

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

<b>TSC Category</b>	Quality Control					
<b>TSC</b>	Raw Materials and Utilities Testing					
<b>TSC Description</b>	Test raw materials and utilities before the start of biopharmaceutical manufacturing processes to verify that they meet the desired quality standards					
<b>TSC Proficiency Description</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Level 4</b>	<b>Level 5</b>	<b>Level 6</b>
			<b>BPM-QUC-3007-1.1</b>	<b>BPM-QUC-4007-1.1</b>	<b>BPM-QUC-5007-1.1</b>	
			Implement tests on raw materials to be used in biopharmaceutical manufacturing processes, and monitor water and air quality	Develop procedures for raw materials and utilities testing and monitoring, and analyse outcomes to identify quality lapses and required improvements	Establish plans and protocols for the testing of raw materials and utilities	
<b>Knowledge</b>			<ul style="list-style-type: none"> <li>Health, Safety and Environment (HSE) procedures to be followed when performing raw material and utilities tests</li> <li>Current Good Manufacturing Practices (CGMPs)</li> <li>Details of sampling and testing plans for raw materials</li> <li>Types of raw materials and utilities to be sampled</li> <li>Types and applications of tools, equipment, software systems, and materials used for sampling and supporting the traceability of sample statuses</li> <li>Types of measuring equipment and methods of calibration</li> <li>Quality assurance and quality control procedures</li> <li>Legislative requirements for the handling, labelling, transport and</li> </ul>	<ul style="list-style-type: none"> <li>Types of raw material sampling equipment and tools</li> <li>Analytical and physical chemistry for raw materials and utilities testing</li> <li>Instrumental and laboratory techniques for raw materials and utilities testing</li> <li>Quantity and concentration considerations for raw material sampling and testing</li> <li>Procedures for handling out-of-specification results</li> <li>Differences in testing processes for raw materials</li> <li>Air and water quality requirements</li> <li>Implications of quality of raw materials and utilities on final product quality</li> </ul>	<ul style="list-style-type: none"> <li>Raw material and utilities requirements for different stages of biopharmaceutical manufacturing processes</li> <li>Raw material and utilities quality monitoring systems</li> <li>Range of analytical methods for testing raw material and utilities attributes</li> </ul>	

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			<p>disposal of hazardous materials</p> <ul style="list-style-type: none"> <li>• Documentation policies and procedures</li> <li>• Equipment and procedures for monitoring air and water quality</li> </ul>			
<b>Abilities</b>			<ul style="list-style-type: none"> <li>• Apply HSE regulations and practices in raw materials and utilities testing</li> <li>• Interpret sampling plans to identify types of raw materials and sampling procedures to be performed</li> <li>• Follow organisational procedures to prepare sampling tools and equipment</li> <li>• Collect and transport raw material and utilities samples to testing areas, in accordance with Standard Operating Procedures (SOPs)</li> <li>• Prepare and check materials and calibrate equipment needed for sample testing, according to organisational procedures</li> <li>• Perform routine quality tests on raw materials and utilities against specified acceptance criteria, in accordance with SOPs</li> <li>• Monitor air and water quality</li> <li>• Document testing results according to documentation policies and procedures</li> </ul>	<ul style="list-style-type: none"> <li>• Develop sampling plans for raw materials and utilities to be tested</li> <li>• Monitor raw materials and utilities sampling, collection and transportation processes, ensuring alignment to organisational protocols</li> <li>• Determine the types of materials, chemicals, equipment and calibration required to perform testing on specific materials</li> <li>• Outline the steps in testing different kinds of biopharmaceutical materials</li> <li>• Specify the quantities or concentrations of materials to be tested, and the acceptance criteria for tests</li> <li>• Monitor the testing of raw materials and utilities, ensuring the correct volumes, conditions and processes are employed</li> <li>• Define air and water quality requirements for biopharmaceuticals manufacturing processes</li> <li>• Review the frequency and severity of raw</li> </ul>	<ul style="list-style-type: none"> <li>• Define testing and monitoring plans for raw materials and utilities based on their intended uses</li> <li>• Determine the analytical methods and procedures that are acceptable for testing the quality of raw materials, according to manufacturing requirements</li> <li>• Determine the monitoring equipment and procedures required to ensure air and water quality standards are maintained</li> <li>• Determine required frequencies for raw material and utilities testing</li> <li>• Establish parameters and standard assay protocols for raw material testing</li> <li>• Set guidelines for handling out-of-specification raw materials and utilities</li> <li>• Oversee all raw material and utilities testing activities</li> <li>• Evaluate raw material testing results over time, identifying trends and their implications</li> </ul>	

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