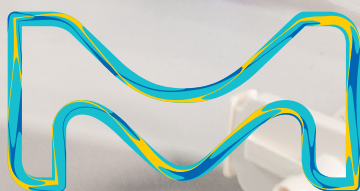


STERILE DRUG PRODUCT MANUFACTURING

Integrated Single-Use Solutions for
Formulation, Final Filtration and Filling

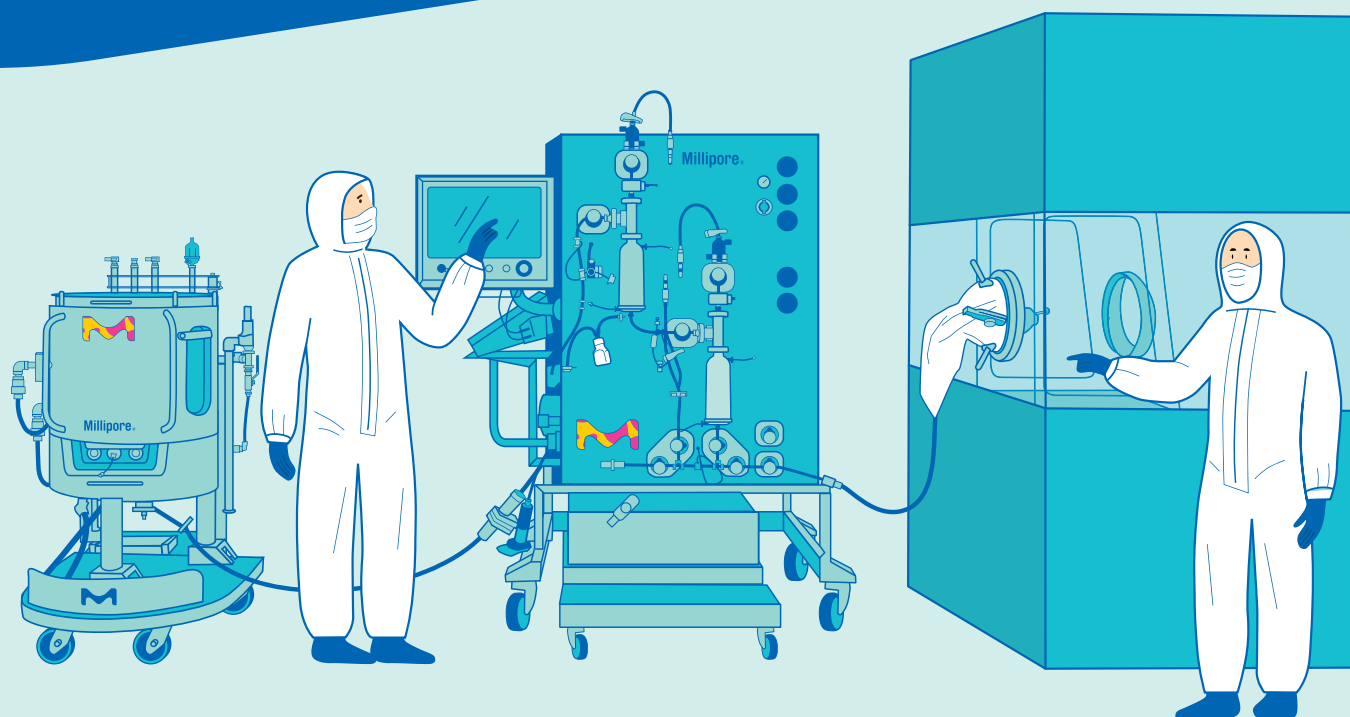


MilliporeSigma is the U.S.
and Canada Life Science
business of Merck KGaA,
Darmstadt, Germany.

Millipore®

Expert Pharm/BioPharm
Products & CTDMO Services

Our integrated aseptic processing ecosystem helps you confidently design and de-risk your sterile drug product manufacturing from formulation through final filtration to filling—protecting your patient safety.



From Formulation to Final Fill: Closed, Single-Use Workflow

Because Every Dose Counts.

Drug product filling is a critical step in biopharmaceutical production and is the focus of regulatory guidance designed to assure drug quality for patient safety. Common challenges include handling complex biologics, scaling from clinical to commercial manufacturing, and maintaining sterility while accommodating the expectations outlined in various regulatory guidelines.

The Advantages of Single-Use Technologies

Single-use technologies lower capital investment and facility footprint, streamline cleaning validation and accelerate changeovers. However, sterile drug product manufacturing is not defined by individual components; it's a cohesive workflow designed to maintain sterility, integrity and regulatory compliance across the entire process.

From Formulation to Final Fill.

Every aseptic process is designed with one goal in mind: delivering safe drug products to patients. Our integrated portfolio of single-use technologies, sterilizing-grade filters, systems and services supports formulation, sterile filtration, and final fill—helping you confidently design and derisk your drug product process. Backed by decades of experience partnering with drug manufacturers and CDMOs across a wide range of modalities, we help you build a comprehensive contamination control strategy, qualify your aseptic process with confidence, and make informed decisions to protect every dose—so you can stay focused on what matters most; your patients.

Our single-use technologies support critical aspects of your process:

- **Maintain compliance** – Confidently support evolving regulatory expectations with comprehensive documentation, validation services, and technical expertise that support qualification, audit readiness, and a robust contamination control strategy.
- **Assure sterility** – Support closed processing from formulation through final fill to help reduce contamination risk, protect product quality, and safeguard every dose.
- **Optimize the process** - Enable consistent, reliable manufacturing with integrated single-use technologies designed to improve process performance, reduce operational risk, and support efficient implementation across your aseptic workflow.

Gentle, and Efficient Mixing

Formulation must protect sensitive biomolecules from shear and temperature stress. An ideal mixer offers reliable in-line control and consistent, high-quality mixing to achieve a homogenous solution with maximum yield.

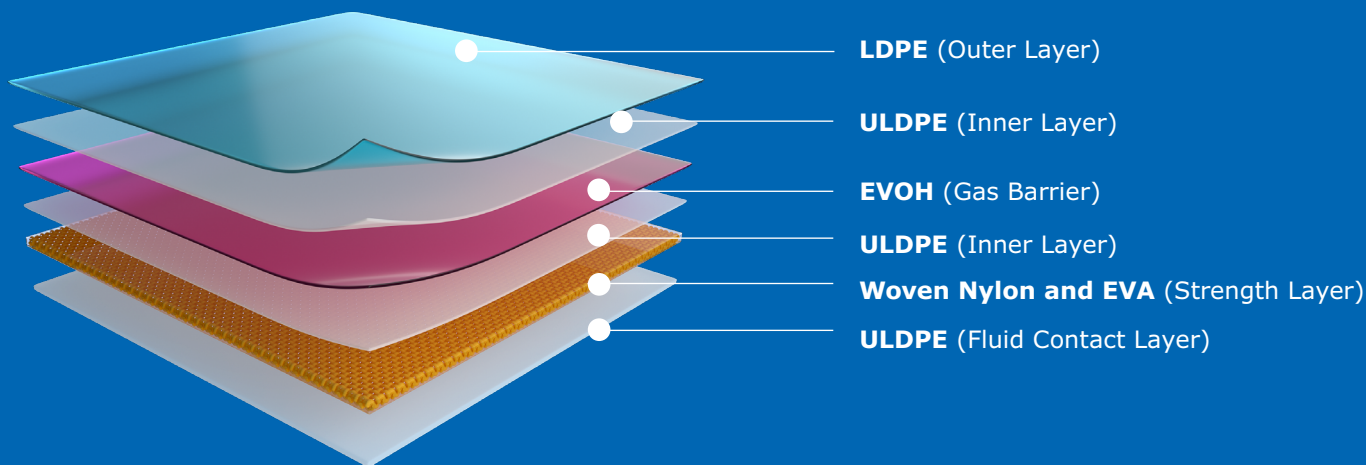
Our Mobius® MIX for Formulation Mixers are based on our Mobius® MIX Systems, configured for efficient drug product formulation and offer:

- Single-use bags with robust Ultimus® film for exceptional durability and performance
- Levitating impeller for low-shear mixing
- Cylindrical tank with a conical bottom for efficient product recovery
- Wide usable volume range with integrated sensors (pH, conductivity, and temperature)
- Sanitary, cleanroom-ready hardware & seamless, closed connectivity to downstream filling



Durable Film Containers for Drug Product Formulation

Formulation mixers frequently handle large fluid volumes using single-use bioprocessing containers designed for strength and leak resistance to protect valuable drug product. Ultimus® film-based bag assemblies incorporate woven nylon within the film structure, providing robustness while enabling easy handling, flexibility, and conformity to the container requirements for single-use processing.



Single-use bag assemblies for Mobius® MIX for Formulation systems offer:

- Exceptional durability and performance
- Extreme Abrasion Resistance
- Greater Tensile Strength
- Reinforced Puncture Resistance
- Superior Flex Durability
- ISTA 3E Transport Test verified using Mobius® 500 L Container with Ultimus® Film in 500 L Stainless Steel Bin
- Comprehensive extractables data

Proven Membranes for Reliable Sterile Filtration

Selecting the right sterilizing-grade membrane is a critical decision in sterile drug product manufacturing, with potential impact on product quality, yield, process scalability, validation strategy, and final fill configuration.

Sterilizing-grade Membranes

These sterilizing-grade membranes deliver performance for liquid filtration, are non-reactive, minimize product and excipient binding, and provide sterilizing-grade performance under actual processing conditions.

Recommended membranes include:

- Durapore® 0.22 µm polyvinylidene fluoride (PVDF) membrane: robust, low protein binding, broad chemical compatibility and low extractables
- Millipore Express® Ace 0.2 µm membrane: low protein binding, non PFAS surface modified polyethersulfone (PES)
- Millipore Express® SHF and SHC: PES membrane with high flux and capacity, broad chemical compatibility, non PFAS



Filter Formats for Reliable Sterile Filtration

Capsule filters for single-use liquid filtration are offered in multiple sizes with different options dependent on membrane type. Some capsules contain specialized aseptic multipurpose ports (AMPP) that prevent microbial ingress and protect the flow-path from contamination during integrity testing, venting and sampling.

- Millipak® Final Fill disposable capsules minimize product loss in high value, small volume processes
- Opticap® and Opticap® Pro disposable capsules are the preferred choice for larger volume operations
- Cartridge filters are used in multi-use, stainless-steel operations requiring larger filtration areas or lower operating costs



Filtration Systems & Integrity Testers

Sterile filtration in fill finish is a focus of regulatory guidance, notably EU GMP Annex 1, which highlights the importance of pre-use post sterilization integrity testing (PUPSIT) for assuring sterility. The Mobius® iPUPSIT Filtration System is a pre-engineered single-use system that streamlines PUPSIT, and mitigates the potential risks of contamination, test failures, and subsequent batch loss. This pre-engineered system simplifies highly complex manual operations, reducing the likelihood of operator error while providing flexibility for different single-use filtration configurations.

The compact system integrates the pump, flush bag, HMI, and integrity tester in a single footprint with CCP® control software for recipe-driven automation, process control, and centralized data handling and reporting via plant SCADA/DCS. Configurable system setups support different batch sizes and filtration configurations and are engineered to minimize yield loss.

Integrity Testers

Regulatory guidelines require integrity testing of final sterilizing filters used in aseptic drug manufacturing. Automated integrity testers, such as Integritest® 5 Filter Integrity Test instrument, enables non-destructive inline or offline integrity testing using pressure decay.



Mobius® Final Fill Solutions

Mobius® final fill Assemblies are single-use units designed for integration with major filling platforms, enabling safe aseptic operations, easy installation in constrained spaces, and flexibility across different configurations and batch sizes.

Patent-protected packaging reduces handling risk and misconnections, backed by extensive experience in single-use final filling solutions.

Mobius® FillReady Solutions further streamline implementation and are available as standardized assembly designs tailored to specific filling platforms, reducing design time and streamlining deployment so you can be up and running faster. These single-use assemblies are designed for robotic installation to minimize manual intervention.

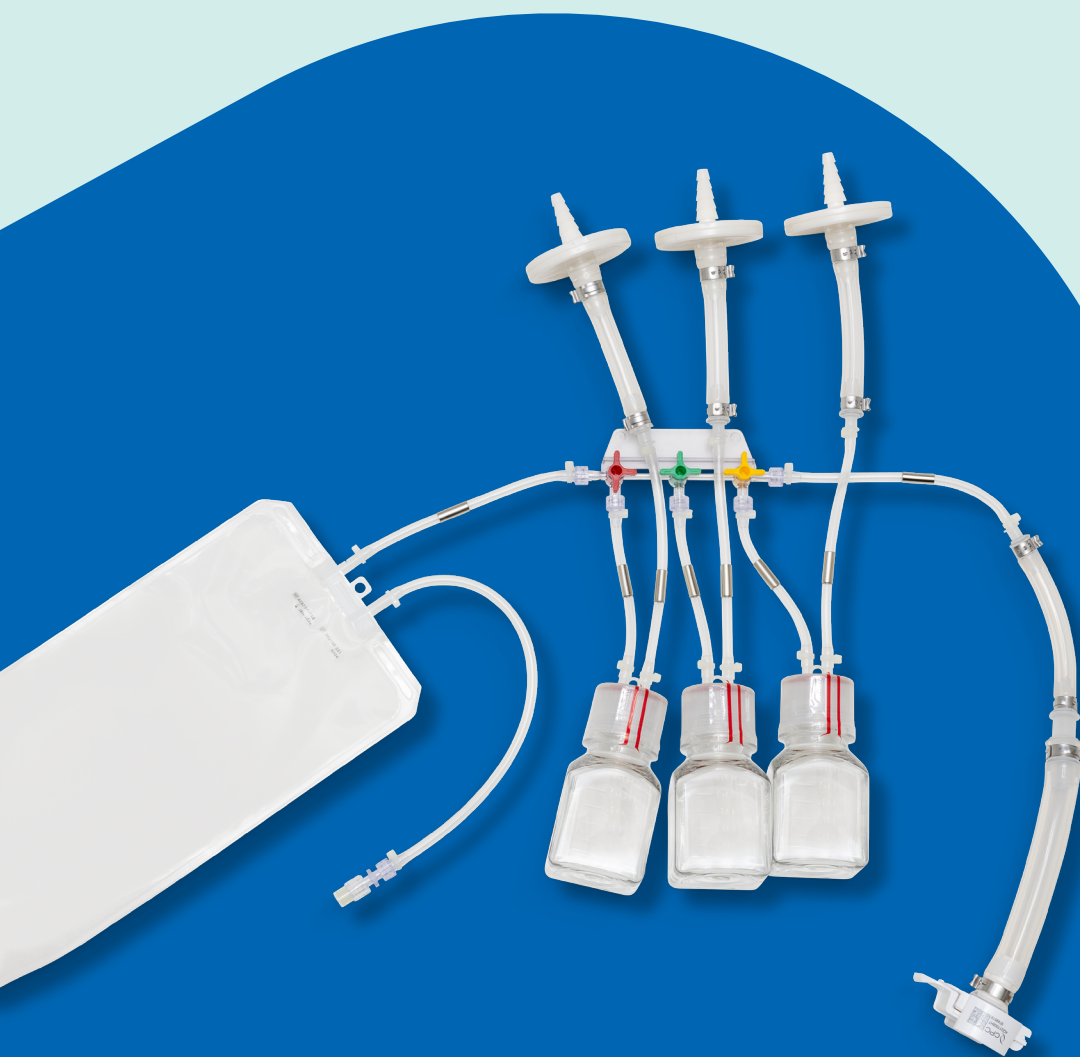


Completing the Aseptic Chain

Sterile Sampling

NovaSeptum® closed sterile sampling systems provide safe and representative sampling in fill finish operations, enabling reliable assessments of bioburden, endotoxin, pH, TOC, and sterility. The plug-and-play design with multiple container options and easy connectivity minimizes the risk of contamination, protecting the integrity of both samples and processes.

- NovaSeptum® SURE sampling assemblies are closed, representative sampling solutions for single-use processes
- NovaSeptum® GO sampling systems are closed, easy to use systems with sampling actuation evidence and control for multi-use processes





Connectors

Lynx® sterile connectors maintain a closed fluid path for secure sterile fluid transfer between disposable fluid paths and the various steps in your aseptic process.

- Lynx® S2S connectors are gamma- and autoclave-compatible single-actuation sterile-to-sterile connections
- Lynx® CDR connectors enable multiple connect-disconnect-reconnect cycles for multiple transfers of sterile fluid
- Lynx® ST connectors allow integration of steamable hard-piped process equipment with disposable sterile fluid paths

Services and Support Beyond Components

The Emprove® Program

The Emprove® Program provides comprehensive documentation (extractables, regulatory statements, bills of materials) to support drug manufacturers material qualification, risk assessments, and regulatory submissions.

To streamline implementation, the Advanced Qualification Dossier consolidates your single-use assembly component information into one comprehensive document.

Learn more about the Emprove® Program at:



Single-Use and Filter Validation Services

Our Single-Use and Filter Validation Services reduce internal workload by delivering standard or custom validation studies to meet regulatory expectations. Offerings include bacterial retention testing, chemical compatibility, filter integrity testing and extractable and leachable assessments.

Learn more at:





Process Development and Manufacturing Support

Partner with our process development scientists and MSAT team at M Lab™ Collaboration Centers to optimize and scale your aseptic manufacturing operations.

Either in person or virtual visit, we can help develop, test or troubleshoot without disrupting your manufacturing schedule.





Design Your Final Fill Ecosystem with Us

Our integrated single-use ecosystem supports drug product manufacturing from formulation through final filtration and filling, and is backed by decades of collaboration with biomanufacturers.

Single-use technologies including the Mobius®, NovaSeptum®, and Lynx® portfolios, our sterilizing-grade Millipore Express® and Durapore® filters, combined with regulatory and validation support through the Emprove® Program and Filter and Single-use Validation Services labs, help manufacturers implement reliable, compliant, aseptic fill finish processes.

We invite you to work with us to review your existing final fill processes, co-design single-use solutions for new or upgraded production lines and explore workflows in practice at one of our M Lab™ Collaboration Centers.

Contact your local representative to learn how our single-use ecosystem can support your next final fill project.

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