Overview of Technical Skills and Competencies

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Technical Skills and Competencies (TSCs)

TSC Category	TSC Title	TSC Description	Proficiency Levels					
			1	2	3	4	5	6
Engineering and Maintenance	Automated Equipment and Control Systems Configuration	Configure automated equipment and control systems to support biopharmaceuticals manufacturing processes			●	●	●	
	Automated Operation Monitoring	Monitor automated equipment and control systems to ensure quality execution of the manufacturing process flow		●	●			
	Automated Process Design	Design processes that utilise automated manufacturing equipment and control systems			●	●	●	●
	Engineering Drawing	Create technical drawings for design specifications to guide electrical, mechanical and structural installation works	●	●	●	●		
	Equipment and Systems Repair	Execute equipment and systems repair procedures to correct faults and restore functionalities		●	●	●	●	
	Equipment and Systems Testing	Execute equipment and systems testing procedures to ensure continuity of operations and meet standards of performance		●	●			
	Equipment Qualification	Verify that biopharmaceuticals manufacturing equipment are installed, operate and perform as per expectations and requirements			●	●		
	Facility Maintenance	Manage facility system maintenance activities to manufacturing and business operations		●	●	●		
	Installation and Assembly	Install equipment and system components by evaluating product specifications and manufacturers' recommendations and aligning them with the needs of the manufacturing facility		●	●	●	●	
	Maintenance Strategy Development	Develop a corrective and preventive maintenance strategy				●	●	●
	Preventive Maintenance	Perform scheduled maintenance procedures on biopharmaceuticals manufacturing equipment without halting manufacturing production to reduce the likelihood of failure		●	●	●	●	
	Test Planning	Develop testing plans and procedures by determining scope and risks, identifying the objects of testing, selecting test methods and tools, and controlling test implementation				●	●	
	Utilities Management	Develop plans to meet manufacturing utilities and energy requirements while conserving and managing the use of energy and utilities by the facility			●	●	●	
General Management	Budgeting	Prepare organisational budgets to support short- and long-term business plans through forecasting, allocation and financial policy setting			●	●	●	
	Business Continuity Management	Execute business impact analysis, risk analysis, testing and exercising to ensure the currency of the organisation's Business Continuity Plans				●	●	●
	Business Networking	Establish mutually beneficial relationships with business stakeholders, potential clients and customers					●	●

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General Management	Business Performance Management	Implement the organisation's performance systems to meet business plans and objectives by establishing performance indicators, tracking progress and addressing gaps				●	●	●
	Business Planning	Develop business plans by reviewing existing resources to identify growth opportunities for achieving sustainable competitive advantage					●	●
	Change Management	Drive successful change outcomes by preparing, equipping and supporting adoption of change			●	●	●	●
	Conflict Resolution	Resolve conflicts by evaluating and implementing resolution approaches, analysing mediation outcomes and finding solutions				●	●	●
	Continuous Improvement	Apply continuous improvement strategies to improve products, services or processes across the organisation		●	●	●	●	
	Innovation Management	Respond to external or internal opportunities by using creativity to introduce new ideas and processes		●	●	●	●	●
	Project Management	Execute projects by managing stakeholder engagement, resources, budgets and resolving problems			●	●	●	●
	Risk Management	Implement risk management strategies to support business operations				●	●	●
	Strategy Development	Develop organisational strategies and policies by analysing the impact of internal and external influencing factors				●	●	●
	Systems Thinking	Integrate understanding of biopharmaceuticals manufacturing with interactions between components when developing manufacturing processes or overseeing manufacturing activities		●	●	●	●	
	Team Effectiveness Management	Set goals with team and evaluate team's effectiveness in achieving the defined goals and objectives				●	●	
	Technical Presentation	Deliver effective and engaging presentations for a variety of audiences				●	●	●
	Technical Report Writing	Produce reports with specific information and evidence presented in a clear and structured format		●	●	●		
	Vendor Management	Manage vendor relationships by ensuring performance as per contracts, operations within standards established by the organisation such as adherence to safety, security, and compliance standards			●	●	●	
Health, Safety and Environment	Biorisk Management	Identify and implement biosafety and biosecurity practices to ensure a safe work environment		●	●	●	●	
	Chemical Risk Management	Implement chemical safety and security practices to ensure a safe work environment		●	●	●	●	
	Emergency and Crisis Situation Management	Implement emergency and crisis response and recovery activities to minimise the impact of disruptive events to the organisation			●	●		

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Health, Safety and Environment	Hazards and Risk Identification and Management	Implement a systematic approach for hazard identification and risk assessment to manage hazards that may occur within biopharmaceuticals manufacturing facilities		●	●	●		
	Health, Safety and Environment Procedures Implementation	Implement Health, Safety and Environment procedures in accordance with legislative requirements to ensure a safe work environment		●	●	●		
Process Development/ Manufacturing Science and Technology	Big Data Analysis	Apply data analytics techniques and tools to analyse significant volumes of data and draw patterns and trends for investigating business problems			●	●	●	
	Biological Product Introduction	Facilitate the introduction of new biological products by designing manufacturing processes needed to achieve cost-effective production and meet design specifications				●	●	●
	Facility Design	Design and integrate biopharmaceuticals manufacturing facilities to optimise operational efficiency and effectiveness				●	●	
	Green Manufacturing Design and Implementation	Design and implement manufacturing processes that reduce waste, conserve energy and use replacements for hazardous substances			●	●	●	●
	Manufacturing Process Design	Design cost-efficient, robust and reliable manufacturing processes aligned with stakeholder expectations, business priorities and industry best practices				●	●	●
	Pharmaceutical and Nutritional Product Introduction	Develop manufacturing plans and processes for new pharmaceutical or nutritional products to achieve cost-effective production and Research and Development design specifications				●	●	●
	Pharmacovigilance Integration	Integrate patient-outcome factors into the design of biopharmaceuticals manufacturing processes				●	●	
	Process Analytical Technology Implementation	Apply Process Analytical Technology to design, analyse and control manufacturing processes to enhance production efficiency and quality			●	●	●	
	Process Modelling	Model manufacturing processes in order to ensure successful implementation				●	●	
	Process Monitoring	Verify that routine manufacturing processes are consistently within a state of control			●	●	●	
	Process Optimisation	Analyse biopharmaceuticals manufacturing processes and identify adjustments that will reduce costs of manufacturing and increase quality, throughput and efficiency			●	●	●	
	Product Improvement	Analyse technical specifications of nutritional products and identify ways to make improvements			●	●	●	

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Production	Automated Process Control	Use automated process control to reduce process variations and detect process deviations			●	●		
	Bioreactor Operation and Control	Operate bioreactors in biopharmaceuticals manufacturing facilities			●	●		
	Cell Culture	Maintain both microbial and mammalian cell cultures as pure cultures during the upstream stages of production			●	●	●	
	Chromatography Equipment Operation and Control	Operate chromatography systems in biopharmaceuticals manufacturing facilities			●	●		
	Cleaning and Sterilising	Clean and sterilise equipment, systems and materials for biopharmaceuticals production		●	●	●		
	Emergency Shut-down and Restart	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		●	●	●		
	Filtration Equipment Operation and Control	Operate filtration equipment in biopharmaceuticals manufacturing facilities			●	●		
	Flexible Facilities Implementation	Facilitate implementation and changeover of flexible facilities, integrating single-use technologies with flexible manufacturing operations		●	●	●	●	
	Good Manufacturing Practices Implementation	Implement Current Good Manufacturing Practices in the design, monitoring, and control of manufacturing processes and facilities to ensure the potency, quality, and purity of biopharmaceutical products		●	●	●	●	
	Manufacturing Equipment Operation and Control	Operate production equipment ensuring optimal conditions for biopharmaceuticals manufacturing production			●	●	●	
	Manufacturing Systems Operation and Control	Operate technical systems in the manufacturing of biopharmaceuticals			●	●	●	
	Materials Management	Manage biopharmaceuticals materials and materials flow according to established procedures for meeting batch requirements		●	●	●	●	
	Production Optimisation	Manage production processes and resources to maximise performance		●	●	●	●	
	Production Planning	Execute the production plans to meet production targets and cycle time indices				●	●	●
	Production Resource Management	Define productivity targets and allocate resources to support and synchronise production processes				●	●	●

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Quality Assurance	Analytical Method Validation	Verify analytical methods used to ensure accuracy, validity and reliability of methods		●	●	●	●	
	Audit Management	Review organisational objectives, policies, procedures, structure, controls and systems to verify that the organisation's activities are efficiently managed		●	●	●	●	
	Cleaning Validation	Validate processes and methods for achieving required standards of cleanliness			●	●		
	Computer Systems Validation	Commission computerised systems for use in biopharmaceuticals manufacturing facilities			●	●	●	
	Document Control	Implement documentation policies to facilitate the referencing of information for processes, systems and equipment, and to comply with regulatory requirements		●	●	●		
	Packaging Validation	Validate the methodologies and processes applied to package biopharmaceutical products to maintain quality standards and regulatory compliance			●	●		
	Process Validation	Verify that processes are reproducible and consistent in delivering quality products according to specifications, and in line with international regulations		●	●	●	●	
	Quality Assurance Management	Implement quality assurance procedures and conduct audits to ensure compliance			●	●	●	●
Quality Control	Cleanliness Testing	Perform tests to verify that residue and contaminants are at risk-free levels during the manufacture of subsequent products			●	●	●	
	Laboratory Data Analysis	Analyse laboratory data		●	●	●		
	Laboratory Management	Implement Good Laboratory Practice procedures to ensure that performance, quality, health, and safety standards are met		●	●	●	●	
	Packaging Testing	Verify that biopharmaceutical packaging materials maintain the desired level of compliance			●	●	●	
	Product Testing	Test biopharmaceutical products to verify that they have been produced to the required quality and regulatory standards			●	●	●	
	Quality Control Management	Establish quality control procedures for biopharmaceuticals manufacturing processes, products, equipment and systems, to ensure the desired level of compliance at all stages				●	●	●
	Raw Materials and Utilities Testing	Test raw materials and utilities before the start of biopharmaceuticals manufacturing processes to verify that they meet the desired quality standards			●	●	●	

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General Descriptors for Technical Skills and Competencies (TSCs)

Level	Responsibility (Degree of supervision and accountabiity)	Autonomy (Degree of decision-making)	Complexity (Degree of difficulty of situations and tasks)	Knowledge and Abilities (Required to support work as described under Responsibility, Autonomy and Complexity)
6	Accountable for significant areas of work, strategy or overall satisfaction	Empowered to chart direction and practices within and outside of work (including professional field/ community), to achieve/exceed work results	Complex	• Synthesise knowledge issues in a field of work and the interface between different fields, and create new forms of knowledge • Employ advanced skills, to solve critical problems and formulate new structures, and/or to redefine exisiting knowledge or professional practice • Demonstrate exemplary ability to innovate, and formulate new ideas and structures
5	Accountable for achieving assigned objectives, decisions made by self and others	Provide leadership to achieve desired work results; Manage resources, set milestones and drive work	Complex	• Evaluate factual and advanced conceptual knowledge within a field of work, involving critical understanding of theories and principles • Select and apply an advanced range of cognitive and technical skills, demonstrating mastery and innovation, to devise solutions to solve complex and unpredictable problems in a specialised field of work • Manage and drive complex work activities
4	Work under broad direction Hold accountability for performances of self and others	Exercise judgement; adapt and influence to achieve work performance	Less routine	• Evaluate and develop factual and conceptual knowledge within a field of work • Select and apply a range of cognitive and technical skills to solve non-routine/ abstract problems • Manage work activities which may be unpredictable • Facilitate the implementation of innovation
3	Work under broad direction May hold some accountability for performance of others, in addition to self	Use discretion in identifying and responding to issues, work with others and contribute to work performance	Less routine	• Apply relevant procedural and conceptual knowledge and skills to perform differentiated work activities and manage changes • Able to collaborate with others to identify value-adding opportunities
2	Work with some supervision Accountable for a broader set of tasks assigned	Use limited discretion in resolving issues or enquiries. Work without frequently looking to other for guidance	Routine	• Understand and apply factual and procedural knowledge in a field of work • Apply basic cognitive and technical skills to carry out defined tasks and to solve routine problems using simple procedures and tools • Present ideas and improve work
1	Work under direct supervision assigned Accountable for tasks	Minimal discretion required. Expected to seek guidance	Routine	• Recall factual and procedural knowledge • Apply basic skills to carry out defined tasks • Identify opportunities for minor adjustments to work tasks