



Single Use Systems For Aseptic Fill Finish— Facility Design Considerations

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- 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**

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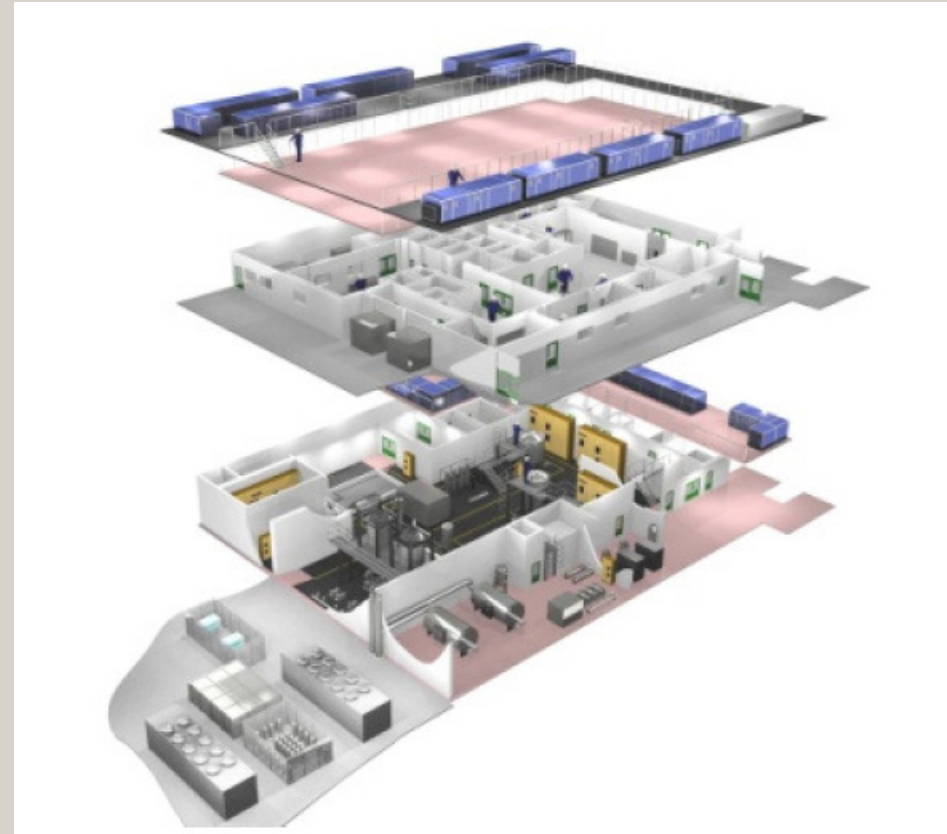
Single Use Formulation for a High Potency Fill Finish Product

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





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



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

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**

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



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



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

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

- 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



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



Conclusion

Any Questions?

Thanks for Listening!

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engineered
solutions**