## Flexible Facilities Implementation

**TSC Category:** Production  

**TSC Description:** Facilitate implementation and changeover of flexible facilities, integrating single-use technologies with flexible manufacturing operations

<table>
<thead>
<tr>
<th>TSC Proficiency Description</th>
<th>Level 1</th>
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<td>BPM-OPR-2008-1.1</td>
<td>BPM-OPR-3008-1.1</td>
<td>BPM-OPR-4008-1.1</td>
<td>BPM-OPR-5008-1.1</td>
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<tr>
<td>Operate and use flexible facilities in biopharmaceuticals manufacturing</td>
<td>Implement single-use equipment and other flexible facilities in biopharmaceuticals manufacturing plants</td>
<td>Develop guidelines and procedures for the changeover and implementation of flexible facilities</td>
<td>Establish organisational directions for the use of flexible facilities and single-use equipment</td>
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**Knowledge**

- Concept of flexible facilities and their purposes  
- Types of single-use manufacturing technologies and their purposes  
- Protocols to handle and transport portable manufacturing equipment, machinery and materials  
- Fluid transfer procedures  
- Processes for rinsing single-use assembly surfaces  
- Standard Operating Procedures (SOPs) for flexible or single-use facilities in biopharmaceuticals manufacturing  
- Current Good Manufacturing Practices (CGMPs) and other regulations and safe working practices  
- Decontamination and disposal procedures  
- Properties and personal protection procedures for handling hazardous products and materials  
- Various types of flexible facilities and equipment, and configuration methods  
- Importance of single-use technologies in producing sterile products and protecting critical process equipment  
- Tests to check compatibility of flexible or single-use facilities with existing fixed process equipment  
- Correct operations of single-use assemblies  
- Components of single-use technologies and their materials of construction  
- Preparation of single-use equipment for product contact  
- Potential impact of poor fluid transfer procedures on product quality or purity  
- Importance of safe and effective decontamination and disposal procedures  
- Industry standards and best practices in managing flexible facilities changeovers  
- Pros and cons of implementing flexible facilities and single-use technologies  
- Single-use assembly cleanliness requirements  
- Optimal flexible facilities changeover timings and conditions  
- Facility and equipment requirements for various biopharmaceuticals products  
- Optimal uses and configurations of flexible facilities and equipment  
- Manufacturing processes and systems connected to and affected by single-use equipment and other flexible facilities  
- Return on Investment (ROI) analysis for flexible facilities implementation  
- Compatibility of chemicals used in flexible facilities
<table>
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<th>Abilities</th>
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<tr>
<td>• Procedures to clear and flush the lines</td>
<td>• Occupational health, safety and environmental impact of poor fluid handling and equipment disposal</td>
<td>• Oversee preparation of portable or single-use manufacturing technologies&lt;br&gt;• Install single-use facilities with fixed process equipment&lt;br&gt;• Check integrity of flexible facilities equipment and parts set-up&lt;br&gt;• Prepare filters and rinsing fluids for integration into single-use assemblies&lt;br&gt;• Monitor usage of single-use assemblies and associated rinsing processes for alignment with cleanliness and quality standards&lt;br&gt;• Disconnect single-use assemblies and facilities from process equipment to allow for changeovers&lt;br&gt;• Reconfigure flexible facilities and equipment as directed to accommodate scaling up of production</td>
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<td>• Prepare portable or single-use manufacturing technologies and other flexible facilities&lt;br&gt;• Move portable manufacturing equipment, machinery and materials as instructed&lt;br&gt;• Rinse single-use assembly surfaces as instructed&lt;br&gt;• Connect flexible facilities equipment and parts according to instructions&lt;br&gt;• Start up single-use equipment according to SOPs&lt;br&gt;• Operate single-use technologies during biopharmaceuticals production&lt;br&gt;• Dispose single-use equipment safely and in accordance to standard protocols&lt;br&gt;• Locate and interpret information in Safety Data Sheets (SDSs)&lt;br&gt;• Document flexible facilities set-up activities performed</td>
<td>• Oversee preparation of portable or single-use manufacturing technologies&lt;br&gt;• Install single-use facilities with fixed process equipment&lt;br&gt;• Check integrity of flexible facilities equipment and parts set-up&lt;br&gt;• Prepare filters and rinsing fluids for integration into single-use assemblies&lt;br&gt;• Monitor usage of single-use assemblies and associated rinsing processes for alignment with cleanliness and quality standards&lt;br&gt;• Disconnect single-use assemblies and facilities from process equipment to allow for changeovers&lt;br&gt;• Reconfigure flexible facilities and equipment as directed to accommodate scaling up of production</td>
<td>• Oversee product and facility changeovers for multiple product lines&lt;br&gt;• Add or remove unit operations based on biopharmaceuticals products manufacturing needs&lt;br&gt;• Set targets and guidelines for facilities changeover time&lt;br&gt;• Establish flexible facilities or single-use equipment cleaning and rinsing requirements within flexible facilities&lt;br&gt;• Lead teams to facilitate changeovers of facilities&lt;br&gt;• Advise on flexible facilities feasibility assessments from biopharmaceuticals products and processes perspectives&lt;br&gt;• Direct suitable placements of flexible facilities and equipment for manufacturing of different products&lt;br&gt;• Establish organisational processes and Standard Operating Procedures (SOPs) to set up, operate, clear out and change over flexible facilities and single-use technologies&lt;br&gt;• Guide use of flexible facilities with the scaling up of production from clinical trial material runs to commercial manufacturing scales&lt;br&gt;• Review evaluations of flexible facilities success and determine if they should be continued&lt;br&gt;• Troubleshoot multi-disciplinary issues with flexible systems</td>
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