Single Use Systems

PDA Missouri Valley Chapter

Spring 2024 Networking and Dinner Meeting

The Challenge for all CDMOs

How does the Contract Development Manufacturing Organization:

- **Complete a timely, effective, & efficient tech transfer for a product while:**
  - Navigate complex requirements?
  - Avoid manufacturing delays?
  - Clear regulatory requirements?
  - Meeting the needs of the business?
- **Annex 1 and other regulatory challenges add to the complex:**
  - Sterile Connections
  - Isolator or RABs Technology
  - Application of PUPSIT

Why Single Use Systems?

- Reduced Risk of Contamination
- Ease of Operation
- Overall Time Savings

But how do we mitigate our risks, complexities, and confirm these statements are true?

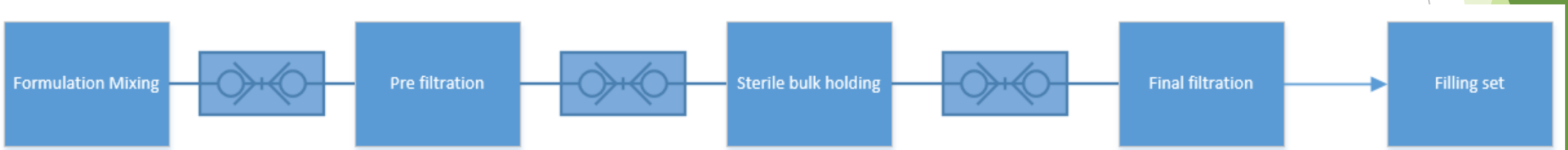
Design of Single Use Systems

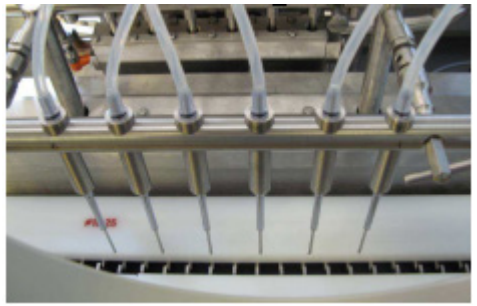
Modulization

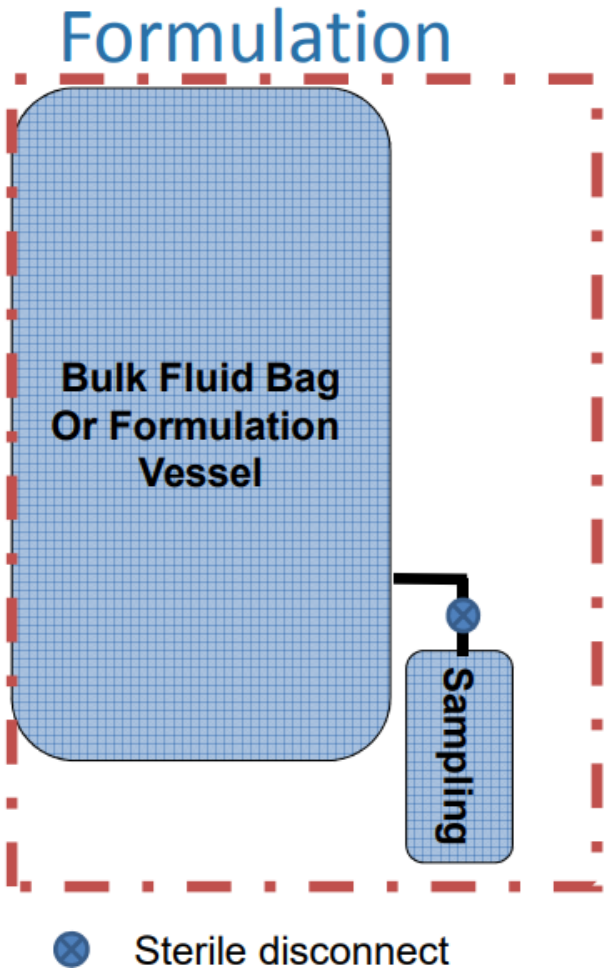
- **For some time, we have built our facilities with modular panels and for suites to have modular controls**
  - This allows for changes to be made easily as the market changes
  - Constructability is easily done as off-site preconstruction is completed and simple install performed on site
  - Provides effective controls to prevent cross contamination
- **How does this compare to Single Use Systems?**

Break Down the Process into Basic Blocks

- **Without a product defined we need the following process:**





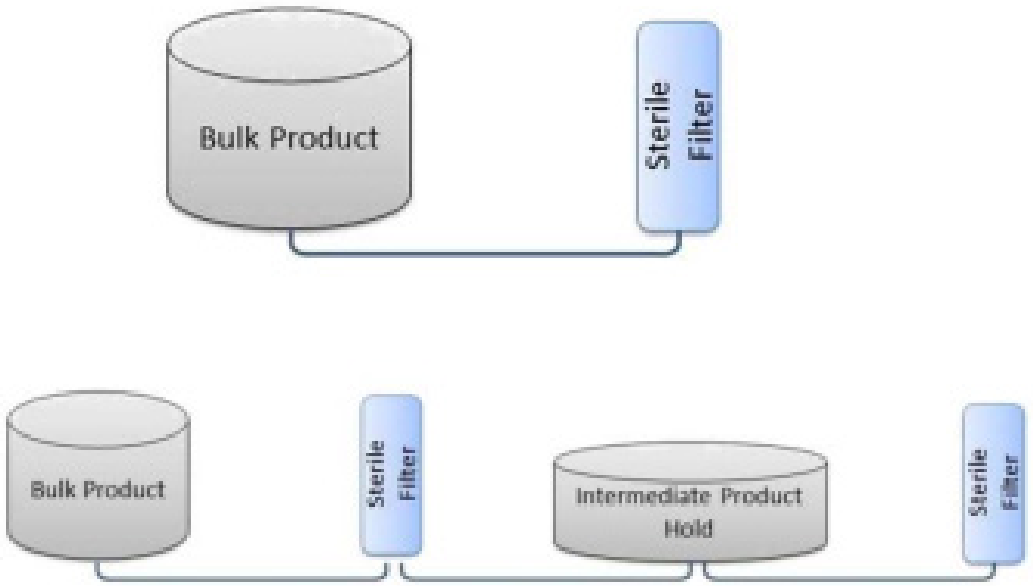


Key Needs

- Component introduction
- Robust mixing
- Temperature control
- Minimize bioburden
- Representative sampling
- Product Recovery

And potentially consider a hybrid system

Filtration



Key Needs

- Robust retention performance
- Well Characterized Materials
- Multiple Device, Size, and Connection Options

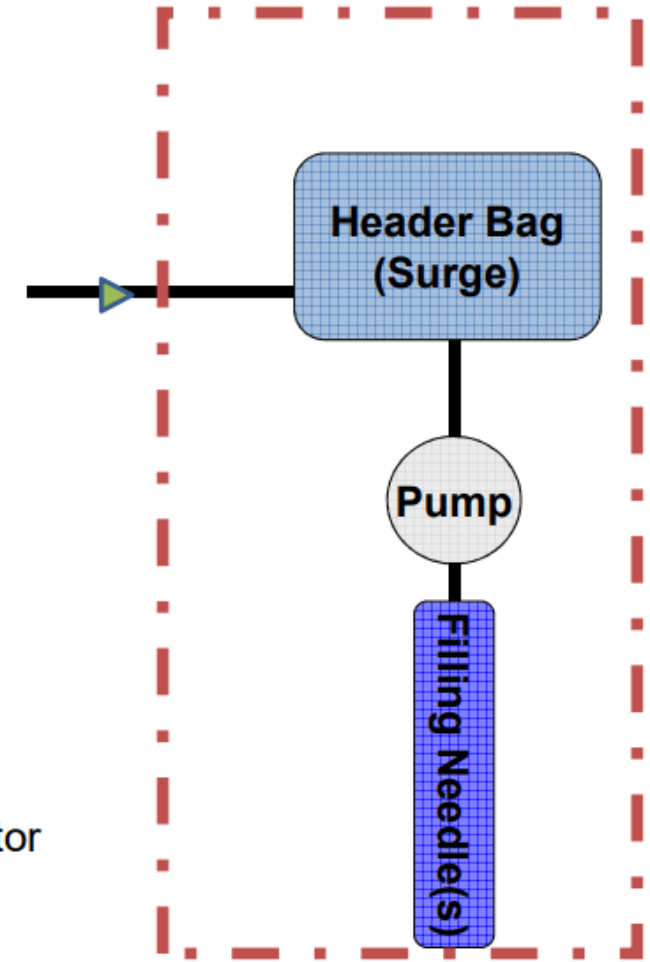
Addressing Risks such as:

- Downstream sterility
- Filter integrity
- Extractables
- Product Recovery
- Operator Interventions

Filling

Key Needs

- Sterility Assurance
- Dosing Accuracy
- Product Recovery



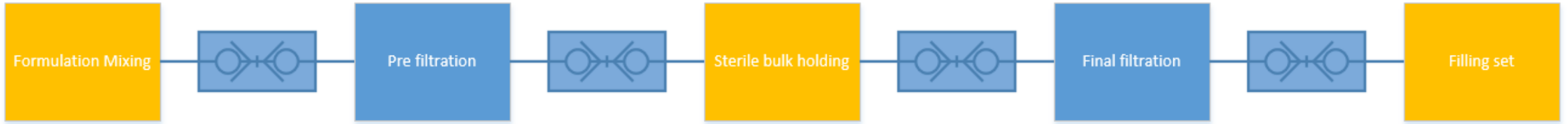
Sterile connector

Single Use Systems

- **Why not think of single use systems as modular?**
  - Typically, SUS (single use systems) are customized to the product needs.
  - This leads to several challenges when doing a tech transfer
    - Higher passthrough cost to the customer – each SUS can cost $20,000.
    - Higher storage needs – more custom SUS & less inventoried stock parts.
    - Increased time - each SUS need to be prototyped and tested in the field to ensure all the components, linkages, and lengths fit the process step for the formulation tanks and filler.

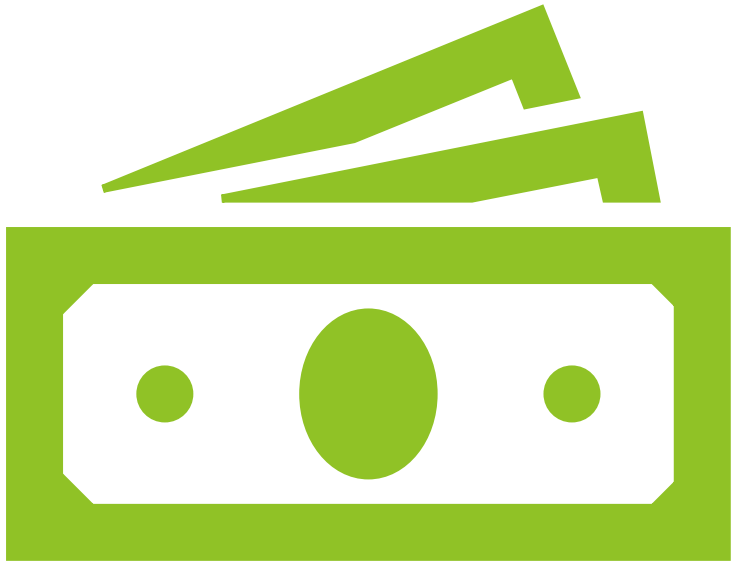
Generally only Filters Need to be Custom

- **Therefore, the following can be standardized:**



- The yellow items are general items that we can order higher QTY's of to get a better price point.
- Having interchangeable filters allow for replacement in case of a filter failure, while saving the batch.
- This also allows for the item in the Grade A to remain the same across products supported by Media Simulation and Air Flow Studies.

Blue = Customer specific
Yellow = Standard KDD parts between formulations



Cost Example

Storage of 4 Products in 100 Pallet Spaces (Custom Assemblies)

- Each single use sub-assembly (assuming 2x per box and 3x boxes per pallet):
  - @ 100 spaces the warehouse can support (((100 spaces/4 sub assemblies) x 6 sets)/ **1 product**) = **150 lots a year**
  - @ 100 spaces the warehouse can support (((100 spaces/4 sub assemblies) x 6 sets)/ **2 products**) = **75 lots a year**
  - @ 100 spaces the warehouse can support (((100 spaces/4 sub assemblies) x 6 sets)/ **3 products**) = **50 lots a year**
  - @ 100 spaces the warehouse can support (((100 spaces/4 sub assemblies) x 6 sets)/ **4 products**) = **37 lots a year**

Storage of 4 Products in 100 Pallet Spaces (Non-Custom Assemblies)

- Each single use sub-assembly (assuming 2x per box and 3x boxes per pallet):
- Assume 30 spaces are non custom assemblies supporting 60 lots/year
  - @ 70 spaces the warehouse can support (((70 spaces/2 sub assemblies)x 6 sets)/ **1 product**) = **210 lots a year**
  - @ 70 spaces the warehouse can support (((70 spaces/2 sub assemblies)x 6 sets)/ **2 products**) = **105 lots a year**
  - @ 70 spaces the warehouse can support (((70 spaces/2 sub assemblies)x 6 sets)/ **3 products**) = **70 lots a year**
  - @ 70 spaces the warehouse can support (((70 spaces/2 sub assemblies)x 6 sets)/ **4 products**) = **52 lots a year**

Price

- SUS can cost $20K for a single use from the mixing tank to the filling needle.
- Ordering in QTY's over 20 usually see a price decrease of 9%.
  - Assuming 30 lots a year equals out to approx. 50K in savings a year
- Every time we must repeat a new air flow study which can cost $5000
  - @ 2 or 3 tech transfers a year this is an additional 15K saved

Results

- Incorporating modulization of SUS in the beginning allows for as flexibility as a CDMO
  - Giving us more efficient pallet space utilization
  - Saving on cost
  - Improved quality

Thank You!