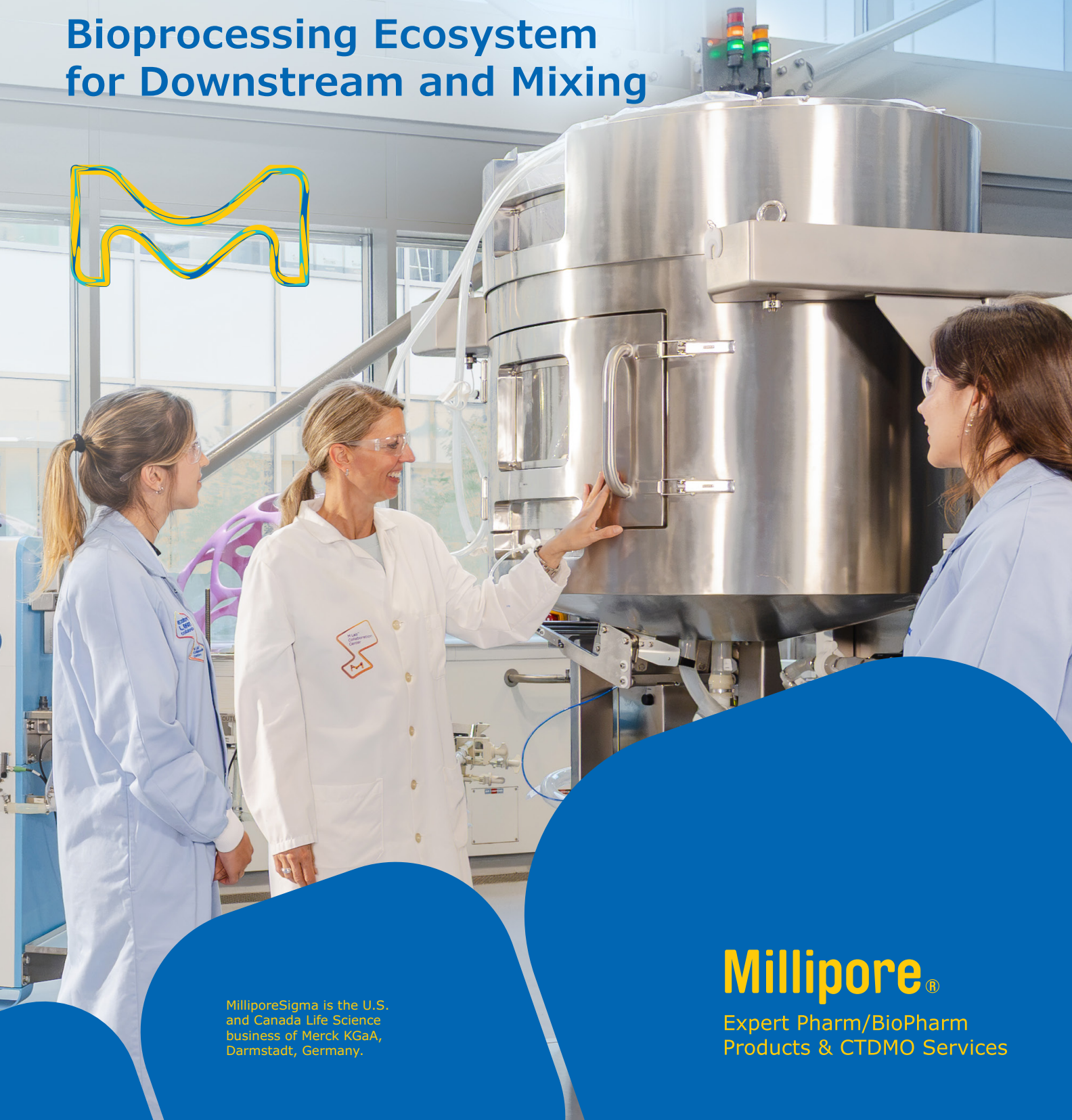


FROM FACILITY CONCEPT TO MANUFACTURING:

Bioprocessing Ecosystem
for Downstream and Mixing



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

Millipore®

Expert Pharm/BioPharm
Products & CTDMO Services

Future-ready

Our bioprocessing ecosystem accelerates your transition from facility concept to manufacturing with process development expertise, engineering support, and scalable single-use solutions backed by data analytics and automation.



Explore our ecosystem

**SigmaAldrich.com/
Flexible-Biomanufacturing**



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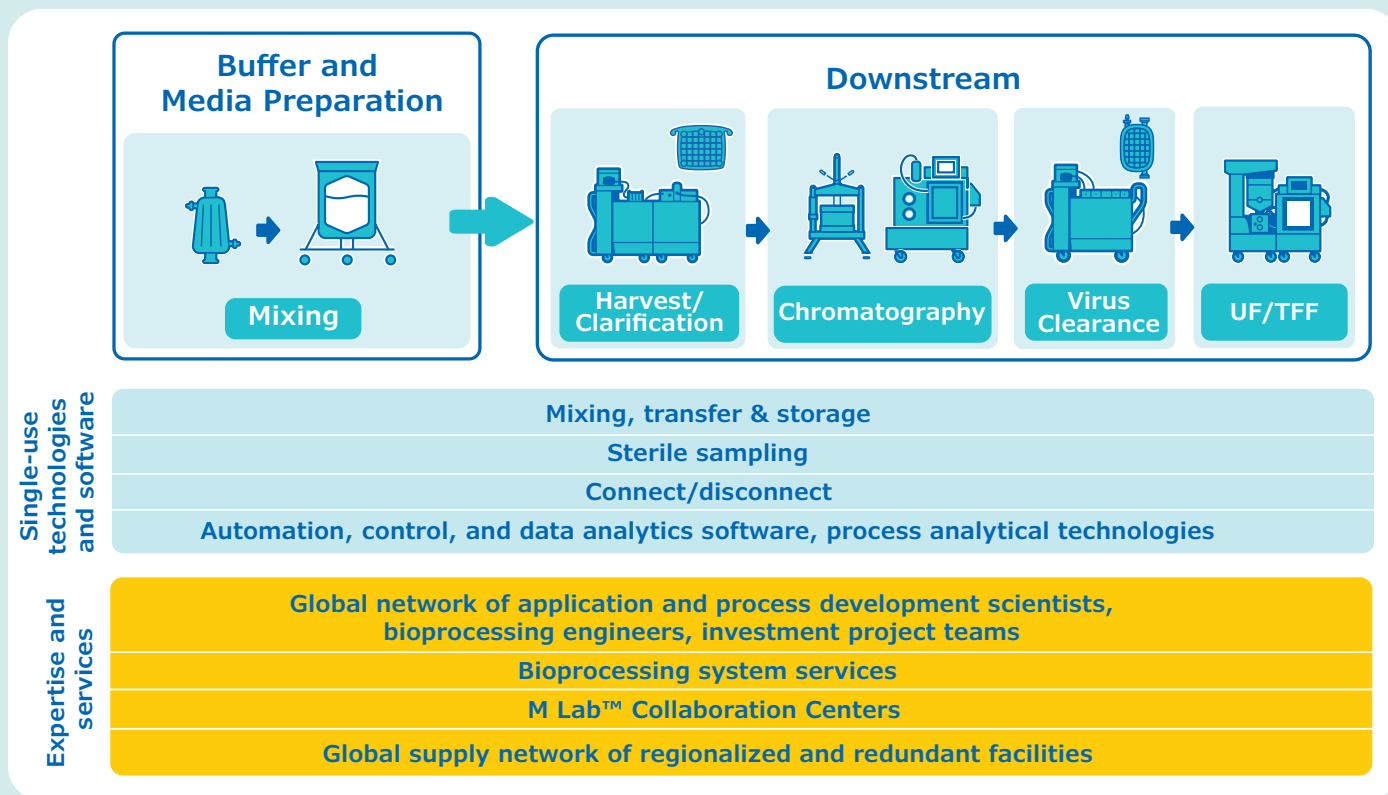
Building Flexible Manufacturing

You're accelerating capital investments to expand and modernize your plant capacity, build new capabilities, and implement future-ready technologies for drug manufacturing.

As you navigate complex investment projects spanning facility concept design, User Requirement Specifications (URS) development, and implementation, you need to ensure your production capacities are flexible enough to meet change in demand.

Successful investment projects, large and small, require multidisciplinary expertise across process development, project management, manufacturing, automation, and validation.

Whatever your molecule or project scope, our experts support you along the way.



Our bioprocessing ecosystem is designed to simplify facility design, equipment selection, and qualification. It is comprised of:

- Full support from our process development scientists, bioprocessing engineers, and investment project teams
- M Lab™ Collaboration Centers where you can solve your toughest development and manufacturing challenges
- A scalable, connected downstream suite of single-use systems and consumables, installation and qualification services, backed by data analytics, automation and control software
- Global supply network of regionalized and redundant facilities to enhance supply resilience

Global Network of Process Development Scientists and Bioprocessing Engineers



Come to our M Lab™ Collaboration Centers where you can explore ideas, learn innovative techniques, and work side by side with our global network of more than 140 scientists, engineers, and technicians including process development scientists, biomanufacturing engineers, and systems process engineers.

Explore M Lab™ Collaboration Centers

A global network to solve your critical bioprocess development and manufacturing challenges, offering you the flexibility to troubleshoot and test without impacting your production line, supporting you from facility planning through commercial manufacturing.

Whether you're developing a novel molecule or reimagining an established production strategy, our experts provide you with best practices and optimize your scale-up approach. We also help upskill your bioprocess team through in-person, livestream, and e-learning formats.

Managing complex biopharmaceutical investment projects?

Our Investment Projects Team partners with you from concept through execution to deliver tailored, end-to-end single-use and integrated platform solutions. We act as your main point of contact to coordinate multidisciplinary teams, ensuring a unified and smooth process from facility design to implementation.

Bioprocessing Services

Maintain your validated system performance.

Our suite of services provides you with support through all stages of your system's life cycle, from installation, qualification, to the training and maintenance needed to keep your equipment running.

All our services are performed by our global experts who have a unique, in-depth knowledge of our equipment, backed by years of experience.

1

Installation and qualification services

- Factory Acceptance Testing (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

2

Specialized services

- Application support
- CCP® software recipe design
- Gradient testing

3

Operator training

- Hands-on and virtual sessions
- CCP® software training

4

System Service Reliance Plans

- Preventive maintenance
- Remote and on-site troubleshooting
- Spare parts



Harvest/Clarification

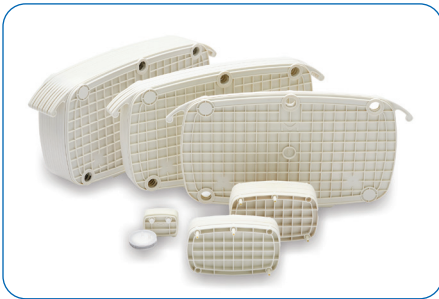
With more than 50 years of clarification experience, we help you improve your productivity and process efficiency with our easy-to-use single-use technologies.



Mobius® Solution for Clarification at Large Scale

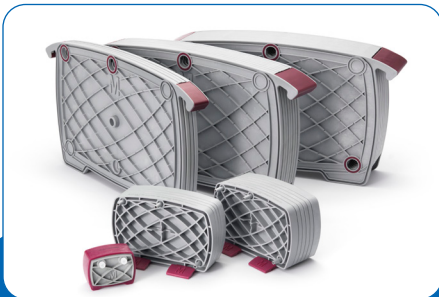
Consists of single-use Flexware® assemblies specifically designed for the process step, innovative separation devices, and process-ready hardware systems to deliver optimal operational flexibility, from clinical production to full-scale commercial manufacturing.

Also available as fully automated system.



Millistak+® Pod Disposable Depth Filters

The industry standard for the clarification of mAb, recombinant protein and other therapeutics. Ideally suited for primary and secondary clarification applications, these disposable depth filters offer flexibility and ease of use through their unique modular design.



Clarisolve® Disposable Depth Filters

A fast and efficient way to clarify challenging, high density cell culture feed streams that require pre-treatment.



Our systems come with CCP® software, that provides robust control and monitoring of bioprocess unit operations. The software automates manual tasks, supplies advanced process control, and facilitates regulatory compliance.



A wide range of our filters and chromatography resins & membranes come with Emprove® dossiers, providing you with comprehensive documentation including the supply, technical, and regulatory information you need to facilitate your risk assessment and regulatory compliance.

Chromatography

Scalable single-use chromatography systems, and a large portfolio of columns, resins, and membranes meet your purification and process efficiency needs.



Mobius® Chrom Systems

A flexible, automated, single-use chromatography solution that enables consistent and reliable separation and purification of mAbs, vaccines, plasma, and therapeutic proteins at clinical and process scales.

The system delivers optimal operational flexibility for processes from 50 to 2,000 L. Its single-use flow path offers the flexibility to operate in functionally or fully closed mode.



Mobius® Multi Column Capture System

A fully automated, single-use solution to operate continuous closed capture chromatography. It manages process parameters in real time. Coupled with an in-line dilution capability and intuitive software, the 3 columns system allows complete control of the capture step of your fed-batch or perfusion process. It is suitable for bioreactor volumes ranging from 50 L to 2,000 L.



Columns

Critical to the successful separation of your valuable molecules, our columns range from lab scale to pilot and process scale, delivering robust and consistent performance with the processing flexibility you need.



Resins and Membranes

We offer a comprehensive portfolio of chromatography resins and membranes to help you increase productivity and process efficiency for affinity, ion exchange, reversed phase/normal phase, and size exclusion chromatography.

Virus Clearance

For over 30 years our application, process development, and virology experts have addressed your regulatory, filtration, and scale-up needs. We can support every phase of your viral clearance strategy and implementation, reducing uncertainty and supporting operator's confidence.



Mobius® Solution for Virus Filtration at Large Scale

An easy-to-use system featuring an optimized single-use flow path designed to fully support your virus filtration needs.

Also available as fully automated system.



Viresolve® Pro Solution

The combination of a Viresolve® Pro Shield in-line with a Viresolve® Pro device enables increased process robustness and high productivity while maintaining high parvovirus LRV, capacity, and flux.



Our systems come with CCP® software, that provides robust control and monitoring of bioprocess unit operations.

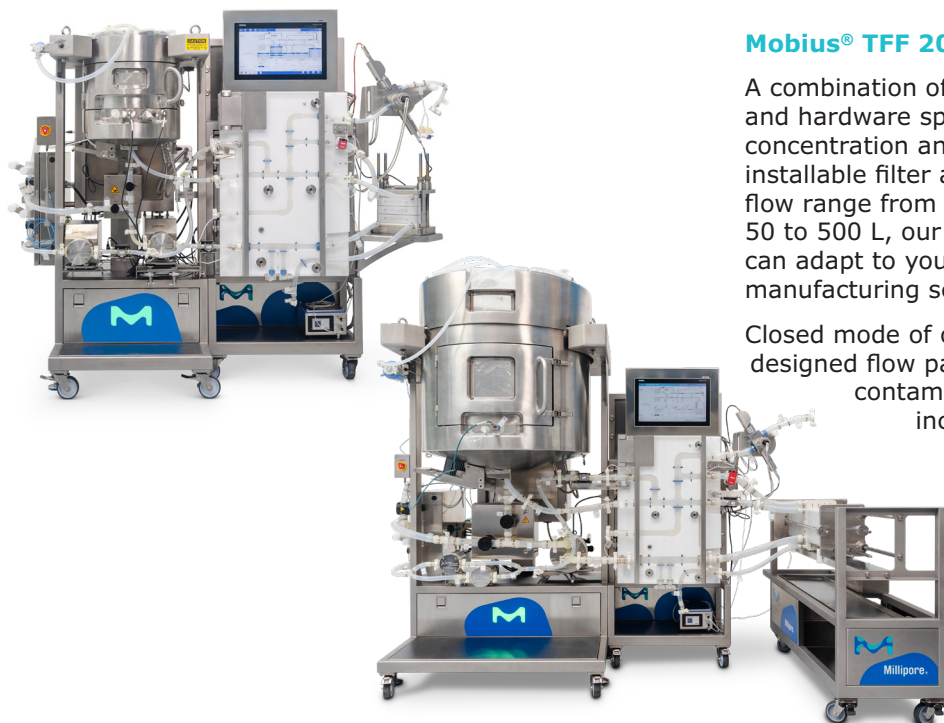
The software automates manual tasks, supplies advanced process control, and facilitates regulatory compliance.



A wide range of our filters come with Emprove® dossiers, providing you with comprehensive documentation including the supply, technical, and regulatory information you need to facilitate your risk assessment and regulatory compliance.

Tangential Flow Filtration (TFF)

For more than 60 years, Pellicon® cassettes and capsules, and single-use UF/DF systems have consistently and reliably delivered purity assurance at every stage of your drug development and manufacturing process.



Mobius® TFF 20 and Mobius® TFF 80 Systems

A combination of single-use Flexware® assemblies and hardware specifically designed for efficient concentration and diafiltration of proteins. With installable filter area ranging from 0.5 to 20 m², flow range from 2 to 80 L/min, and tank size from 50 to 500 L, our range of single-use TFF systems can adapt to your process needs from pre-clinical to manufacturing scale.

Closed mode of operation is possible with specifically designed flow path, allowing you to reduce contamination risk and protect operators while increasing flexibility and efficiency.



Pellicon® 3 Cassettes

Recommended for the most demanding ultrafiltration processes, Pellicon® 3 cassettes consistently deliver high protein yield, flux, and product quality.



Pellicon® Capsules

Single-use TFF devices featuring Ultracel® membrane, optimized for efficient concentration and purification of biologics like antibodies, viral vectors, and ADCs while minimizing contamination risks.

Designed for faster, smarter bioprocessing, they offer plug-and-play, high-yield filtration with superior flux and scalability, enabling rapid setup and seamless process integration.

Bioconjugation

Single-use technologies enhance the efficiency and scalability of the conjugation step, offering greater process flexibility and reducing cross-contamination risks.

Mobius® ADC Reactor

- Available in 10 L, 100 L, and 500 L sizes from process development to large-scale manufacturing
- Proven compatibility and resistance to solvents such as DMAc and DMSO for uncompromised product quality, elimination of cross-contamination concerns, and toxic waste streams reduction
- Uncompromised safety with a bag made of robust components and film, and addition ports for tailored material configuration

A scalable family of single-use mixing systems perfected for bioconjugation



Evaluate chemical compatibility!

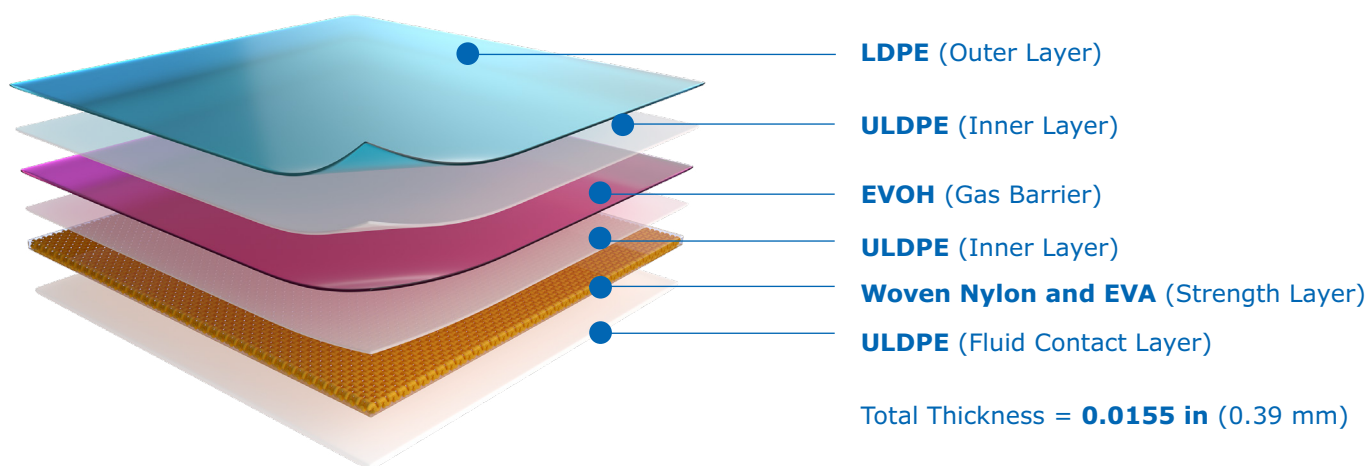
Read our study about the physical compatibility of single-use components in the Mobius® ADC Reactor and the level of extractables when exposed to dimethyl sulfoxide (DMSO) and dimethyl acetamide (DMAc).

[SigmaAldrich.com/chemicalcompatibility](https://www.sigmaaldrich.com/chemicalcompatibility)



Film Technology

Safe, ergonomic, and flexible films for a wide range of bioprocessing applications, or the most demanding manufacturing environments. Both films share the same fluid contact layer, enabling straightforward qualification transitions.

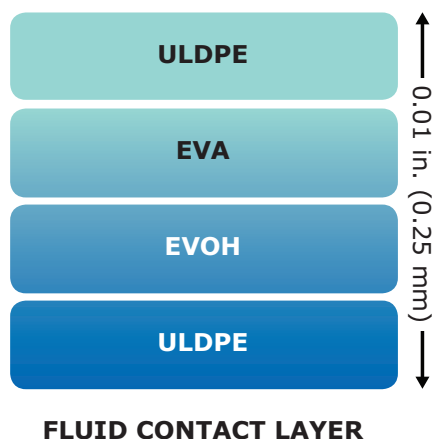


Made with a proprietary woven nylon structure, Ultimus® film demonstrates superior strength and resilience to protect against leaks, abrasions, tears, and material fatigue.

Fluid contact layer is free of animal origin components.

Ultimus® Film

Designed for challenging, high-value, single-use bioprocessing liquid applications, Ultimus® film delivers increased durability for leak-proof storage and transport, and enables easy handling, flexibility and conformity for different bioprocessing demands. It is the foundation of our Mobius® 3D bag assemblies for storage and mixing, ensuring consistent performance across your entire single-use process train.



PureFlex™ Film

High-purity, medical grade, co-extruded film designed with low gas permeability and an inert product contact layer. It is used to construct our Mobius® single-use assemblies and NovaSeptum® sampling bags and enable you to scale your process with a single fluid contact material.

Fluid Management

Lynx® Connectors

Reliable and easy to use, the unique design of Lynx® sterile connectors enables risk-free fluid transfer. Available in a wide range of sizes and configurations.



NovaSeptum® Sterile Sampling Solutions

Enable you to manually sample throughout your drug manufacturing to monitor both your product quality and process control. These sampling solutions are suitable for every process step, for both multi-use and single-use processes.



Our single-use assemblies, connectors, and sampling solutions are covered under the Emprove® Program which supports your risk assessment and management efforts with online access to regulatory information and comprehensive documentation.

Buffer preparation is one of the largest footprint and capital cost drivers in downstream, while media preparation can represent a similar footprint and capital cost burden in upstream. Our scalable, ready-to-use mixers are available from 10 L to 3,000 L and can be used throughout your process, including buffer & media preparation and process intermediates.



Mobius® MIX

For gentle mixing applications such as protein and shear-sensitive product homogenization

- Available in 10 L, 50 L, 100 L, 200 L, 500 L, and 1,000 L sizes (jacketed stainless steel or plastic depending on size)
- Fast, easy setup and use
- Compact footprint and mobile carrier construction for enhanced flexibility
- Instant-on electronics with no warmup needed



Mobius® Power MIX

For hard-to-dissolve materials and buffer preparation

- Available in 100 L, 200 L, 500 L, 1,000 L, 2,000 L, 2,500 L, and 3,000 L (jacketed stainless steel or plastic depending on size)
- Stainless steel versions have wide doors for easy bag loading
- Optional integrated load cells and temperature sensor on stainless steel versions



Mobius® 2D and 3D Assemblies

For safe and efficient fluid management

- Provide efficient and scalable bioprocessing fluid management solutions, from media and buffer preparation to process intermediates storage and transfer
- A full spectrum of standard and custom solutions available across varying certification levels
- Designed to reduce operator error and process risks while improving efficiency



In addition to standard Emprove® dossiers, the on-demand Advanced Qualification Dossier (AQD) provides all the qualification information (including extensive USP <665> extractables data) to expedite the risk assessment and patient safety evaluation for each specific Mobius® Assembly.

Data Analytics Software

Data analytics software helps biopharma manufacturers improve process understanding and make more informed, data-driven decisions. Our platform combines process analytics, visualization, monitoring, and reporting to improve reproducibility, reduce manual effort, and support regulatory compliance.

Bio4C ProcessPad™ software

A data collection, visualization, and analytics platform for bioprocess monitoring, reporting, investigations that automates continued process verification (CPV) regulatory activities.

- **Data aggregation**

Automatically aggregates manual records, spreadsheets, batch records, QC data, LIMS, QMS, MES, historians, and machine data into a single, contextualized, analysis-ready format

- **Advanced data analytics**

Multivariate data analysis (MVDA) enables proactive, real-time monitoring, control, and predictions of quality and productivity

- **Regulatory compliance**

Facilitates compliance for electronic records and signatures, and data integrity through access control, immutable audit trails, and electronic backups; automates APQR and CPV reporting and activities

Intuitive Analytics and Visualizations

Regionalized Single-Use Supply Chain

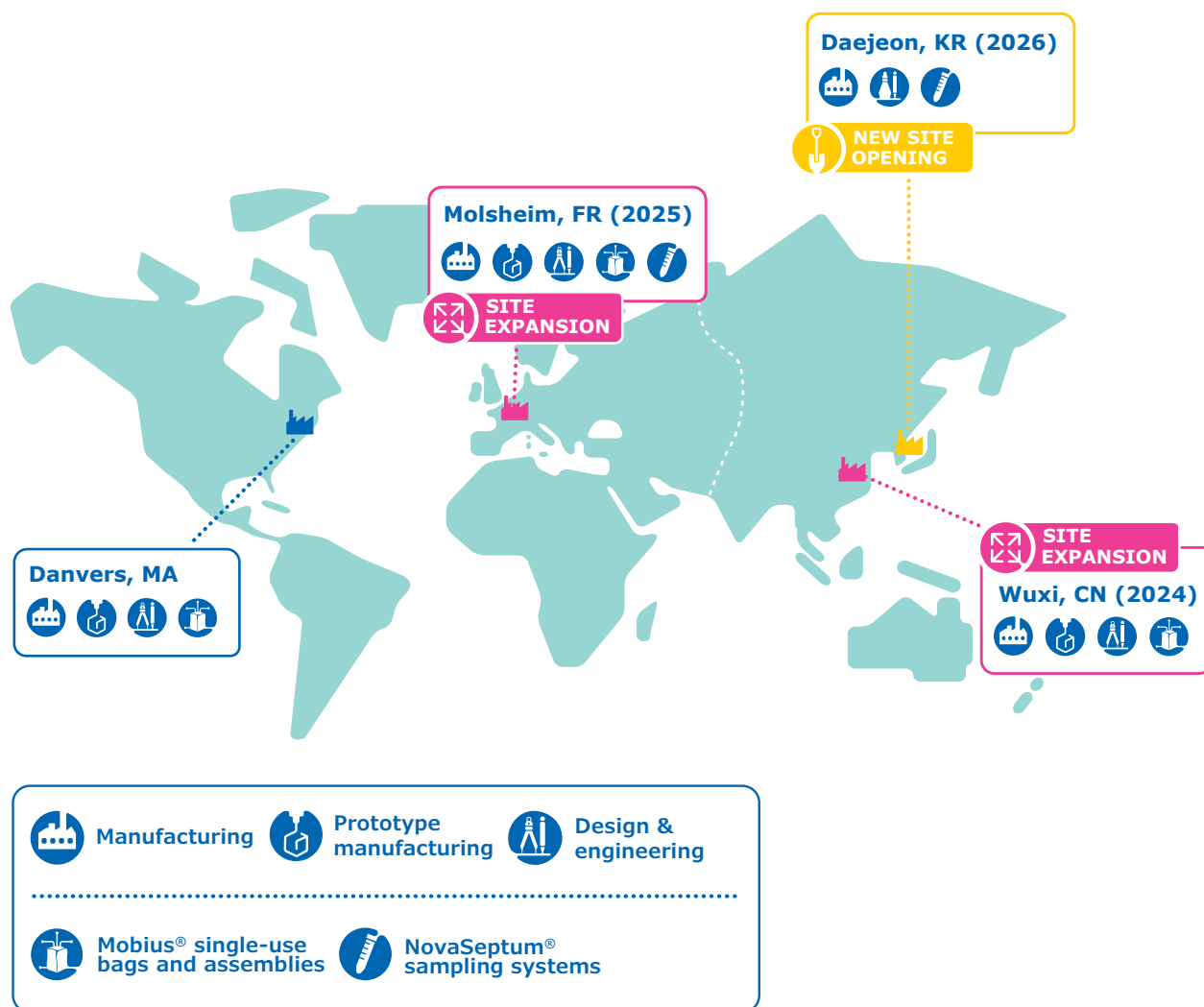
In our global-local hybrid model, global oversight meets regionalized manufacturing to provide supply resilience and reliability. We're strengthening our agility and improving flexibility by increasing our in-region for-region production capabilities across the globe. In addition to our existing site in Danvers, USA, we're expanding our sites in Molsheim, France, Wuxi, China and opening soon a new facility in Daejeon, South Korea.

By expanding existing and building new manufacturing sites, we're providing critical supply redundancy for our customers. We're going a step further, reducing risk in our raw material supply chains by partnering with current suppliers to diversify and regionalize raw materials sourcing, qualifying additional local raw material suppliers to enhance resilience through dual sourcing, and increasing safety stocks to improve supply robustness.



Learn more

[SigmaAldrich.com/
singleusenetwork](https://SigmaAldrich.com/singleusenetwork)

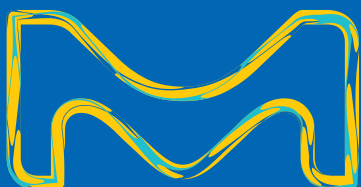


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Burlington, MA 01803

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For local contact information:
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To learn more about our
support from facility
design to implementation
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We have built a unique collection of life science brands with
unrivalled experience in supporting your scientific advancements.

Millipore® Sigma-Aldrich® Supelco® Milli-Q® SAFC® BioReliance®

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