Leveraging the advantages of single-use in plasma processing

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SAFC®
Pharma & Biopharma Raw Material Solutions

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our portfolio brands

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The Millipore® portfolio offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and time-tested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

Denotes Millipore® Products

SAFC®

The SAFC® portfolio offers customized and ready-to-use raw material solutions, backed by deep regulatory expertise. Our high-quality products and services are supported by an experienced and responsive team of raw material and regulatory experts who are committed to understand your requirements and provide tailored solutions that meet your exact needs.

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BioReliance®

The BioReliance® portfolio encompasses biopharmaceutical characterization, safety testing and process development, as well as clinical and commercial biomanufacturing. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

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Strategically leveraging single-use technologies in key areas of the process provides significant advantages including:

- Elimination of CIP and SIP processes, as well as the utilities and validation to support them
- Decreased risk of contamination (closed processing) and minimized operator exposure
- Increased processing flexibility and efficiency

Watch our Webinar on Implementing Single-Use Technologies: Plasma Case Study

Designing an Economic and Efficient Buffer Operation

Buffers are the largest component by volume in the processing of plasma proteins. New plasma facilities are trending towards centralized buffer operations in order to increase efficiency and productivity. Single-use technologies can facilitate rapid preparation, filtration and distribution of buffers in a centralized location without the risk of cross-contamination. Additionally the turnaround time between batches is significantly reduced.

Key Considerations:

- Choosing the right filter that incorporates sterility assurance, high flow rate and chemical compatibility
- Working with a trusted single-use partner that can provide fast delivery and supply assurance for critical bags and components
- Seamless component integration linking filters and single-use assemblies

Watch our Webinar on Designing an Economic and Efficient Buffer Operation

Mixing Solutions | Buffer Filtration | Process Containers | Lynx® Connectors | Emprove® Buffers

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using single-use technology for viral inactivation

Solvent/detergent and low pH treaments are critical components of virus inactivation steps in plasma manufacturing.

Plasma fractionators typically employ single-use solvent/detergent inactivation technologies in the following circumstances:

1. As a quick solution to adapt to increasing plant utilization
2. When designing a new facility that will require processing a variety of proteins at small volumes
3. As a means of isolating specific proteins like hyperimmunes or coagulation factors as part of routine processes

The advantages of implementing single-use solutions in these situations is a reduction of process contamination risk, an increase in the speed of implementation, lower capital investment costs, and greater processing flexibility.

The selection and qualification of single-use materials for virus inactivation steps should include a thorough assessment of the chemical compatibility, non-specific chemical adsorption, and extractables profiles of the product contact components.

Watch our webinar on Solvent Detergent Viral Inactivation using Single-Use Technology in Blood Fractionation Processes

Process Containers

Solvent/Detergent Inactivation

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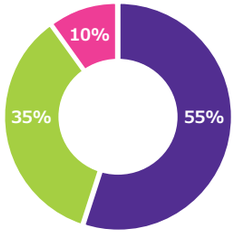
sampling with confidence

It is critical to sample and monitor your product throughout the process. An imprecise or false positive result can lead to costly investigations, production delays and even quarantined product. With the NovaSeptum sterile sampling system, contamination is no longer a threat. The closed design ensures your sample will be isolated and remain sterile, from point-of-sample to analysis.



Sampling related deviations caused by 3 factors:

- Manufacturing Errors
- Improper Sampling
- Measurement

Case Study: The tables below outline the advantages that a single-use sterile sampling system can provide, when multiple samples are required from the same process step/vessel.

Process Step	Traditional Glass Bottle Sampling	Single-Use Sampling System	Time savings
Prep and install	20-30 mins	5 mins	15 - 25 mins
Steam in Place (SIP)	60 mins	60 mins	0 mins
Sample port sterilization	45-60 mins	Not required	45-60 mins
Collect sample	10 mins	2 mins	8 mins
Post-sample flush/clean/SIP	30-40 mins	Not required	30-40 min
Total	3 - 3½ hours	1 hour	1½ -2½ hours

Watch our webinar on Improve Process Management by Optimizing Your Sample Plan with single-use Technology

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Sterile Sampling

Meeting stringent requirements of a final filling process

The adoption of single-use technologies for final filling process is steadily increasing, as it provides the flexibility to respond to the demands of manufacturing a variety of drug products and fill volumes and significantly reduces changeover and turnaround time from batch to the next.

Process Design Considerations

Sterile filtration in your final filling process is a critical operation. There are multiple options in designing a sterile filtration process, for example using single stage vs. redundant filtration. There are multiple options in designing a sterile filtration process, for example using single stage vs. redundant filtration, or the decision to perform a pre-use, post-sterilization integrity test. Regulatory compliance, risk tolerance and cost efficiency are considerations that require an understanding of the cost-benefits analysis.

Questions to consider when planning design:

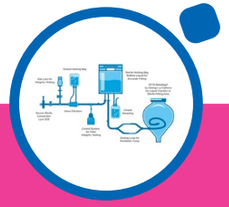
1. Do you require single, dual or redundant filtration?
2. Do you require the filter in or out of the isolator?

Case study comparing traditional and Mobius® final fill processes at a biologics manufacturer.

	Traditional Fill-Finish	Single-use Solution
Cleaning and set-up	14 hours	< 1 hour
Cleaning validation	Extensive	Zero
Filling time	24 hours	10 hours
Average vials/hour	2,000	10,000
Aseptic connections	30	0
Rate limiting factor	Facility	Materials
Tome for filling campaign	36 hours	12 hours

Source: V. Guptas, E. Jenness, Implementing a single-use solution for fill-finish manufacturing operations, BioProcess International, May 2011

Watch our webinar on Overcoming Quality and Regulatory Challenges of Implementing single-use Pharmaceutical Manufacturing



Final Fill

Need support in developing your plasma manufacturing process?

Whether you are looking to implement proven solutions while reducing costs and mitigating risk, or looking for a partner who will work with you from Process Development through Facility Design and Construction anywhere in the world, we have options that will streamline your process and set you on the path to success.

BioReliance® Services

BioReliance® Services can help you to design, optimize, and validate your own fractionation process with the latest single-use technologies, then tech transfer to your own local production site. Our services are customized to address your specific needs, from individual operations to a full process executed at your facility.

Learn more about BioReliance® Services

Millipore® Products BioReliance® Services

Mobius® MyWay Assemblies

Final Filtration

Integritest® 5

Emprove® Program

For additional information, please visit

EMDMillipore.com/plasma

To place an order or receive technical assistance, please visit

EMDMillipore.com/contactPS

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