

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

TSC Category	Production					
TSC	Emergency Shut-down and Restart					
TSC Description	Manage shut-down and restart of production processes to minimise loss and damage of assets as well as ensure the safety of personnel during emergency situations					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-OPR-2006-1.1	BPM-OPR-3006-1.1	BPM-OPR-4006-1.1		
		Execute emergency shut-downs according to guidelines and instructions	Coordinate the shut-downs and restarts of production processes in a safe and efficient manner	Manage shut-downs and restarts of production processes ensuring maximum safety to personnel and minimum impact to the biopharmaceuticals manufacturing facilities and production productivity		
Knowledge		<ul style="list-style-type: none"> Organisational processes to shut down manufacturing equipment, systems and facilities during emergencies Safe handling of equipment to protect oneself and others from risks Organisational procedures to isolate utilities supplies and other components of the manufacturing systems and processes Organisational procedures to restart manufacturing equipment, systems and facilities following emergencies 	<ul style="list-style-type: none"> Organisational procedures for assessing emergency situations and controlling automatic shut-downs Methods of minimising loss and damage and of dealing with waste and residual materials during shut-downs Lock-out, tag-out, isolation and de-isolation requirements, procedures and related equipment Start-up operating procedures, facilities and equipment operation parameters and production steady state Commissioning, pre-start checking and troubleshooting of start-up associated equipment Methods and limitations of depressurisation, pressurisation, blow-down, temperature 	<ul style="list-style-type: none"> Principles of operations of manufacturing facilities and equipment Routine problems, faults and their resolution Methods of starting, stopping, operating and controlling processes Corrective actions appropriate to the problem causes Functions and troubleshooting of major components and their problems Types and causes of problems within one's scope of skills level and responsibilities Emergency shut-down procedures Organisational procedures relating to manufacturing facilities shut-downs and restarts Workplace Safety and Health (WSH) regulations 		

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			<p>control, relief systems, drains, flares and vents</p> <ul style="list-style-type: none"> • Use of process auxiliary equipment for safe shut-downs of the manufacturing facilities • Purging, draining and venting plants and equipment 			
Abilities		<ul style="list-style-type: none"> • Perform shut-downs of the manufacturing facilities and their associated control systems and equipment according to instructions • Isolate and shut down utilities supplies and services to the manufacturing facilities, confirming the environments are secure • Perform restarts of the manufacturing facilities and their associated control systems and equipment • Document actions performed during emergency shut-downs and restarts 	<ul style="list-style-type: none"> • Assess critical situations to determine appropriate shut-down responses based on type of incidents and nature of the situations • Implement preparatory work for emergency shut-downs • Identify areas to isolate in the event of an emergency shut-down • Inspect the equipment and systems for visible faults and defects to request maintenance of the equipment and systems as required • Complete shut-down records • Approve permits allowing employees to work during plant shut-downs • Determine holding sites in the event of an emergency shut-down • Conduct pre-operational checks on utilities and equipment conditions and start up the manufacturing facilities • Check that the process control systems are operating and make appropriate adjustments to meet specifications 	<ul style="list-style-type: none"> • Review safety systems to ensure that the units have been made safe • Identify the causes of the shut-downs • Obtain confirmation of the identified shut-downs from production teams to verify both the nature and the reliability of the shut-downs • Initiate procedures to rectify the faults or shut-down causes through repair of the operational faults or re-adjustments before returning the systems to start-up status • Commission the start-up processes in accordance with organisational procedures and workplace safety and health procedures • Escalate any further ongoing production problems to appropriate persons or authorities 		

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