



# Design and Selection of Single Use Technology for a Commercial Biologic

A Case Study

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## Program Background

Tech Transfer of a Commercial Scale Biologic

- **Existing process/facility**
  - Mostly stainless equipment
  - Single Use in place
    - **Bags and filter for intermediate storage**
    - **Some tubing**
- **New facility**
  - Single product
  - Shell/structure already in place
    - **Defined footprint**



## Program Background

### Goals

- **Increase capacity / yearly output**
- **Balance capital cost with operating cost**
  - Process
  - Utilities
- **Successful filing and approval of transferred process**



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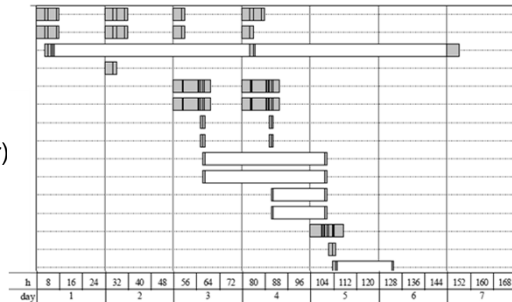
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## Where to Use Single Use Technology?

### Understand The Process

- **Mapped out our process / operations**
  - Developed a manufacturing schedule, material balance, equipment utilization
- **Evaluated three options using modeling software**
  - All Stainless
  - Hybrid
  - All Single Use
- **Model Outputs**
  - Capital Cost
  - Operational Cost
  - Single Use Usage (Bags/yr)
  - Manpower requirements
- **Review of Outputs by Team**



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## Where to Use Single Use Technology?

### Understand The Environment

- **Ensure the chosen approach worked for the facility**
  - Manufacturing footprint / buffer prep and hold space
  - Warehouse space for single use components
  - Utilities requirements, space needed for utilities generation
- **Ensure the chosen approach worked for the team**
  - Training / experience with single use in MFG
  - Do we have the right skill set to prepare for and implement the SUT?
    - **Science (MSAT) and Engineering**
    - **Quality**
    - **Materials Management**
    - **Procurement**
- **What benefits are we gaining from implementing? Are we ready?**



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## Where to Use Single Use Technology?

### Understand The Quality Requirements

- **Expected to demonstrate and maintain control of our processes / product quality**
- **Single use introduces a new variability**
  - Extractables / Leachables
  - Product Stability
  - Supplier Management
    - QTA's
    - **Vendor Qualification/Auditing**
    - **Vendor Change Management**
- **Where are the gaps? How do we fill them?**



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## Where to Use Single Use Technology

### Final Outcome – Hybrid Approach

- **Capital Costs vs Operational Costs**
  - Use single use where it makes sense
- **Schedule / capacity requirements met**
  - Reduced turnaround times / increased equipment utilization
- **Utilities / Facility footprint**
  - Major reduction in utilities (CIP, WFI, steam)
  - Warehouse / Utilities space adequate
- **Company environment**
  - Comfortable with implementing bags, filters, tubing
    - **Quality Systems in place**
    - **Manufacturing experience**
    - **Skill sets required readily available or easily obtained through training**



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## What Single Use Technology to Use?

### Setting up for Success

- **Developed User Requirement Specifications (URS's) and understanding of needs**
  - Specifics of operation, potential dealbreakers
  - Space requirements
  - Ease of use



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## What Single Use Technology to Use?

### Setting up for Success

- **Gathered existing knowledge**
  - What vendors did we already have a relationship with?
  - What vendors were we potentially looking to build a relationship with?
  - What single use equipment have we used successfully?
  - What single use equipment have we had issues with?
- **Took stock of the options on the market**
  - Reviewed existing technologies / vendors (not just those you are most familiar with)
  - Selected top 3-5 options
  - Brought vendors in for discussions , learned more
  - For key equipment, took it for a test drive
- **Worked with procurement group**



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## What Single Use Technology to Use?

### Example – Mixing System

- **Selected 5 potential vendors / mixing systems**
- **Visited and tested out all mixing systems**
  - MFG, MSAT, Engineering present
  - Tests with water / sodium phosphate performed to evaluate mixing
- **Procurement solicited and received bids**
- **Example output (not actual results of our work)**

	Vendor 1	Vendor 2	Vendor 3	Vendor 4	Vendor 5
<b>Mixing Capability</b>	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
<b>Min / Max Volume and Volumes available</b>	25/110L (100L Mixer) 40/220L (200L Mixer)	30/100L (100L Mixer) 60/200L (200L Mixer)	25/110L (100L Mixer) 40/220L (200L Mixer)	30/100L (100L Mixer) 60/200L (200L Mixer)	Doesn't bracket range required for step x
<b>Footprint</b>	Smallest	Footprint too large for Rooms x,y	Acceptable	Acceptable, but on the higher side	Acceptable
<b>MFG Ease of Use</b>	Acceptable	Acceptable	Mixer install difficult	Acceptable	Acceptable
<b>Other Feedback</b>					
<b>Capital Cost</b>	\$	\$\$	\$\$	\$	\$\$\$
<b>Operational Cost</b>	\$\$	\$	\$\$\$	\$\$\$	\$



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## What Single Use to Use

### Reducing Risk – Multiple Sourcing

- **Separated Mixers, Bags, and Tubing Assemblies as separate packages**
- **Evaluated potential dual sources for bags and tubing assemblies**
  - Mixers were not considered since each vendor has its own mixing technology
  - Final decision was made based on bid packages and team discussion
- **Selected two bag vendors**
  - Vendor 1: Same as mixing system
  - Vendor 2: Affordable custom bag to same dimensions
  - Totes: Selected a manufacturer that could build a tote capable of using either bag
- **Selected two tubing assembly vendors**
  - Vendors 1 and 2: Vendors with open architecture, one of which su



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## What Single Use to Use

### Reducing Risk – Multiple Sourcing

- **Implementation**
  - Both vendors single use systems added to material specifications, batch records
  - All materials (bag films, tubing) were evaluated for E/L
  - Primary vendor was selected for each subset
- **Advantages**
  - Able to negotiate pricing with two vendors for future planning
  - Backup vendor if there are issues with supplying components
- **Disadvantages**
  - More upfront work dealing with multiple vendors and components
    - E/L
    - **Materials Management (Part Numbers)**
    - **Quality (more companies for QTA's, audits)**
  - Maintaining documentation for two suppliers
  - Overall more complex



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## Key Takeaways

- **Understand your goals and needs**
  - Company
  - Program
  - Facility
  - Process
- **Understand the strengths and weaknesses of your company as they relate to single use**
  - Quality
  - Material Handling
  - Employee Training / Experience
- **Do your homework when selecting single use equipment**
- **Leverage procurement**



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## Questions?

Please use the microphone indicated so our recording includes audio of your question

14

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