

SAFC[®]

Pharma/Biopharma Raw Materials

Global Sterile Liquid Capabilities



The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

MERCK

WHY US?

Our Global Sterile Liquid capabilities are designed to enhance and streamline your process from clinical phase trials all the way through to commercial production:

- Cell culture media: off the shelf or custom formulation
- Downstream buffers
- CIP and SIP solutions

As a trusted partner in your biopharmaceutical supply chain, we bring together products and services from across Merck to offer the industry's highest quality sterile liquid capabilities.

Our global presence is your sourcing advantage

We operate GMP manufacturing locations around the world so we can address your Global needs and provide faster turnaround for your orders. An additional facility in Nantong, China, will be up and running soon.



We help our clients meet commercial needs in achieving patient care:

As your reliable partner as you progress to clinic, we ensure speed-to-market and a cost-effective process by providing the supply chain and quality you need to mitigate risk.

We understand the needs of the biopharmaceutical environment and will support you in developing a robust, economical (or efficient), and scalable process that will help you get your product to market faster.

We provide:

- 350 years of understanding critical raw materials
- Safe and on-time delivery anywhere in the world
- Access to our team of subject matter experts who can help you achieve your production goals

QUALITY IS THE KEY

every step of the way...

The highest standards of manufacture yield the highest-quality products:

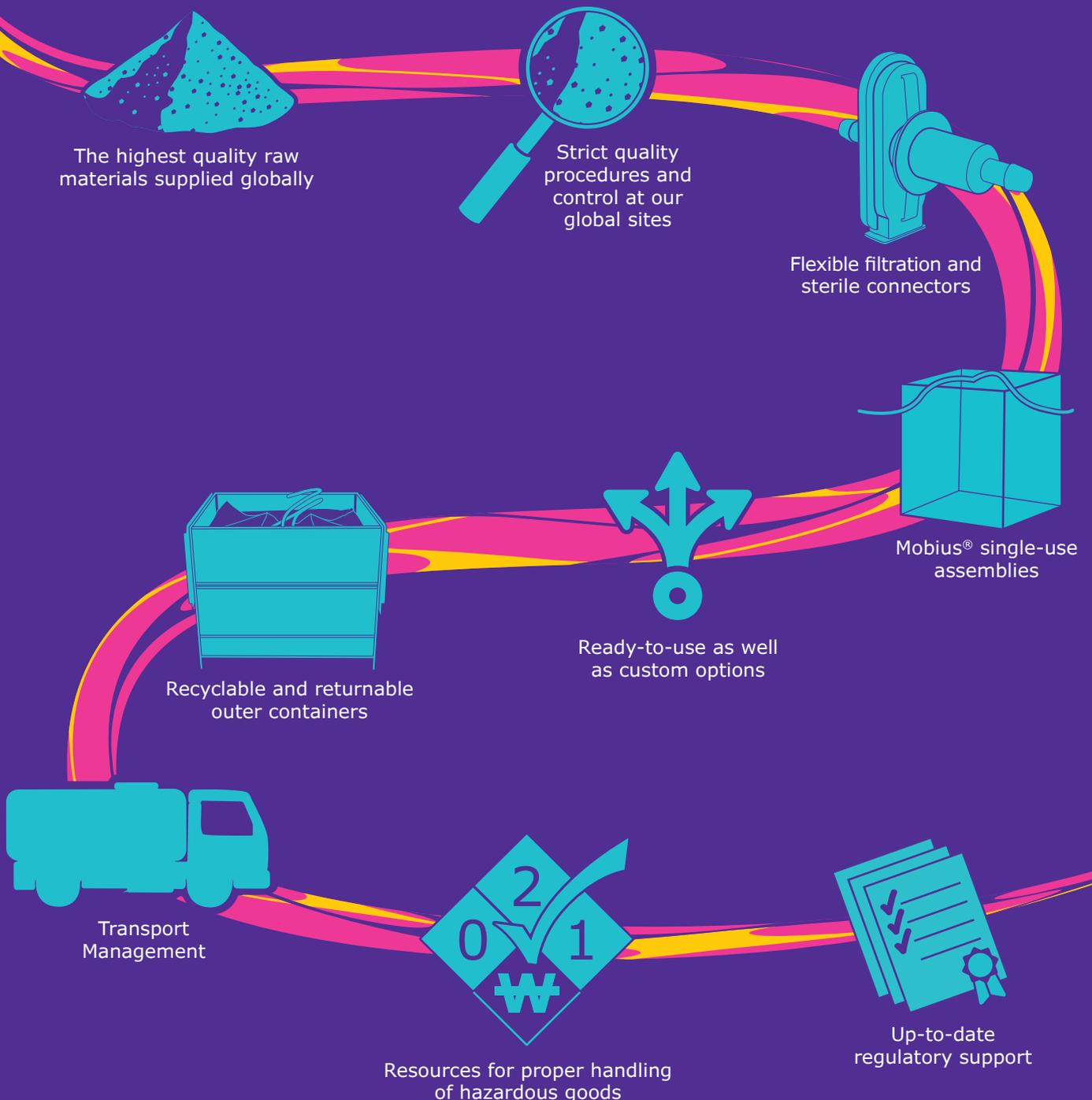
- The highest quality raw materials supplied globally
- Strict quality procedures and control at our global sites

Clean, robust packaging:

- Ready-to-use as well as custom options
- Up-to-date regulatory support

Sustainable transport management:

- Resources for proper handling of hazardous goods
- Recyclable and returnable outer containers



WE LIVE QUALITY

Ready-to-use sterile liquid solutions to optimize biopharm production

Media and buffer preparation, from the hydration of bulk powders, requires time, labor and manufacturing floor space. Eliminating this from your process provides a number of advantages;

- Streamlined processes with fewer operational and contamination risks.
- Reduced manufacturing floor space.

- Elimination of extra tasks associated with hydrating bulk powders; no filtration steps, tubing and refilling, sample taking and additional quality control testing.
- Resources can be aligned to more value-added tasks.

Your sterile liquid arrives ready-to-use in the quantities you need, with no waste and no excess to inventory.

Quality products start with quality ingredients

It all starts with the quality of the water

Quality water is the key starting ingredient for all our liquid products. We ensure consistency, security, and EP and USP compliance by establishing redundant water for injection (WFI) supplies at all of our facilities.

This bulk-packaged water is suitable for the preparation of both upstream and downstream process solutions in industrial bioprocessing applications.

- Upstream applications: cell culture media, cell suspension and wash solutions, and reconstitution of products.
- Downstream applications: process and biological buffers, cleaning and rinsing agents, and diafiltration and purification buffers.

We have a transparent and secure raw material program

Our Global Raw Material Management Program, which includes access to our Global Emprove® program, is robust, controlled, and coordinated to provide a consistent supply of material for your business continuity.

We ensure our incoming supply is safe and secure to mitigate your quality concerns

Through Supplier Relationship Management programs, we maintain active dialogues with suppliers to establish working forecasts and inventory levels.

We make sure your supply chain is secure

- We constantly monitor materials and audit manufacturers and suppliers to assure quality, qualification, and management.
- We reduce variability by identifying and mitigating risks in the supply chain.
- We work with subject matter experts to establish appropriate release criteria and specifications.
- We maintain comprehensive change notification from our suppliers through to our customers.



Quality continues at our liquid media facilities

A comprehensive company-wide Global Quality Management System assures the highest product quality:

- Consistency
- Reproducibility
- Performance
- Expertise

We are committed to meeting or exceeding all relevant international guidelines and regulations, and we maintain quality certification programs at all global facilities.

Our quality systems provide for a certain degree of customization to meet individual customer requirements.

We have quality programs at every facility

- Segregated areas for animal components
- Supplier and material qualification programs
- Risk assessment
- 21 CFR Part 820 compliance
- ISO 9001:2015 Certification
- Equipment Qualification and Process Validation

We are audit-ready every day

To schedule an audit, please contact your account representative. We welcome an opportunity to show you our quality systems. These systems assure that we maintain product control and produce high-quality products consistently.

We perform on-site quality control testing

We maintain a quality control laboratory at each of our liquid media facilities. Standard quality control assays for liquid media are conducted using harmonized current compendia methodologies.



EMPROVE® PROGRAM

Streamline your qualification and drug filing

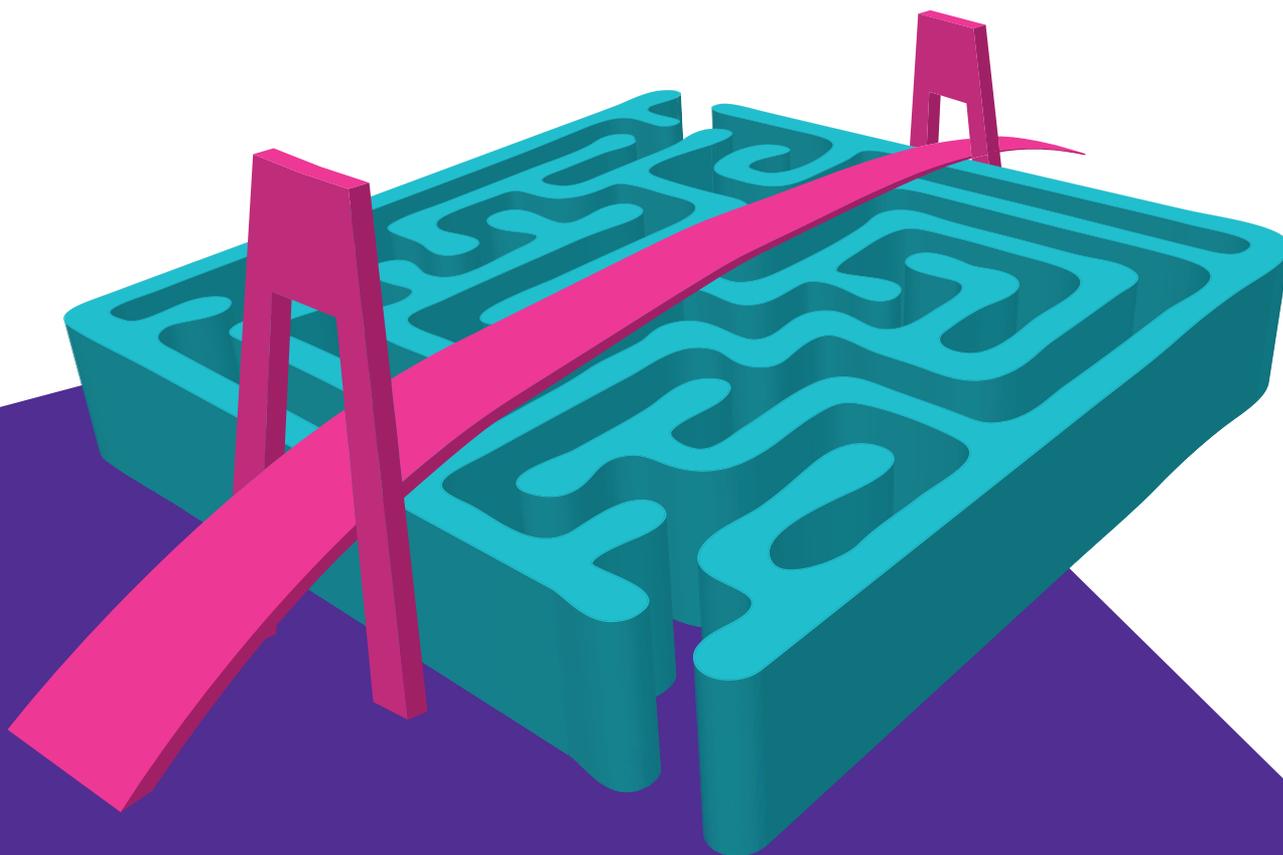
Our manufacturing sites have 100% access to the entire Emprove® program. This enables us to help you to stay on top of regulatory changes and simplify your processes:

- Speeds approval preparation and extending compliance
- Facilitates the qualification process
- Supports risk assessment
- Increases supply chain transparency

The Emprove® program is a powerful, always up-to-date repository of current and anticipated regulatory data supporting our high-quality pharmaceutical and biopharmaceutical raw materials and consumables. The Emprove® program is available online, organized into three dossiers:

- Material Qualification Dossier
- Quality Management Dossier
- Operational Excellence Dossier

The Material Qualification dossier is available on our website. Subscribers can access all dossiers. To learn more, visit: [MerckMillipore.com/emprovesuite](https://www.merckmillipore.com/emprovesuite)



PROCESS EXPERTISE

Hand in hand, from cell line development to commercial manufacturing

Our services and programs meet your needs

The imMEDIATE Advantage® program provides small volume custom media and buffers

Small volumes of non-GMP upstream and downstream materials, such as cell culture media, buffers, and liquid concentrates, are available to support scale-up from development to commercial production, reducing the need for expensive revalidation later on. Our imMEDIATE Advantage® laboratories worldwide are dedicated to supporting the study and development of complex materials such as cell culture media. These labs are uniquely equipped to support developers and manufacturers with access to non-GMP, small-volume custom media with expedited timing. All media formulations are produced using comparable compounding methods and qualified raw materials where possible to provide consistency in development studies. We routinely support scalability efforts across all stages of development and manufacture. Small-volume custom liquid formulations can be shipped within ten business days and are ideal for prototyping, troubleshooting, and scale-up studies.

M Lab™ Collaboration Centers provide information and assistance

Partner with our experienced process development scientists in one of our nine non-GMP facilities around the world. They specialize in upstream, downstream, and final fill challenges.

BioReliance® Validation Services help you manage drug manufacturing process risks

These services are designed to help you meet regulatory guidelines and demonstrate the robustness of your process. We provide scientific evidence to satisfy regulatory expectations, and stability studies are also available upon request. Process validation and equipment qualification are key to ensuring product quality, patient safety, and regulatory compliance.

End-to-End Services speed your process to clinic and to market

We provide the support and expertise you need to accelerate clinical drug development, scale your process, and implement local production facilities globally.

- **Process support**
- **Analytical support**
- **Products are scalable and transferable for GMP readiness**
- **Spent media analysis**

VIRAL RISK MITIGATION

Add a layer of safety to your process

We offer options for the mitigation of viral contamination. Even in a controlled manufacturing environment, there is a risk of viral contamination of raw materials due to geographic origin, physical source, and identity. We can mitigate this risk through high-temperature, short-time (HTST) treatment or filtration. Our expert teams will work with you to determine which method is best for your product. HTST significantly reduces the number of

infection agents by 4–6 LRV in liquid media products. The technology is based on pasteurization and is applicable for a variety of media, buffers and feeds/supplements such as glucose. Virus filtration provides increased compatibility for heat-sensitive components of chemically defined media, buffers, and feeds/supplements. Our industry-leading Viresolve® products provide reliable virus removal at all scales.

READY-TO-USE SOLUTIONS

Simplify your production process

State-of-the art, ready-to-use, single-use packaging options

Single-use technology and systems for bioprocessing both clinical and commercial drug products reduce costs, improve flexibility, and reduce multiple risks.

Our manufacturing facilities are specifically designed to provide sterile products in a number of final vessel formats, from standard PET bottles to standard or custom bags. We also provide custom volumes and formats.

We can help you minimize chemical handling risks

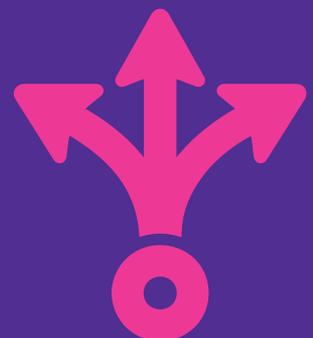
Our site-based project management experts help you through the maze of hazardous shipping management, providing product and packaging solutions that minimize chemical handling risk.



Improved
Economics



Reduced
Risk



Enhanced
Flexibility

PACKAGING & TRANSPORT TECHNOLOGIES

Mobius® Single-use bags

Our Mobius® single-use bag assemblies lead the industry. Our clear, multilayer films are inert to fluid contact, and the contact layers are compliant with FDA 21CFR 177.1520. The bags are resistant to flex-crack and provide enhanced mechanical strength, creep resistance, and limited permeability to air and gases.

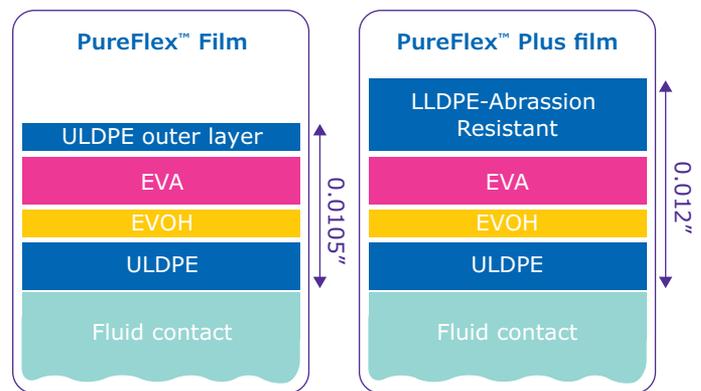
Mobius® single-use bags are constructed using our robust PureFlex™ Plus film, which demonstrates a very low extractables profile when tested according to BPOG guidelines. This newly developed film is built in layers of low-density and ultra-low-density polyethylene, ethylene vinyl acetate (EVA), and polyethylene vinyl alcohol (EVOH).

Mobius® 3D Large Liquid Transportation Systems

Our Mobius® 3D Large Liquid Transportation Systems consist of standard bulk liquid bags protected by outer containers. They are intended for shipment of bulk sterile liquid product (media, buffers, in-process intermediates, and final bulk drug product) by road or air locally or globally, or even within a facility.

- Four single-use bag assembly options with working volumes of 100, 200, 500 and 1,000 liters.
- Two connector options: Lynx® sterile connector or a general non-aseptic connector
- Bags are constructed using our robust PureFlex™ Plus film, which demonstrates a very low extractables profile when tested according to BPOG guidelines.

Mobius® flexible packaging



MOBIUS® MY WAY

The Mobius® MyWay Portfolio: Customizable single-use packaging solutions that are ready when you are

Our single-use packaging solutions provide the flexibility and speed you need. Choose from three options that range from off-the-shelf to highly customized solutions. For more information, visit [MerckMillipore.com/singleuse-myway](https://www.MerckMillipore.com/singleuse-myway)

Recycle, reuse, and store your rigid outer containers

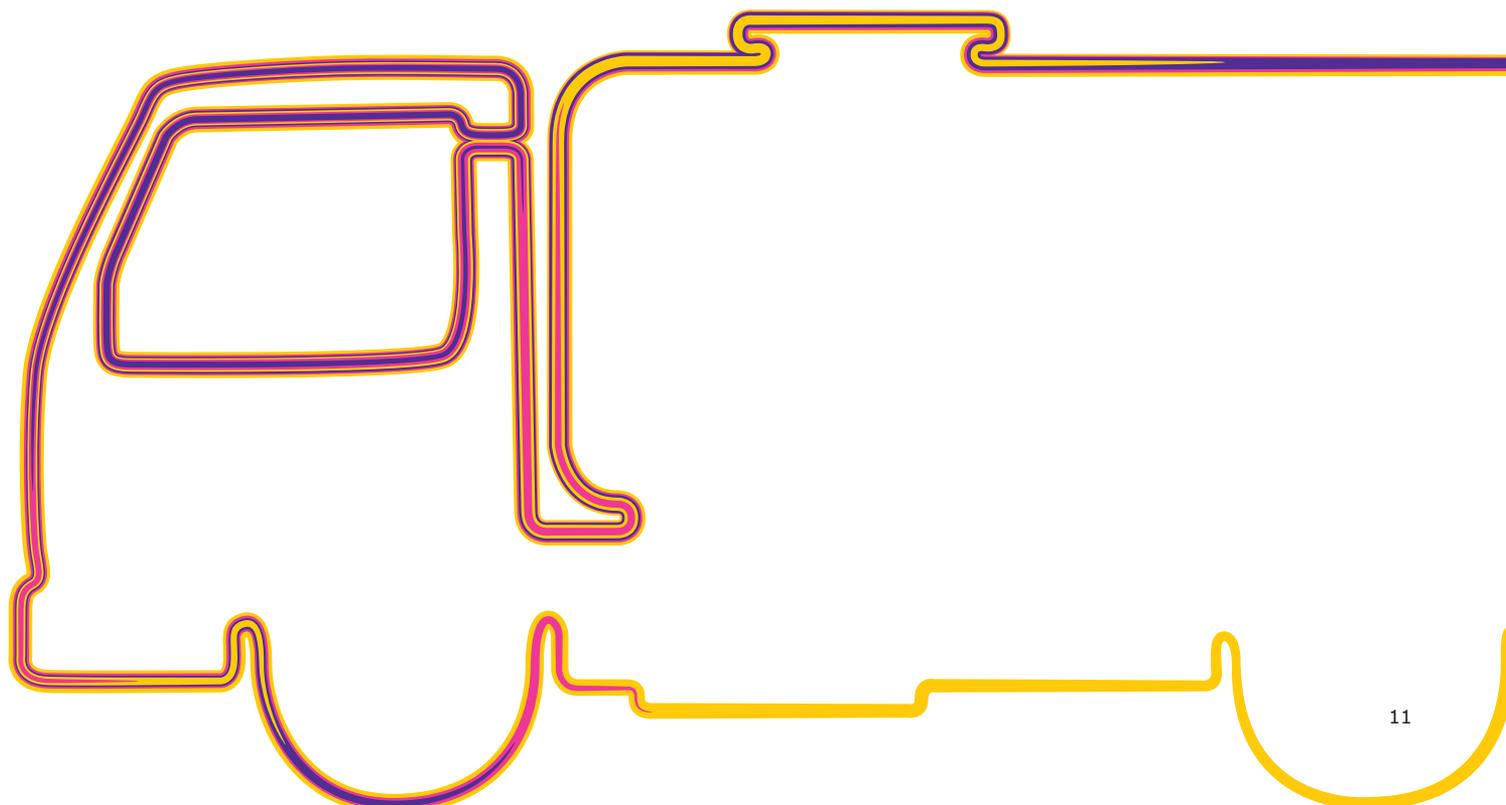
All of our rigid outer containers that have qualified for use as secondary packaging and transport of bulk liquid are recyclable and/or returnable. You can schedule the return of 200 L, 500 L and 1000 L containers. 200 L and smaller containers are available as one-way shipping options, in drums.

Reducing waste in your supply chain improves cost efficiencies, promotes a cleaner environment, and helps to meet customer demand for sustainable products and services.

Each of our containers is individually bar coded. We own our fleet and manage the cleaning and recycling of returnable outer containers (ROCs).

Our containers provide you with complete flexibility and control:

- Track the number of uses for each container
- Contract for customer ownership
- Identify specific lots
- Establish and track clean-in-place protocols
- Control storage
- Simplify ongoing large-volume supply





To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645	Spain: 901 516 645 Option 1
Germany: 069 86798021	Switzerland: 0848 645 645
Italy: 848 845 645	United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

For Technical Service visit: [MerckMillipore.com/techservice](https://www.MerckMillipore.com/techservice)

[MerckMillipore.com](https://www.MerckMillipore.com)

