

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

TSC Category	Engineering and Maintenance					
TSC	Equipment and Systems Repair					
TSC Description	Execute equipment and systems repair procedures to correct faults and restore functionalities					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-ENM-2005-1.1	BPM-ENM-3005-1.1	BPM-ENM-4005-1.1	BPM-ENM-5005-1.1	
Knowledge		<ul style="list-style-type: none"> Identify the causes of minor faults with equipment and systems and make necessary repairs 	<ul style="list-style-type: none"> Implement repair procedures to ensure correct operation of biopharmaceuticals manufacturing equipment and systems 	<ul style="list-style-type: none"> Develop solutions to restore and sustain optimal functionality of biopharmaceuticals manufacturing equipment and systems 	<ul style="list-style-type: none"> Provide technical expertise to guide the development of solutions to repair, restore and optimise equipment and systems functionality 	
Abilities		<ul style="list-style-type: none"> Types of mechanical, structural and electrical malfunctions and defects Methods of repairing mechanical, structural and electrical malfunctions and defects Types of tools required for repair works Safety isolation procedures for equipment and systems Cleaning and preparation processes Hazards and safety precautions associated with repair works 	<ul style="list-style-type: none"> Repair procedures Resources required for repairs Methods of analysing equipment manuals, system diagrams and structural plans Techniques for targeting and determining malfunctions and defects Methods of determining follow-up measures to ensure repair works are successful Manufacturing processes and workflows 	<ul style="list-style-type: none"> Root-cause analysis and other techniques for determining the causes of major malfunctions and defects Impact of equipment and system faults on other parts of the manufacturing processes Methods of determining follow-up measures to ensure repair works are successful 	<ul style="list-style-type: none"> Impact of repair activities on wider operations and processes in the facility Interdependencies among processes in a biopharmaceutical manufacturing facility Best practices in equipment and system repairs 	
		<ul style="list-style-type: none"> Identify mechanical, electrical or structural faults with equipment or system components Dismantle equipment according to standard operating procedures and safety protocols Remove defective parts, using appropriate tools Inspect damaged machine parts and mark defective areas 	<ul style="list-style-type: none"> Estimate time and costs needed for repair activities Oversee the resolution of minor equipment and system component failures, and provide guidance and input where required Conduct more complex repair work of non-standard equipment or system components 	<ul style="list-style-type: none"> Identify the root causes of complicated equipment and system failures and malfunctions Guide repair procedures and provide information on standard protocols Measure the impact of major repair works on manufacturing processes Develop interim solutions to replace faulty equipment if there 	<ul style="list-style-type: none"> Evaluate root cause analysis of major equipment and system failures Assess viability of recommended activities and steps to repair and restore equipment and systems Review equipment breakdown trends and analyses Design modifications to minimise or eliminate 	

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		<ul style="list-style-type: none"> • Conduct minor repairs on system components • Adhere to relevant Health, Safety and Environment risk control measures when conducting repair works • Record repair steps and results in accordance with organisational procedures 	<ul style="list-style-type: none"> • Monitor success of repair work • Maintain repair logs for future analysis • Ensure repair work is conducted in compliance with Health, Safety and Environment policies, procedures and regulations 	<p>are no alternative solutions</p> <ul style="list-style-type: none"> • Analyse patterns in equipment breakdowns to identify potential design or process modifications • Develop risk control measures to mitigate possible issues in executing repair works • Outline procedures for monitoring successes of repair works • Oversee documentation procedures in relation to equipment and systems repair works • Outline standard quality and safety procedures to adhere to during repair works 	<p>machine or system malfunctions</p> <ul style="list-style-type: none"> • Provide expert technical guidance for repairing and restoring equipment and systems to optimal performance 	
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