Impact of Single-Use Systems on Biopharmaceutical Facility Design and Project Delivery

ISPE Marseille
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What Does the Future of Your Facility Look Like?
Agenda

- Introductions
- Industry Drivers
- Impact of Closed Processing
- New Technologies (SUS)
- Case Study – Biotech Greenfield Facility
- Overcoming Challenges / Summary
Industry Drivers
Business as Unusual

Cost Pressures threaten stability of Biopharm Market:

- Patent Expiration
- Global Competition
- Less Available Capital
- Economic Climate
- Government Healthcare Reform
- Drug Price Control
- Regulatory Challenges
Definition: Future Facility

Flexibility:
- Easy to Modify / Expand
- Adaptable for Multiple Products / Future Technologies

Value:
- Reusable / Adaptable Asset / Fits Changing Business Needs
- Low Initial Capital / Operating Cost

Lower Risk:
- Low Compliance / Supply Chain Risk
- Low Project / Business Risk
- Compressed Schedule
Best of All

Incorporate best of latest technologies, design philosophies, and compliance strategies

- Lean Manufacturing
- Green Design
- Closed Processing
- Risk-based Compliance
- Continuous Processing
- Modular Construction
- Single-Use
- Plug-N-Play Operations
- Modular Construction

FutureFacility
Best of All

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FutureFacility
Designing the Future Facility

Impact of Closed Processing & New Technologies
Baseline Guides – FDA Approved Concepts
This approach does not allow for the positive effects of innovation – static GMP view
The new project

Project 1

Project 2

Project 3

Project 4

Project 5

GMP Understanding

Design

Construction

Base line Guide

Gather Data

Approved concepts

Newly completed facility designed to current FDA cGMP thinking

An industry baseline adjustment


Cheaper
Better
Faster

Reduce lag to 4 years
The cost of ‘current’ – it is cheaper

Option 1: Traditional thinking
Option 2: Baseline Guide thinking

Facility Cost

Less competitive
More cost

More competitive
Less cost

Out Dated  Yesterday  Now  Tomorrow  Future

1 process tech on A room scale
New Technologies / Single-Use
Single-Use Systems

- Flexibility
- Schedule advantage
- Reduction in cleaning
- Reduction in operating complexity
Plug-N-Play

- Flexibility / Quick turnover
- Production advantages
- Simplification of changes
- Short deliveries
- “Closable”
- C&Q off site
Generation 7

Legend

- **ISO 5**
  - Grade A

- **ISO 7**
  - Grade B

- **ISO 8**
  - Grade C

- **ISO 9**
  - Grade D
  - CNC

- **Non-classified**
The cost of ‘current’ – it is cheaper

Option 1: Traditional thinking

Option 2: Baseline Guide thinking

Facility Cost
Greenfield Biotech Facility
Case Study 1
Case Study 1

Comparison of 2 Bulk Biotech Manufacturing Facilities

**Traditional Case**
- (2) 5000L Production Bioreactors
  - Large Batch
  - Stainless Steel
- 625 kg/year
- 5 g/L Titer
- Segregation by Unit Operation
- ISO (Classified) Space
- CIP
- SIP
- Conventional Construction

**Future Facility (FF) Case**
- (5) 2000L Production Bioreactors
  - Lean Approach
  - Disposable Technology
- 625 kg/year
- 5 g/L Titer
- One Large Production Suite (closed processing and sampling)
- Minimal ISO Space
- Minimal CIP
- Minimal SIP
- Plug-N-Play Process
- Modular Construction
Sustainable Improvement

Impact of reduced footprint, lower energy costs and less water usage make the FutureFacility much more **green** ...

- 30-40% Lower Capital Investment
- 75-95% Water Usage Reduction
- 50-95% Chemical Reduction
- 50%+ Energy Reduction
- 25-50% Smaller Carbon Footprint
- 30-40% Smaller Land Requirement
- 40-50% Shorter Project Schedule
Case Study 1 – Project Execution

Improvement on Project Timeline

Traditional Facility

Future Facility

ΔT = 23 mo.
Overcoming Challenges
What’s next …

AND THEN TO CAP IT ALL I GET HOME TO FIND A LETTER TELLING ME THAT I'M EXTINCT!
Overcoming Internal Inertia

- Engineering Standards
- View of consistency across Supply Chain
- Operators trying something new
- Better understanding of your processes
- Quality buy-in
Application of Concept

Could be extended to:

- Concurrent multi-product / multi-expression system facilities (eg - mammalian and microbial)
- Concurrent clinical and commercial manufacturing
- Multi-use functionality

More limited suitability for processes with containment requirements:

- Live viruses
- Highly potent / toxic compounds
- Solvent processing
Summary

- Facility of Future Concepts = Business Flexibility
- Disconnecting Facility from Process
- Incorporating New Technologies such as SUS
- Facility as an Indirect Impact System
- Overcoming Internal Inertia
- Result: Better Business Solution