<table>
<thead>
<tr>
<th>TSC Category</th>
<th>Process Development/Manufacturing Science and Technology</th>
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<tbody>
<tr>
<td>TSC</td>
<td>Biological Product Introduction</td>
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<tr>
<td>TSC Description</td>
<td>Facilitate the introduction of new biological products by designing manufacturing processes needed to achieve cost-effective production and meet design specifications</td>
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<tr>
<th>TSC Proficiency Description</th>
<th>Level 1</th>
<th>Level 2</th>
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<th>Level 6</th>
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<td>BPM-PST-4002-1.1</td>
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<td>BPM-PST-5002-1.1</td>
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<td>BPM-PST-6002-1.1</td>
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<td>Develop manufacturing process steps and identify materials required for the introduction of new biologics products</td>
<td>Review manufacturing process plans to achieve requisite product quality and production requirements for new biologics products</td>
<td>Direct the introduction of manufacturing processes for new biologics products by aligning manufacturing plans with Research and Development (R&amp;D) design specifications and sales forecasts</td>
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**Knowledge**
- Current Good Manufacturing Practices (CGMPs) related to biologics manufacturing
- Principles of biochemistry
- Principles of chemical engineering
- Concepts of bioprocess and biologics technology
- Principles of fluid and particle mechanics
- Types and properties of materials used in biologics manufacturing
- Types of cell culture and fermentation processes
- Types of purification and filtration processes
- Types and uses of equipment in biologics manufacturing
- Use of mammalian cells and other advances in biologics manufacturing
- Regulatory and other requirements related to new biologics product manufacturing
- Detailed product specifications
- Impact of product specifications on biologics manufacturing processes
- Methods of developing manufacturing process flow maps
- Methods of developing manufacturing plans
- Methods of formulating new product trial and re-trial objectives
- Criteria for analysing trial and re-trial results
- Principles of risk and feasibility assessments
- Principles of biochemistry
- Concepts of bioprocess and biologics technology
- Principles of fluid and particle mechanics
- Interpretation of Research and Development (R&D) specifications and implications on manufacturing processes
- Impact of introducing new biologics products on sales, revenue and other business priorities
- Methods of evaluating manufacturing plans and process flow maps

**Abilities**
- Consolidate initial assessments of manufacturing requirements
- Determine technical specifications, aesthetic and regulatory requirements, timelines, cost and other market
- Assess manufacturability of product designs
- Endorse business and infrastructural support

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- Identify manufacturing constraints
- Develop manufacturing process steps for cell culture, purification, filling and finishing of new biologics products
- Detail components of manufacturing process flow maps
- Identify equipment and materials for production
- Record details of manufacturing plans, consultation and evaluation processes
- Perform manufacturing trials

- Review process equipment and materials suggestions
- Evaluate technical, operational and financial viability to manufacture new biological products
- Lead the design of manufacturing plans that reflects Current Good Manufacturing Practices (CGMPs), product specifications and other regulations
- Conduct risk and feasibility assessments of the manufacturing plans
- Design manufacturing trials and outline the objectives
- Review trial and re-trial product quality results and compare with trial objectives
- Present manufacturing plans to seek endorsement
- Monitor implementation of manufacturing plans and transfer of processes into manufacturing facilities

- Endorse material and equipment selections
- Align complexity and resource requirements of manufacturing plans and processes with actual and projected business value of the biologics products
- Establish implementation strategies to support technology transfer and deployment of new production processes
- Establish methodologies for technology transfer and scale-up activities
- Oversee technical transfer of processes into manufacturing facilities
- Facilitate cross functional collaboration and activities to drive successful transition to full scale production

- Review process requirements of the new biologics products
- Evaluate manufacturing plans against Research and Development (R&D) design specifications and sales forecasts
- Endorse material and equipment selections
- Align complexity and resource requirements of manufacturing plans and processes with actual and projected business value of the biologics products
- Establish implementation strategies to support technology transfer and deployment of new production processes
- Establish methodologies for technology transfer and scale-up activities
- Oversee technical transfer of processes into manufacturing facilities
- Facilitate cross functional collaboration and activities to drive successful transition to full scale production