<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Quality Assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSC</td>
<td>Analytical Method Validation</td>
</tr>
<tr>
<td>TSC Description</td>
<td>Verify analytical methods used to ensure accuracy, validity and reliability of methods</td>
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<tr>
<td>TSC Proficiency Description</td>
<td></td>
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<tr>
<td></td>
<td>Level 1</td>
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<td>BPM-QUA-2001-1.1</td>
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<tr>
<td>Collect data to support analytical method validation</td>
<td>Perform critical analytical method validation characteristics studies</td>
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</tbody>
</table>

**Knowledge**

- Purpose of analytical test method validation
- Types of data required for analytical method validation
- Methods of data collection
- Importance of following Standard Operating Procedures (SOPs)
- Procedures for quality assurance and quality control in biopharmaceuticals manufacturing plants
- Principles of analytical test method validation
- Importance of analytical test method validation
- Types of quality control tests
- Differences between pharmacopeial and non-pharmacopeial methods
- Analytical method validation characteristics
- Timing and frequency requirements for conducting analytical method validation
- Applications of different analytical methods
- Impact of different analytical methods on the accuracy, validity and reliability of analytical results
- Methods of troubleshooting analytical methods and results for inaccuracies, invalidities and unreliability
- Quality control management procedures
- Regulatory agency inspections and audit procedures
- Importance of analytical test method validation throughout various steps of the biopharmaceutical manufacturing process
- Importance of cross-functional collaboration in validating quality control testing procedures and analyses

**Abilities**

- Identify data collection methodologies to be applied based on critical method validation characteristics to be studied
- Follow work plans and schedules to complete data collection work on time
- Collect data on critical method validation
- Identify critical method validation characteristics to be studied for specific analytical methods
- Prepare lead-time, resources and schedules based on specific analytical methods
- Perform critical method validation characteristics studies according to Standard Operating Procedures (SOPs)
- Develop analytical method validation plans
- Articulate objectives of and key indicators of successful analytical method validation
- Specify the quality control test requirements to be validated
- Evaluate the impact of quality control test process changes on analytical methods
- Advise on critical process steps requiring quality control testing and analysis
- Collaborate with key stakeholders across functions to approve validations of analytical methodologies
- Drive analytical method validation improvements

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<table>
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<tr>
<th>Characteristics according to SOPs</th>
<th>Analyse method validation results</th>
<th>Develop analytical method validation Standard Operating Procedures (SOPs) and documentation for the organisation's internal use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store data in appropriate formats</td>
<td>Document method validation results as per organisational procedures</td>
<td>Review analytical method validation results</td>
</tr>
<tr>
<td>Clean up data to remove incomplete, duplicated or incorrect data</td>
<td>Implement training on new analytical methods</td>
<td>Evaluate validation reports to identify areas for improvement</td>
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<td>Support the identification of process deviations from data collected</td>
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<td>Recommend changes to quality control testing procedures and analysis</td>
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<tr>
<td>Submit data for evaluation</td>
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<td>Facilitate training on new analytical methods</td>
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</tbody>
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- Analyse method validation results
- Document method validation results as per organisational procedures
- Implement training on new analytical methods
- Develop analytical method validation Standard Operating Procedures (SOPs) and documentation for the organisation's internal use
- Review analytical method validation results
- Evaluate validation reports to identify areas for improvement
- Recommend changes to quality control testing procedures and analysis
- Facilitate training on new analytical methods