Optimization of Drug Product Stabilizer Processes

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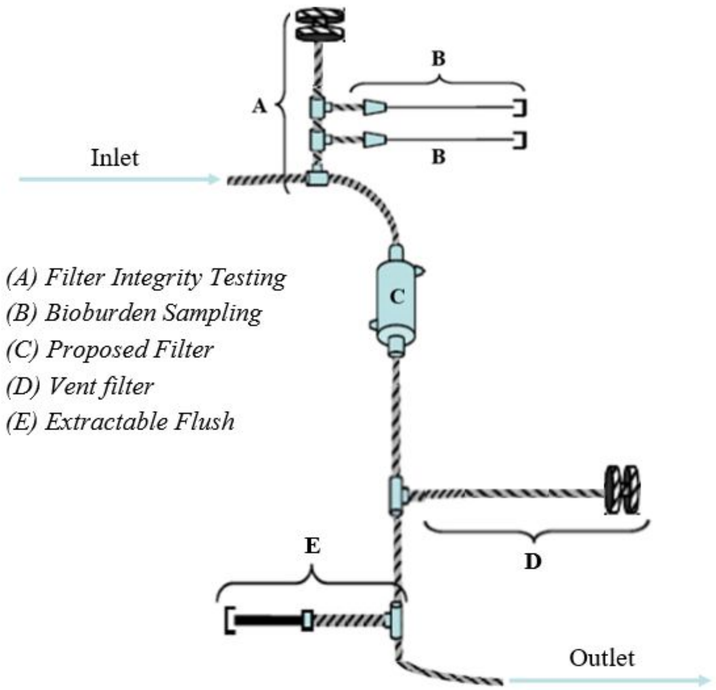
GOALS

- Evaluate single-use versus reusable filtration technologies for best process fit
- Perform a cost-benefit analysis between existing and proposed filtration skid assemblies
- Propose implementation plan for new filtration skid including validation requirements, change management, training, and safety
- Develop a tool for optimizing media bag fills based on shifts in dilution models
- Author a procedure for operation of the filtration skid
- Filtration documentation (maximum flow rate for medias, filter integrity test specifications, etc.)

MOTIVATION

- The facility aims to reduce cost per dose across its vaccine franchise
- Stabilizer preparation has been identified as a central area for optimization
- Tasks like extractable flushes and filter integrity testing extend preparation time and increase resource use
- Streamlining these steps can:
  - Lower operation costs
  - Improve manufacturing efficiency
  - Increase throughput
  - Support vaccine affordability and accessibility

PROCESS DIAGRAM



SINGLE-USE FILTERS

Advantages

- Prevents risk of cross contamination between processes
- Eliminate cleaning and sterilization steps
- Increased flexibility between batches
- Lower upfront cost
- Less energy used to ensure the skid remains sterile

Limitations

- Increased waste production
- Dependent on availability of supplies
- Material compatibility
- Scalability

REUSABLE FILTERS

Advantages

- Environmental benefits due to less waste produced
- Long term cost savings
- Scalability

Limitations

- Increased risk of cross contamination between batches and runs
- Cleaning and sterilization processes can increase time between runs
- Time associated with frequent filter function validation tests
- Material loss involved in increased frequency of function tests

CURRENT FILTER

Opticap® XL4 Durapore® 0.22 µm filter (Single-Use)

PROPOSED FILTER

AcroPak™ 1500 Capsule with Supor™ Hydrophilic Polyethersulfone (PES) Membrane (Single-Use)

COMPARISON OF FILTER SPECS

	Current: Opticap® XL4 Durapore®	**Proposed: AcroPak™ 1500**
Manufacturer	Millipore	Cytiva
Pore Size	0.2 µm	0.2/0.2 µm
Membrane Material	PVDF	PES
Filtration Area	0.19 m^2	0.15 m^2
Cost	$456.00 per run	$289.00 per run

COST ANALYSIS

	Product 1	**Product 2**	**Product 3**
Extractable Flush Volume Saved	1.15L	1.15L	1.15L per Media
Annual Loss due to Extractable Flush (Original)	$525,000.00	$32,000.00	$247,000.00
Annual Loss due to Extractable Flush (Proposed)	$207,000.00	$12,000.00	$97,000.00
Total Amount Saved per Year	**$488,000.00**		

CONCLUSIONS

- Switching to the **AcroPak™ 1500** reduces filter cost by **$167.67 per run**.
- **Total annual savings: ~$488,000** from reduced media loss and an **additional $56,000** due to reduction in filter cost.
- Extractable flush volume is **reduced by 1.15L per run**, cutting material waste.
- Using one pre-sterilized filter streamlines the process and lowers manual handling.
- Slight efficiency loss due to smaller filtration area needs to be further evaluated to determine cost of loss
- Validation tasks (e.g., bacterial retention, compatibility, extractables) are required before implementation.