Introduction

• My Background

• What’s this lecture about?

• What should you get out of it?
Benefits of Single Use Technology

• Flexibility
• Minimise cross contamination
• Reduce utility demand
Case Studies
Case Study 1:
Single Use Formulation for a High Potency Fill Finish Product
Case Study 1:

**Single Use Formulation for a High Potency Fill Finish Product**

**The Challenge**
- Highly toxic product
- Small batch size
- Dedicated facility
- Budget Constraint

**The Solution**
- Disposable Carboy Mated with Isolator for Formulation
- Gamma Irradiated Filtration Assembly
Case Study 1

Single Use Formulation for a High Potency Fill Finish Product

Pro’s
• No CIP Skids or COP/SOP Stations
• Low Utility Usage
• Simple Formulation Suite
• Cost effective

Con’s
• Difficult to facilitate future products
Case Study 1
Case Study 2:
Single Use Formulation and Filling for a Multi-Product Fill Finish Facility
Case Study 2:

Single Use Formulation and Filling for a Multi-Product Fill Finish Facility

The Challenge
• Multiple Product Formats
• Cross Contamination
• Turnaround Time
• Future Products

The Solution
• Formulation using Single Use or SS Vessels. Multiple vessels/bags per product.
• Single use final filtration
• Peristaltic filling pumps with single use surge bag
• Dedicated Filling Needles
Case Study 2:

Single Use Formulation and Filling for a Multi-Product Fill Finish Facility

Pro’s
• Flexible
• Short Turnaround
• Minimise risk of cross contamination

Con’s
• Infrastructure included for future SS System – Cost and real estate
Case Study 3:
Single Use Formulation and Filling for an Existing Multi-product Fill Finish Facility
Case Study 3:

Single Use Formulation and Filling for an Existing Multi-Product Fill Finish Facility

The Challenge
• Existing Facility
• Multiple Products Formats
• Cross Contamination
• Re-engineering of Existing Formulation and Filling

The Solution
• Single use: The right answer for future products
• Not advised to change existing product format designs
Case Study 4:
Accelerating a Project Schedule
Case Study 4:

Accelerating a Project Schedule

The Challenge

- New Bioreactor Installed
- WFI Distribution System Upgrade Qualification Complete 6 months later
- Bioreactor sitting Unused

The Solution

- Bagged WFI for Cleaning
- Sanitary Diaphragm Pump for Transfer
Case Study 4:

**Accelerating a Project Schedule**

**Pro’s**
- Extra Batches produced
- Risk Mitigation

**Con’s**
- More Man-hours Spent
How to Process Single Use Assemblies
How to Process Single Use Assemblies

- Ready to Use
- In-House Processing
Facility Considerations
Facility Considerations – Processing Method

- LAF Booth – In-House
- Autoclave Capacity – In-House
- Warehouse Capacity – All
- Waste Treatment – All
- Waste Disposal and Transport – All
Facility Considerations – Cleaning

• No CIP Skids/Not in initial scope

• No COP/SOP Stations/Not in initial scope

• Typically Parts Washer required, but less bespoke racks required
Facility Considerations – Sterilisation

- Autoclave Capacity
- VHP Not Acceptable
- Transport of Sterile Components
Facility Considerations – Filling

- Pump Technology
- Surge Container
- Transfer into Isolator/RABS
Conclusion

Any Questions?

Thanks for Listening!
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