<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Quality Control</th>
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<tbody>
<tr>
<td>TSC</td>
<td>Raw Materials and Utilities Testing</td>
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<tr>
<td>TSC Description</td>
<td>Test raw materials and utilities before the start of biopharmaceutical manufacturing processes to verify that they meet the desired quality standards</td>
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<thead>
<tr>
<th>TSC Proficiency Description</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Level 5</th>
<th>Level 6</th>
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<tr>
<td></td>
<td>BPM-QUC-3007-1.1</td>
<td>BPM-QU C-4007-1.1</td>
<td>BPM-QUC-5007-1.1</td>
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<tr>
<td>Implement tests on raw materials to be used in biopharmaceuticals manufacturing processes, and monitor water and air quality</td>
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<td>Develop procedures for raw materials and utilities testing and monitoring, and analyse outcomes to identify quality lapses and required improvements</td>
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<td>Establish plans and protocols for the testing of raw materials and utilities</td>
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Knowledge

- Health, Safety and Environment (HSE) procedures to be followed when performing raw material and utilities tests
- Current Good Manufacturing Practices (CGMPs)
- Details of sampling and testing plans for raw materials
- Types of raw materials and utilities to be sampled
- Types and applications of tools, equipment, software systems, and materials used for sampling and supporting the traceability of sample statuses
- Types of measuring equipment and methods of calibration
- Quality assurance and quality control procedures
- Legislative requirements for the handling, labelling, transport and

- Types of raw material sampling equipment and tools
- Analytical and physical chemistry for raw materials and utilities testing
- Instrumental and laboratory techniques for raw materials and utilities testing
- Quantity and concentration considerations for raw material sampling and testing
- Procedures for handling out-of-specification results
- Differences in testing processes for raw materials
- Air and water quality requirements
- Implications of quality of raw materials and utilities on final product quality

- Raw material and utilities requirements for different stages of biopharmaceutical manufacturing processes
- Raw material and utilities quality monitoring systems
- Range of analytical methods for testing raw material and utilities attributes
### Abilities

- **Disposal of Hazardous Materials**
  - Documentation policies and procedures
  - Equipment and procedures for monitoring air and water quality

- **Abilities**
  - Apply HSE regulations and practices in raw materials and utilities testing
  - Interpret sampling plans to identify types of raw materials and sampling procedures to be performed
  - Follow organisational procedures to prepare sampling tools and equipment
  - Collect and transport raw material and utilities samples to testing areas, in accordance with Standard Operating Procedures (SOPs)
  - Prepare and check materials and calibrate equipment needed for sample testing, according to organisational procedures
  - Perform routine quality tests on raw materials and utilities against specified acceptance criteria, in accordance with SOPs
  - Monitor air and water quality
  - Document testing results according to documentation policies and procedures

- **Develop sampling plans for raw materials and utilities to be tested**
- **Monitor raw materials and utilities sampling, collection and transportation processes, ensuring alignment to organisational protocols**
- **Determine the types of materials, chemicals, equipment and calibration required to perform testing on specific materials**
- **Outline the steps in testing different kinds of biopharmaceutical materials**
- **Specify the quantities or concentrations of materials to be tested, and the acceptance criteria for tests**
- **Monitor the testing of raw materials and utilities, ensuring the correct volumes, conditions and processes are employed**
- **Define air and water quality requirements for biopharmaceuticals manufacturing processes**
- **Review the frequency and severity of raw material and utilities testing activities**
|   |   | • Identify abnormal occurrences affecting sample conditions and conduct re-tests where required  
  |   | • Service and replace test equipment and materials used during testing  
  |   | material defects or quality lapses  
  |   | • Determine and document follow-up actions required to maintain required quality of raw materials and utilities  
  |   | • Determine whether to release, quarantine or reject raw materials based on quality standards guidelines  
  |   | • Liaise with raw material and utilities vendors to ensure quality standards are met |