

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

TSC Category	Engineering and Maintenance					
TSC	Preventive Maintenance					
TSC Description	Perform scheduled maintenance procedures on biopharmaceuticals manufacturing equipment without halting manufacturing production to reduce the likelihood of failure					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-ENM-2011-1.1	BPM-ENM-3011-1.1	BPM-ENM-4011-1.1	BPM-ENM-5011-1.1	
		Perform routine inspections and maintenance of manufacturing equipment	Oversee routine maintenance activities	Develop technical preventive maintenance plans to reduce the likelihood of failure	Lead preventive maintenance activities, and provide technical expertise and business operations perspectives	
Knowledge		<ul style="list-style-type: none"> Preventive maintenance procedures Operating principles and normal behaviour of equipment to be maintained Methods of identifying equipment faults Methods of identifying early warning signs of potential problems with equipment Measures for identifying probable causes of faults Factors that increase maintenance requirements of equipment used Health and safety practices related to maintenance procedures Maintenance recording procedures 	<ul style="list-style-type: none"> Maintenance procedures for biopharmaceuticals manufacturing equipment Principles and techniques of calibrations Principles of mechanical, hydraulic and electrical systems Principles of mechanical engineering Principles of Overall Equipment Effectiveness (OEE) 	<ul style="list-style-type: none"> Methods of determining Overall Equipment Effectiveness (OEE) Principles of condition monitoring analysis Methods of developing calibration and maintenance schedules Techniques for determining Mean Time Between Failure (MTBF) Techniques to analyse condition monitoring data Biopharmaceuticals manufacturing processes 	<ul style="list-style-type: none"> Advanced principles of mechanical, hydraulic and electrical systems, and their calibration Advanced principles of mechanical engineering and calibration Requirements of proactive maintenance strategies and their implementation Operating principles and procedures for all equipment and systems in the manufacturing facility Business values, costs and implications of preventive maintenance activities Methods of calculating return on investment (ROI) 	
Abilities		<ul style="list-style-type: none"> Perform routine checks on mechanical equipment or structures Identify nature of maintenance activities and tools required Prepare equipment for maintenance 	<ul style="list-style-type: none"> Review equipment and manufacturing facility performance records and documentation Implement preventive maintenance guide, and ensure equipment and manufacturing facility are 	<ul style="list-style-type: none"> Analyse manufacturing equipment to determine performance of equipment and systems Undertake condition monitoring analysis to predict required maintenance types and 	<ul style="list-style-type: none"> Establish key performance indicators and targets for the Maintenance Excellence Programme (MEP) for the manufacturing facility Evaluate maintenance Standard Operating Procedures (SOPs) 	

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		<ul style="list-style-type: none"> • Select tools according to task requirements • Perform cleaning, fluid replacement waste removal and other routine maintenance procedures on equipment • Replace worn machine parts • Return equipment to operating order and store tools according to workplace procedures • Adhere to relevant Health, Safety and Environment (HSE) risk control measures when conducting maintenance work • Report maintenance activities according to workplace reporting requirements • Update maintenance and repair logs 	<p>serviced and adjusted as required</p> <ul style="list-style-type: none"> • Schedule maintenance activities in consultation with affected work areas to minimise disruption to manufacturing • Conduct repair work of non-standard equipment, machinery or pipelines • Estimate time and costs needed for maintenance and repair activities • Analyse maintenance logs and documentation to identify trends and common issues • Submit requests to replenish stock required for maintenance works as needed • Review preventive maintenance activities to ensure early warning signs of potential problems with equipment are identified in a timely manner • Ensure maintenance works are conducted in compliance with Health, Safety and Environment (HSE) policies, procedures and regulations 	<p>timings for different equipment</p> <ul style="list-style-type: none"> • Develop maintenance Standard Operating Procedures (SOPs) and guides that detail the key maintenance activities and procedures to be performed • Estimate resources needed to implement preventive maintenance plans • Review logs of all repair works pending and conducted, and maintain records of the solutions applied to each case • Analyse MTBF from maintenance and other maintenance performance criteria • Develop solutions to minimise or eliminate machine or system malfunctions and improve deterioration rates • Direct reliability studies • Implement tool and equipment inventory control procedures • Outline standard quality and safety procedures to adhere to during maintenance work 	<ul style="list-style-type: none"> • Provide expert technical guidance on new or non-routine engineering and maintenance activities and processes • Facilitate training on new engineering and maintenance processes • Evaluate the tangible and intangible benefits of enhancements to preventive maintenance processes • Assess current practices with relevant stakeholders to determine any manufacturing facility and equipment reliability implications • Develop plans for root cause analyses and reliability studies • Review effectiveness and ROI of preventive maintenance activities • Recommend changes to enhance preventive maintenance processes and effectiveness 	
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