

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

TSC Category	Production					
TSC	Production Optimisation					
TSC Description	Manage production processes and resources to maximise performance					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		BPM-OPR-2013-1.1	BPM-OPR-3013-1.1	BPM-OPR-4013-1.1	BPM-OPR-5013-1.1	
		Monitor production processes against expected performance levels	Analyse production resources and manage resource planning to meet production performance targets and standards	Review production performance by inspecting production processes, identifying constraints and restoring stability of operations	Lead management and optimisation of production workflows for biopharmaceuticals manufacturing facilities	
Knowledge		<ul style="list-style-type: none"> Standard Operating Procedures (SOPs) Production metrics Production terminologies Processes to monitor production performance Production targets Types of information to be recorded and reported Relevance of types of performance data in the production processes Methods of recording and reporting information 	<ul style="list-style-type: none"> Production workflows Production monitoring tools Techniques for collecting and collating information Principles of preserving information integrity, including accuracy levels and timeliness Objectives for single production processes Manufacturing facilities management roles and responsibilities Requirements and criteria of manufacturing operations Methods of reviewing process parameters to ensure quality of final products Methods of improving production processes 	<ul style="list-style-type: none"> End-to-end manufacturing process flows Critical process performance parameters Applications and limitations of manufacturing tools, equipment, machines and processes Evaluation criteria of manufacturing processes Techniques for assessing information, including typical recording outcomes to identify unusual or incorrectly recorded information Root cause analysis Resource allocation frameworks and techniques Types of corrective actions to improve processes Automation of manufacturing processes 	<ul style="list-style-type: none"> Organisation's production requirements Methods to select Key Performance Indicators (KPIs) of production processes Key principles and considerations for production targets setting Resource and infrastructure requirements for production processes Methods to evaluate production processes in terms of business and technical implications Factors affecting the manufacturing of biopharmaceuticals products Economics, environment and safety considerations in production process changes 	

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				<ul style="list-style-type: none"> Quality- or performance-control systems that can be applied to production 		
Abilities		<ul style="list-style-type: none"> Interpret production terminologies and metrics Perform checks to identify performance issues Monitor outputs against expected production levels Collect and collate production information to be recorded and reported Report delays and additional time required to complete production Identify performance variations, lapses and shortfalls against the production plans and targets Prepare standard performance reports in required formats 	<ul style="list-style-type: none"> Communicate production objectives and targets to team members Review production execution and ensure operations are in line with set expectations Analyse production yields against target performance Verify performance of the production processes against production plans Identify appropriate monitoring, recording and reporting formats and systems Review performance reports Analyse causes of performance problems and process deviations that may impact achievement of production objectives and targets Address anomalies in production performance Implement process changes or modifications to restore optimal production processes Escalate issues which may impact other manufacturing processes 	<ul style="list-style-type: none"> Relate production plans to production line operations Draw insights and trends from production performance reports Identify production constraints in accordance with production plans Employ problem-solving techniques and root cause analysis to identify causes of performance variations Investigate shortcomings in materials quality or machinery performance Identify opportunities to leverage upon to increase process efficiency Identify manufacturing bottlenecks and evaluate their root causes Formulate solutions to address bottlenecks, inefficiencies or deviations in the production processes Develop in-process defect control and testing plans Manage impact of production performance variations or failures on other manufacturing processes 	<ul style="list-style-type: none"> Develop production KPIs Establish production objectives and targets Review overall production performance Direct initiatives to optimise production workflows and processes Review production workflows to stream-line processes Review recommended solutions to address bottlenecks, inefficiencies or deviations in the production processes Allocate resources to overcome constraints Lead the implementation of new production processes and technologies Evaluate whether processes meet organisational requirements 	