Mobius® Bioreactors
A scalable ergonomic system with the flexibility to fit your process

Mobius® Bioreactors are a scalable portfolio of stirred tank bioreactors that provide flexibility by configuring software, hardware, and single-use assemblies for use in suspension and adherent cell culture applications.

Our bioreactor platform has been designed to ensure that ease-of-use and operational flexibility at small scale can be translated to full scale production.

Benefits
- Installation of single-use assemblies designed with you in mind for safe and repeatable operation
- 5:1 turndown ratio provides you with the most flexible seeding and growth strategy
- Works as a standalone system or integrated as part of your facility’s automation platform
- Demonstrated scalability of key engineering parameters gives you confidence to scale up your process
- Lynx® Connectors assure a critical sterile connection
Mobius® Bioreactors follow a Quality-by-Design approach, providing end-users with a clear characterization of key engineering parameters including power input per volume, mixing time, oxygen transfer capabilities and temperature mapping across all scales of the portfolio.

Our characterization of the key engineering parameters, coupled with consistent scaling ratios, give you confidence that this system will match your process needs for adherent or suspension cell culture.

Each Mobius® Bioreactor is characterized at the minimum (20%) and maximum (100%) working volumes from 1 - 2000 L providing true operational flexibility needed from laboratory to production scale.

Intuitive, ergonomic operations

Mobius® Bioreactors have been designed to provide intuitive and ergonomic operator interactions that simplify workflows at all scales. Each system is comprised of a vessel, Flexware® assemblies and a control box containing mass-flow controllers (MFCs), pumps, a human machine interface (HMI) and optional Common Control Platform® (CCP®) software.

The 50, 200 and 2000 L Mobius® Bioreactors are all fully jacketed to optimize heating and cooling steps. All systems have doors and viewing windows, providing easy access to expendables and visibility on the status of the working volume and mixing steps. Additionally, they all have integrated load cells for precise volume monitoring and a 2:1 aspect ratio.

Full scale production with an innovative twist

Since handling single-use assemblies above 1000 L can be cumbersome, the 2000 L bioreactor has additional features that optimize the experience for the operator including a vessel drawer, allowing the easy installation and removal of Flexware® assemblies. With the ability to self-deploy and self-deflate using air, the EZ-Fold feature of the Flexware® assembly assures ease-of-use and safety for the operator.

In the absence of a baffle, a bottom mounted impeller can result in the formation of a vortex during mixing. The presence of a vortex, especially at the large scale, can result in zones that are not completely mixed. To overcome this issue, the Mobius® Bioreactor benefits from an internal baffle resulting in homogeneous mixing in under a minute at low power input.

In addition, the bottom mounted impeller maintains gentle agitation during the clarification step down to the minimum working volume without generating foaming and reducing the time by delivering a consistent harvest to your clarification system. Dual sparger options, microsparger and open pipe, provide process flexibility. The microsparger is located directly under the impeller to promote the dispersion of bubbles and provide maximum mass transfer of oxygen (kLa). The open pipe, located adjacent to the impeller, is efficient at delivering macro-bubbles. It can be used on its own or in combination with the microsparger to provide increased process control capabilities such as macro-bubble oxygen delivery, addition of carbon dioxide for pH regulation or as a tool to strip carbon dioxide.

Temperature management is another critical requirement for successful cell culture. Temperature profiles of our Mobius® Bioreactors have been fully characterized at minimum and maximum working volumes to give you confidence that your process can be controlled during all steps of the cell culture run.

Consistent process engineering characteristics that provide easy and reliable scale up
Mobius® 2,000 L Hardware

Ergonomic Design

- Door for visual monitoring of the culture
- Jacketed vessel for optimal heat transfer
- Protected support for Mobius® SensorReady Loop
- Integrated automation including MFC’s, pumps and software
- Vent filter heaters
- Tubing management system
- Drawer for easy Flexware® assembly, installation and removal
Common Control Platform® (CCP®) software for multiple unit operations

From Mobius® Bioreactors to clarification, chromatography, tangential flow filtration and virus filtration, CCP® software can provide you with one familiar interface that simplifies software management and reduces the learning curves of new operators. This software package is available to support all application sizes, accelerating tech transfer and scale up of your process.

Optimized for Cell Culture

The user interface, common across multiple unit operations, brings our process know-how into your hands. The home screen is optimized for the Cell Culture unit operation with easy access to all of the relevant information needed to control your process. Procedures can be automated into recipes, and operators can adjust and optimize control loops in just a couple of clicks.

Monitors processes and enables batch reporting

Create process operations using the recipe editor, monitor the process in the home screen, and create reports for the batch using the configurable report generator.

Comprehensive and secure data acquisition

21 CFR Part 11 compliance-ready and developed under GAMP5 guidelines, the software includes an accessible audit trail and electronic signatures for verification. CCP® software is designed for development to large-scale manufacturing equipment, and uses industrial computers and controllers for reliability.

Network Integration

Data transfer to the plant control system or historian enables data collected by CCP® software to be centrally stored and managed.

Backup and restoration

Backup and restoration of data can also be managed via network integration.

Security synchronization

Security synchronization allows user accounts to automatically coordinate with the networked plant control system for faster and simpler user account control and editing.
Innovative and flexible process monitoring

The Mobius® SensorReady technology is used to monitor and control all sizes of Mobius® Bioreactors, providing you with absolute confidence in the reliability of your control strategy. The Mobius® SensorReady assembly is attached via a sterile connection to the bioreactor using Lynx® S2S Connectors. The modular, easy to operate design provides the user with ultimate flexibility to monitor and control the bioreactor processes, allowing users to incorporate new sensing technologies as they become available without changing the design of the Flexware® assembly.

Extensive characterization has been performed to demonstrate that the readings in the Mobius® SensorReady loop are representative of the bulk cell culture environment.

Flexware® Assemblies

Flexware® assemblies are designed for maximum operational flexibility, ergonomic usability and operational safety. All sizes of the Flexware® assemblies have an off-centered bottom mounted magnetic levitating impeller with internal baffles, a turndown ratio of 5:1, and integrated pressure sensors with lines for primary and backup vent filter assemblies comprised of the hydrophobic Opticap® XL5 capsule with Aervent® membrane to prevent overpressuring the assembly.

The 50 L and 200 L bioreactors are constructed of Pureflex® film. At 2000 L volumes, Pureflex® Plus film is employed for added robustness. The two films have identical product contact layers, maintaining consistent extractables profile and gas barrier properties.

To improve operational safety and ease-of-use, all weldable tubes are labelled for easy identification and all assemblies have a unique layout ensuring correct fit in the jacketed vessel. The 50 L and 200 L Flexware® assemblies have rigid bases that make installation safe and easy, minimizing any chance of stretching, tearing or damage to the Flexware® assembly. The 2000 L Flexware® assemblies feature EZ-fold technology, which allows for automatic deployment utilizing the on-board MFC’s. The Flexware® assemblies provide two sparging options using either open pipe or Microsparger (Tyvek® with grid).
Comprehensive services and support

Provantage® Implementation Services approach

Provantage® Implementation services for Mobius® Bioreactors are tailored to solving your challenges, saving you significant time. Our approach revolves around your specific needs and requirements so that we can best address your concerns.

To help us understand your specific needs, we will send you an application questionnaire that will inquire about your process requirements. Once we receive the completed questionnaire, we will send you the appropriate protocols for your qualification service.

Our team of experts will meet your team so that together we can determine who will be servicing your product on-site. In addition, we will send you a letter prior to the service, listing all of the tools, materials and expendables you will need to prepare before our engineer arrives. Once the implementation service has been performed, our engineer will create a report for your approval and signature.

Comprehensive range of value-added services

All of our Provantage® services include a team of experienced engineers who are personally committed to ensuring your processing success and will partner with you to overcome any challenge.

Site acceptance test, installation and operational qualification (SAT, IQ/OQ)

Our pre-written service protocols contain procedure and acceptance criteria to ensure your Mobius® Bioreactor is fully operational and easily validated on site. Completing IQ/OQ with our service protocols ensures your system will function as specified in cGMP environments.

The support includes one on-site visit by a qualified field service engineer to perform the Site Acceptance Test, Installation and Operational Qualification Protocol in compliance with cGMP regulations, and verification of:

- System documentation and identification
- Instrument and component installation
- Electrical and pneumatic specifications
- Instrument transmitter and converter settings
- Software and pump frequency drivers

In addition, all of the controllers, alarms, graphical interfaces, critical alarms, minimum/maximum flow rates of the pumps and MFCs are verified and tested.

As a pre-requisite to the SAT, IQ/OQ service, our field service engineers can install and start the system, as well as run tests.
Operator training

Designed for pharmaceutical and biotechnology, manufacturing personnel who operate upstream processing equipment, our interactive course provides an overview of the Mobius® Bioreactors. Installation of Flexware® assemblies and upstream CCP® software use are also described and practiced in hands-on sessions. To satisfy cGMP requirements, course graduates will receive a certificate upon completion.

With us as your guide, your operators will be better prepared to operate and manage your Mobius® Bioreactors with greater confidence.

CCP® Software recipe design

Every process is unique and to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will translate your process into your own CCP® software recipe in order to maximize the performance of your bioreactor system within your process.

CCP® Software training

If your system will be used in process development and needs to adapt to varying process characteristics, our biomanufacturing engineers can also provide you with a specific training, including a hands-on session so that you are able to create and manage your own recipes and system.

Support for performance qualification

Performing the qualification of your whole process with new equipment can be challenging. To help with this step, our biomanufacturing engineers can assist you with targeted advice, in order to allow you to focus on your own process.

The support includes one on-site visit by a trained biomanufacturing engineer to assist you while you perform your qualification, preparation of the equipment, dry run your process recipe, and support for real run during the qualification, for which you will remain the owner.

Preventative Maintenance

Preventative maintenance delivers the most cost effective approach to ensure consistent reliable performance of your Mobius® Bioreactor. Regularly scheduled maintenance of your Mobius® Bioreactor significantly reduces potential downtime and costly repair.

Services packages

We offer a wide range of comprehensive packages to meet your unique manufacturing requirements, resulting in peace of mind and maximum operational flexibility.

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Full cGMP Package is designed for 2 to 4 attendees at manufacturing site and delivered by a qualified Field Service Engineer and/or a Biomanufacturing Science Engineer. Upon completion a Certificate of Achievement will be delivered.
Cell culture media
When you choose us as your cell culture media supplier, you benefit from optimized media formulations, high-quality raw materials, consistent, homogeneous deliveries, and documentation for faster time to market.

Cellvento® CHO medi platform for top performance in cell culture
Our Cellvento® CHO platform provides you with process and cell line specific cell culture media and feeds – so that you can find the most suitable product for your application.

Benefits
- High media consistency and reliable homogeneity
- Superior cell growth and productivity
- Flexibility on specific nutrient cell type requirements
- Flexibility in application: batch, fed-batch and perfusion
- Comprehensive documentation for faster time to market

Customized cell culture media
With our extensive in-house formulation knowledge, we are able to design reliable, robust media for your specific processes according to your recipe and create innovative solutions that can enhance the consistency and efficiency of your processes.

Our cGMP facility enables smooth transitions from pilot to commercial-scale cell culture production. We also apply our resources to assist you in troubleshooting and optimizing your media and processes.

Regulatory support and documentation
To facilitate full traceability, our raw materials are subjected to a defined qualification process before being released as suitable for cell culture media production. All materials are carefully screened and selected to confirm their non-animal origin. We also provide comprehensive regulatory information on the manufacture, characterization and control of our cell culture products.

Related resources
Mobius® Bioreactors Specification & Ordering Information Sheet, SP1237EN00

For more information on Mobius® Bioreactors including additional documentation, videos and animations, please visit

www.merckmillipore.com/bioreactor

To place an order or receive technical assistance
In Europe, please call Customer Service:
France: 0825 045 645
Germany: 069 867 98021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

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