost of maintenance Methods to improve the reliability of equipment in a biopharmaceuticals manufacturing facility

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					<ul style="list-style-type: none"> • Spare inventory management techniques 	
Abilities				<ul style="list-style-type: none"> • Analyse maintenance targets • Analyse past maintenance rates and impact on production schedules • Present data and analyses to support and maximise accuracy of maintenance forecasts • Plan maintenance timelines according to organisational requirements and resource availability • Communicate the maintenance plan to relevant personnel • Confirm that resources and personnel are available to meet schedule • Match work allocation to competencies available in the work team according to enterprise procedures • Monitor actual maintenance rates against plan and adjust as necessary 	<ul style="list-style-type: none"> • Formulate corrective and preventive maintenance plans to provide reliable equipment performance with minimal disruption to manufacturing processes • Assess the impact of maintenance plans on manufacturing processes performance • Determine performance data indicators that must be monitored • Review proactive maintenance and performance monitoring information to identify factors that affect equipment reliability • Review state of the art technologies, equipment and tools to prevent wear and tear • Spearhead preventive maintenance training events • Evaluate risk factors that could affect the maintenance plan • Assess time lost due to equipment malfunctions, and articulate implications on maintenance strategy • Formulate contingency plans for equipment breakdowns and other risk factors • Manage purchasing and inventory control of tools, 	<ul style="list-style-type: none"> • Liaise with key stakeholders to determine objectives of maintenance strategies • Examine maintenance plans to determine major areas requiring improvement • Compare possible strategies, techniques and tools to select preferred maintenance strategies to improve reliability of equipment • Justify resource requirements of maintenance strategies to senior management • Establish key performance indicators for the maintenance department in a biopharmaceutical manufacturing organisation • Manage impact of spare inventory levels on businesses • Determine hardware, other resources and skills required to implement maintenance strategies • Oversee integration of maintenance sub-functions and activities to add value to the manufacturing site • Evaluate key performance indicators against desired levels to

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					parts and spare parts required for maintenance	identify areas requiring adjustment <ul style="list-style-type: none"> • Deliver regular reports on engineering and maintenance activities to senior management and leadership teams
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