

МУЛЬТИКОЛОННЫЕ СИСТЕМЫ ПОДАЧИ MOBIUS MULTI COLUMN



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Mobius® Multi Column Capture System

A fully automated, simple, and flexible single-use solution for intensified and continuous chromatography, enabling increased throughput while reducing manufacturing costs

In traditional capture chromatography, the resin is only utilized up to 60–70% of its capacity to minimize potential product loss. Continuous capture chromatography allows for improved resin capacity, through continuous loading of multiple columns in series, reducing cost of goods.

The Mobius® Multi Column Capture system is a single-use solution for continuous chromatography, utilizing 3 columns, an intuitive and intelligent software, and standardized Flexware® assemblies that allow you to select whether you want to run chromatography in a closed mode.



Features and benefits:

Robustness

The user-friendly software allows for robust operation with in-process, real-time adaptability to variation in feed concentration and resin performance.

Simplicity

Inline dilution capabilities enhance facility fit by reducing buffer preparation volumes and required operational footprint. Flexware® assemblies installation has been streamlined through color-coding to reduce errors.

Flexibility

Flow rates from 1–120 L/H provide flexibility across scales to enable seamless scale up from early clinical development to commercial manufacturing on a single system. Our offering of Flexware® assembly configurations accommodates different processing modes, reducing contamination and carry-over risks. Flowpaths have been evaluated for continuous processing for up to 20 days prior to exchange.

Expert support

We offer a variety of product services to meet the demands that your work requires. These services include qualification, training, application support, recipe design, spare parts and repair, and System Service Reliance Plans.

System Components

1 concentrate/buffer line and 1 diluent line allowing for dilution of up to 6 buffers.

Optional pre-column filter to protect the column.

2 pre-column sensors (pH and conductivity) and 3 post-column sensors (pH, UV, and conductivity). All instruments are fully single-use. pH probe can be single- or multi-use.

Product and buffer lines running in parallel, allowing to load the product continuously over 20 days.

Select between a Flexware® assembly with TC and CPC® MPC connectors, and a Flexware® assembly with CPC® AsepticQuik® connectors, enabling closed processing.

We offer 3 possible UV configurations:

- 280 nm
- 280–308 nm
- 280–254 nm

and 2 possible optical path length configurations on the Flexware® assembly:

- 1 mm
- 2.5 mm

Pre-packed columns can be placed on the system trolley for further footprint optimization.

Single-use Flexware® Assemblies

The single-use Flexware® assemblies meet the requirements of USP <88> Class VI and are free of animal origin or compliant to EMA/410/01 rev.3., delivering equivalent performance to that of traditional stainless-steel systems, while maximizing system flexibility. These assemblies are also clearly labeled and color-coded, significantly reducing the risk of operator error and the challenges typically associated with installing single-use flowpaths. Our flowpath eliminates moving parts and minimizes dead space, decreasing the risk of contamination.

Closed processing

In addition, we offer a flowpath designed to enable closed processing, providing the necessary segregation from potential contaminating factors present in the environment, thanks to CPC® AsepticQuik® connectors. It prevents contamination while reducing or eliminating reliance on environmental controls, enabling reduced area classification.

Common Control Platform® (CCP®) Software

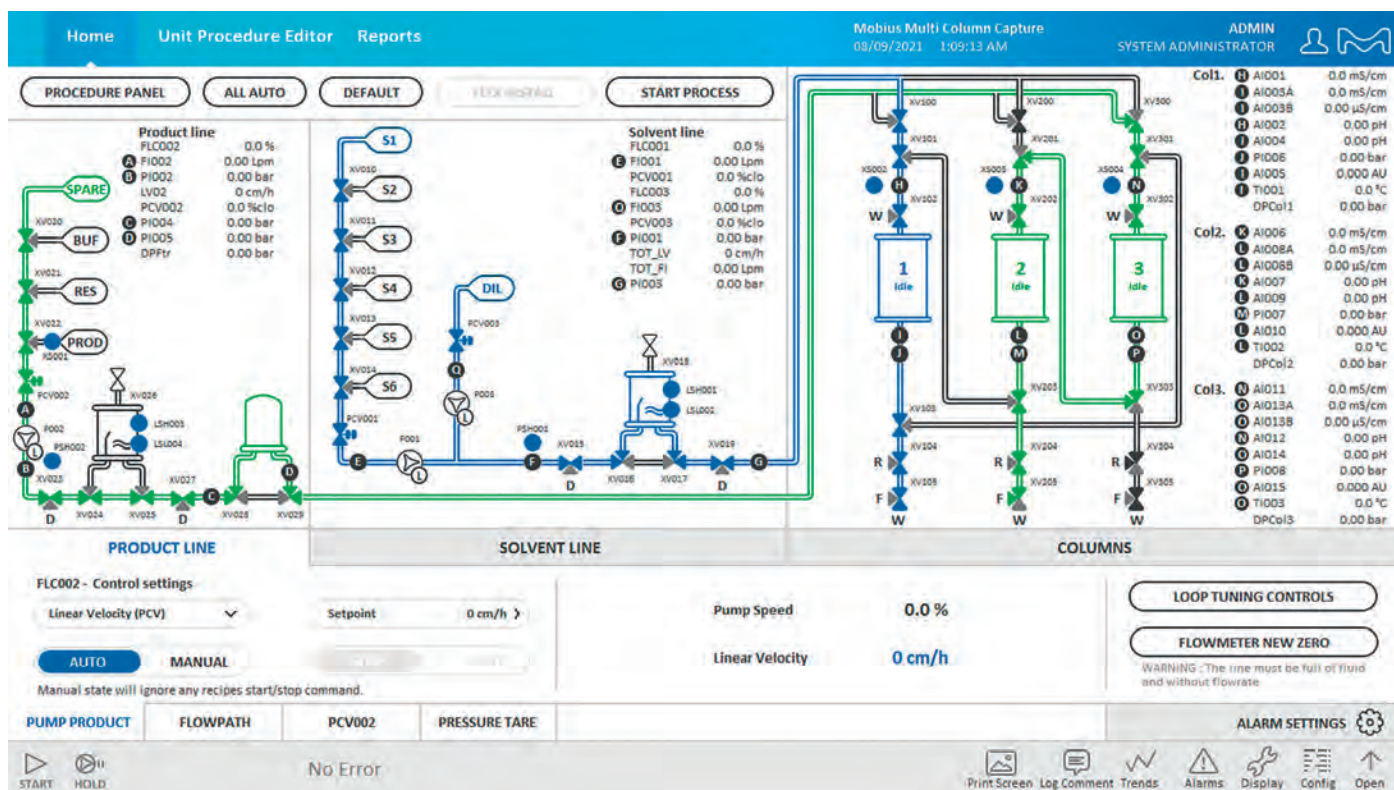
The Common Control Platform® (CCP®) is a powerful automation software with an intuitive graphical interface that provides real-time monitoring and in-depth control of the process.

Each aspect of the process can be monitored and controlled from the home screen through the interactive P&ID. Process operations can be created using the **recipe editor**. There are **pre-defined steps** for continuous chromatography. These, together with

6 programmable phases, make recipe creation very simple. Reports can be easily created using the configurable report generator.

CCP® software is designed for GMP facilities, developed in line with GAMP® 5 recommendations for automation software, and fulfills EU GMP Annex 11 & FDA guideline 21 CFR Part 11 requirements for electronic records and signatures.

Our CCP® software provides one software platform across our portfolio of automated systems for a familiar look and feel at each step of the process.



Related Products to Support your Intensified Chromatography Process

OPUS® Pre-packed Columns

OPUS® pre-packed columns are a convenient and flexible solution suitable for biomanufacturing processes at any stage of development. Ranging in size from 5 cm to 80 cm internal diameter and a bed height from 5 cm to 30 cm configurable to the nearest millimeter, OPUS® GMP columns can handle resin volumes from 0.5 L to 150 L. The Mobius® Multi Column Capture system can accommodate OPUS® columns from 5 cm to 25 cm diameter.



Eshmuno® A Resin

Eshmuno® A affinity chromatography resin has a high dynamic binding capacity for primary mAb capture. The rigid base bead and novel ligand combination is optimized for acid and alkaline resistance for efficient cleaning and sanitization while still maintaining high capacity for improved throughput of processed mAb by resin volume.



QuikScale® Chromatography Columns

Designed to achieve maximized throughput, our QuikScale® columns are easily packed to deliver optimal resolution across a wide range of chromatographic applications, accommodating all media types. The flow distributor assures full, uniform media utilization within the column, assuring reproducible and reliable separations. QuikScale® chromatography columns offer fast packing and unpacking, predictable and scalable performances, and flow adjuster seal technology for fail-safe operation in a choice of column tube materials for any application.



Buffer Concentrates

As a trusted partner in your biopharmaceutical supply chain, we bring together products and services to offer the industry's highest quality sterile liquid capabilities. We manufacture a broad range of ready to use, pre-titrated buffer concentrates, that require minimal adjustment, post dilution. Concentration factors >30x are achievable, allowing for significant reductions in operational footprint.



Mobius® Multi Column Capture System Services

The pharmaceutical and biotechnology industries are highly regulated and, to help you navigate this challenging environment, we offer a wide range of services. These services help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment backed by decades of experience.

Qualification Services

Our qualification services are designed to make the integration of our system into your process as seamless as possible and ensure your equipment is properly installed and functioning per your pre-defined requirements.

- Factory acceptance test (FAT)
- Site acceptance test (SAT) (combined with IQ/OQ)
- Installation qualification/operational qualification (IQ/OQ) (combined with SAT)
- Performance qualification support (PQ)

Training Services

Appropriate training for users is not only a GMP requirement, it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process.

Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money. Our training services cover system use and programming with interactive hands-on sessions and, depending on the training you select, may also include:

- Installing the Flexware® assemblies
- Interacting with the Human Machine Interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

These trainings can be delivered either at your site or in our M Lab™ Collaboration Centers.

Specialized Services

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 configure your process into your own CCP® software recipe. This allows your system to run fully automatically, resulting in consistency and reduced operator error.

Application Support

Our chromatography experts can help you design your process and scale-up, ensuring smooth operations and efficient process.


System Service Reliance Plans

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed a complete range of services for your systems and equipment: System Service Reliance Plans. These comprehensive packages offer priority access to a wide range of services and support, ensuring your equipment is properly maintained and allowing you to select a coverage level that best fits your needs.

Spare parts & Repair Services

Repair services

In the unlikely case your system does experience a problem, our worldwide engineering organization will provide on-site technical support to get you back up and running as quickly as possible.



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