Biologic manufacturing capacity expansion with

**single-use technologies**

*Key variables to consider*
The following presentation is based on a simulation of a 2 × 2000 L mAb process. The simulation compares a single-use process train (SU) with a comparable stainless steel-based process train (SS), both modelled in a traditional, stick-built facility. Are you interested in a simulation of your biomanufacturing process? With our range of simulation tools, we can assist in this, whether it is for scale up/down, “de-bottlenecking”, process intensification, transition from stainless to single use, or general optimization.
Time to market and capital expenditure

Single-use vs stainless steel technologies

<table>
<thead>
<tr>
<th></th>
<th>Single-use (SU)</th>
<th>Stainless Steel (SS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to market</td>
<td>9-12 months</td>
<td>24 months</td>
</tr>
<tr>
<td>CAPEX</td>
<td>52%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**STAINLESS STEEL TECHNOLOGIES** take longer to procure, source, qualify, and validate. The initial cost is also higher.

**SINGLE-USE TECHNOLOGIES** provide faster time to market at lower capital expenditure.
Operating expense

Single-use vs stainless steel technologies

<table>
<thead>
<tr>
<th></th>
<th>SU</th>
<th>70% *</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>SU</th>
<th>68%</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

*Industry reports vary from 70% to 120%

Single-use technologies allowed 32% reduction in labor, based on elimination of cleaning and sanitization in place (CIP, SIP), and related testing.
Changeover and output

Single-use vs stainless steel technologies

<table>
<thead>
<tr>
<th></th>
<th>Changeover</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>SU</td>
<td>1–2 days</td>
<td>44 batches per year</td>
</tr>
<tr>
<td>SS</td>
<td>5–10 days</td>
<td>40 batches per year</td>
</tr>
</tbody>
</table>

**mAb_01**: batch 1 ...... 2 days changeover...... 2 days changeover...... mAb_02: batch 1 .........
Single-use technologies enable smaller facility, less cleanroom space—resulting in lower utilities and HVAC costs.

HVAC = central heating ventilation and air-conditioning
DSP = downstream processing
Equip. prep. = equipment preparation
Inoc./prep. = inoculation/preparation
GE’s single-use technologies

Across the entire bioprocess workflow
**Medium preparation:**
Xcellerex™ XDUO 100 to 2500 L mixers, HyClone™ cell culture media

**Cell culture seed train**
- ReadyToProcess WAVE™ 25 system
- Xcellerex XDR 200 L bioreactor
- Xcellerex XDR 500 L bioreactor

**Cell culture production**
- Xcellerex XDR 2000 L bioreactor
- Xcellerex XDUO 100 to 2500 L mixers
- ReadyToProcess™ filter for CFF

**Buffer preparation:**
Xcellerex XDUO 100 to 2500 L mixers, HyClone buffers and process liquids

**Harvest operations**
- FlexFactory™ harvest
- BioProcess™ NFF Pump System

**Virus reduction**
- Xcellerex XDUO mixers
- ReadyToProcess filter for CFF

**Purification operations**
- ÄKTA™ ready system
- ReadyToProcess chromatography column
- ReadyToProcess filter for CFF

**Virus filtration**
- FlexFactory viral clearance
- BioProcess NFF Pump System

**Bulk formulation and sterile filtration**
- Bulk fill equipment

**Fluid management**
- ReadyToProcess portfolio
- ReadyCircuit™ bag and filter assemblies
- ReadyToProcess bins and
d- ReadyCircuit bags
- ReadyMate™ aseptic connectors

**Fast Trak Services**
- Process development
- Bridge Manufacturing Services
- Training and education

NFF = normal flow filtration
UF/DF = ultrafiltration/diafiltration
CFF = crossflow filtration
For more information visit:
ge lifesciences.com/singleuse