Pionic®

A Modular Platform for Continuous Downstream Biomanufacturing

Simplifying Progress

SARTORIUS

Simplify Progress in Biomanufacturing With Pionic®

Biopharmaceutical manufacturing continues to evolve, placing greater emphasis on efficiency, sustainability, and innovation. This increases pressure to reduce costs and resource use while maintaining yield, quality, and productivity. Despite these pressures, the industry often hesitates to change due to risk aversion stemming from limited data availability, strict approval processes, and product quality concerns.

Modifying existing infrastructure is resource-intensive and presents challenges like operational disruption, scalability, compliance, and safety, which lead to the slow adoption of new technologies. The growing demand for cost-efficient and sustainable solutions is driving the industry toward process intensification and continuous manufacturing. Pionic® is a new intensification platform developed by Sartorius to address these evolving needs.

A modular platform for integrated continuous processing

Pionic® is a modular, ready-for-use platform for chromatography, filtration, viral inactivation, and ultrafiltration | diafiltration (UF | DF) in downstream processes, with a GMP-compliant design suitable for integration into new and existing facilities. The Pionic® platform consists of five modules: Quad, Spin, Dual, Cross, and Flow. Its modular design allows manufacturers to smoothly transition from traditional batch methods to continuous manufacturing, either through stepwise intensification or fully continuous processing, reducing footprint, increasing throughput, and ensuring compliance and connectivity from the start.

Developed in collaboration with leading biomanufacturers and contract development and manufacturing organizations (CDMOs) that also served as early adopters, Pionic® offers an evidence-backed solution with data references that reduce uncertainty and address the real-world needs of the industry.

Pionic® offers a fully automated and orchestrated continuous downstream platform, enhanced by robust analytics for precise process control and real-time monitoring. Automation is central to Pionic®, with the Biobrain® automation platform providing a plug-and-play solution for bioprocessing flexibility. Biobrain® integrates robust industrial hardware and software with fully traceable, flexible configurations, allowing for quick adaptation to evolving process requirements. This approach saves months of engineering and qualification work while significantly reducing the implementation risk associated with adopting new technology.

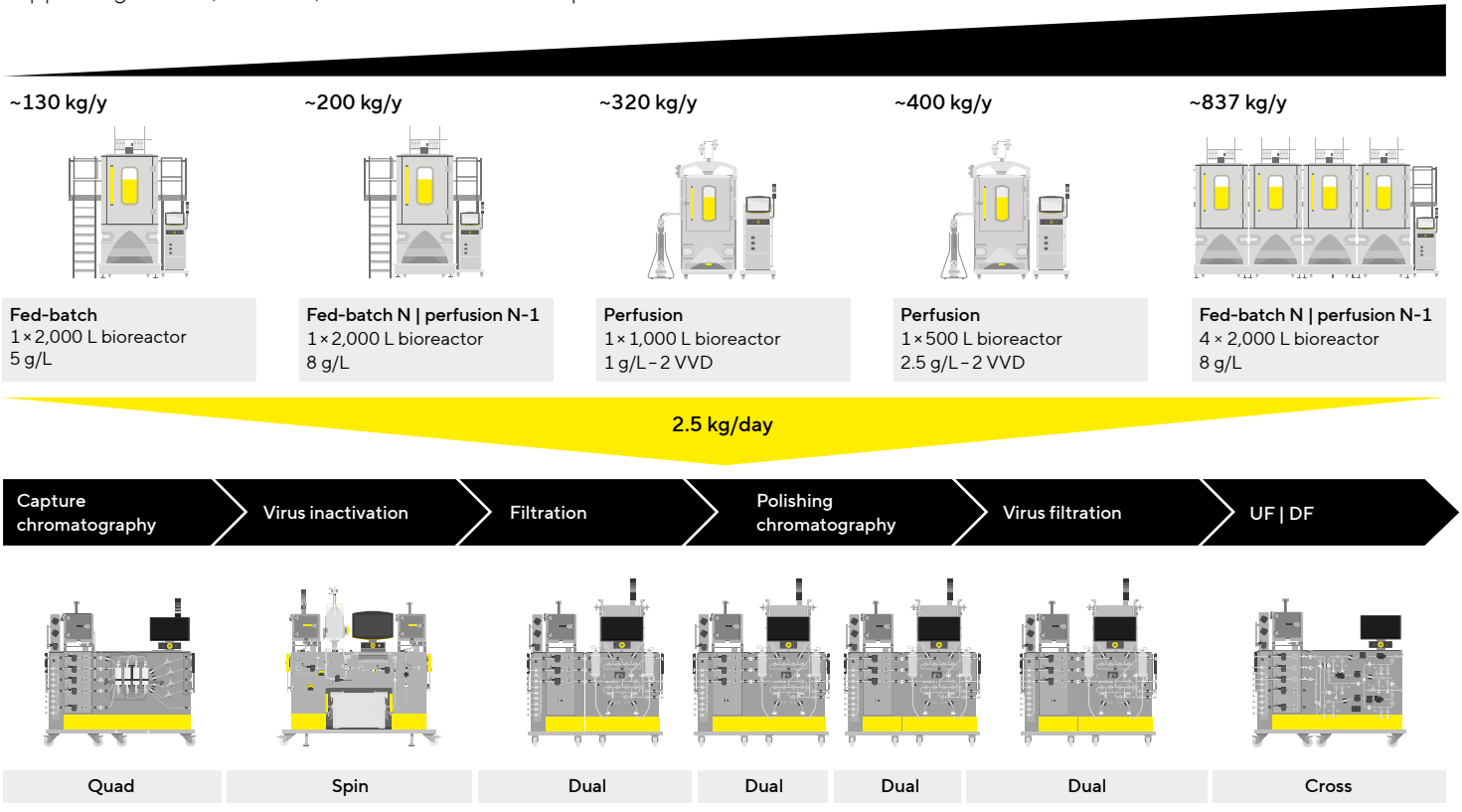
Delivering exceptional flexibility for multi-product facilities

By enabling continuous, 24/7 lights-out operation, Pionic® can increase facility output (kg/year/m^2) by up to threefold. The platform achieves a maximum output of 2 – 3 kg of drug substance per day, making it highly compatible with diverse upstream processes, from single or multiple fed-batch bioreactors to perfusion processes, while maintaining a compact, connected downstream processing (DSP) footprint. Beyond productivity gains, Pionic® significantly reduces DSP time, enabling more batches per year. This efficiency can even support the integration of an additional upstream processing (USP) line feeding into the same DSP system, further maximizing throughput (Figure 1).

Key Benefits

- **Significant time savings and increased throughput**
- **Lower costs and smaller facility footprint**
- **Reduced environmental impact**
- **Reduced labor through flexible manufacturing**

Figure 1: Schematic showing how Pionic® enables different upstream processes—from fed-batch to perfusion at varying productivity levels—to feed into a single downstream line without modification, enabling scalable annual output while supporting flexible, efficient, and economical multiproduct facilities.



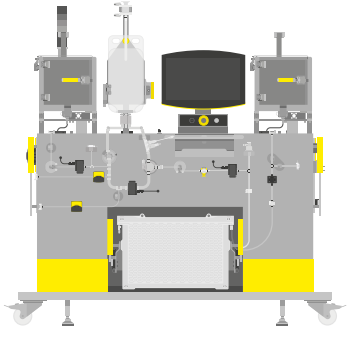
A single Pionic® DSP accommodates multiple USP conditions
Increases facility output and reduces downstream bottlenecks

DSP time is reduced from > 5 days to less than 1 day
Enables additional batches per year and supports upstream capacity expansion

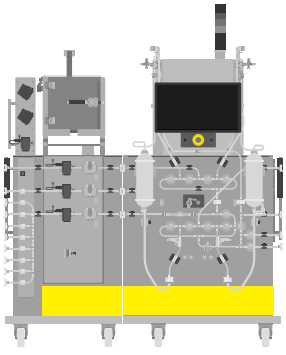
Chromatography media (resin) utilization is optimized, and extended processing durations are supported
Reduces cost per gram and improves labor productivity

Pionic® Platform Modules

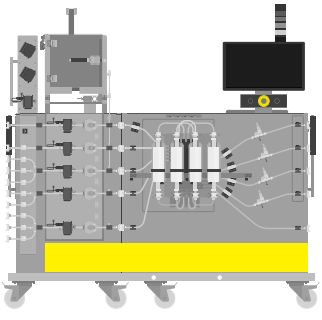
Pionic® Spin
for continuous low-pH virus inactivation.
- Unique incubation chamber
- Acidification, incubation, and neutralization



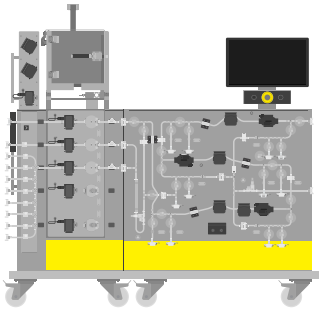
Pionic® Dual
for continuous filtration and chromatography.
- Dual filters or dual chromatography units
- Dynamic loading
- Aseptic venting



Pionic® Quad
for continuous high-productivity chromatography.
- Four chromatography devices
- Parallel or sequential process
- Simple installation with valve cassette



Pionic® Cross
for continuous UF | DF.
- Single-pass UF and DF
- Combines both UF and DF steps
- Up to three steps in one system (UF1 | DF | UF 2)



Pionic® Flow
with three or five pumps, connects to the Dual, Quad, and Cross modules for flexible pumping capabilities.
- Inline dilution capability
- Modular (three or five pumps)
- Product conditioning in surge tank

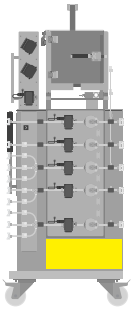
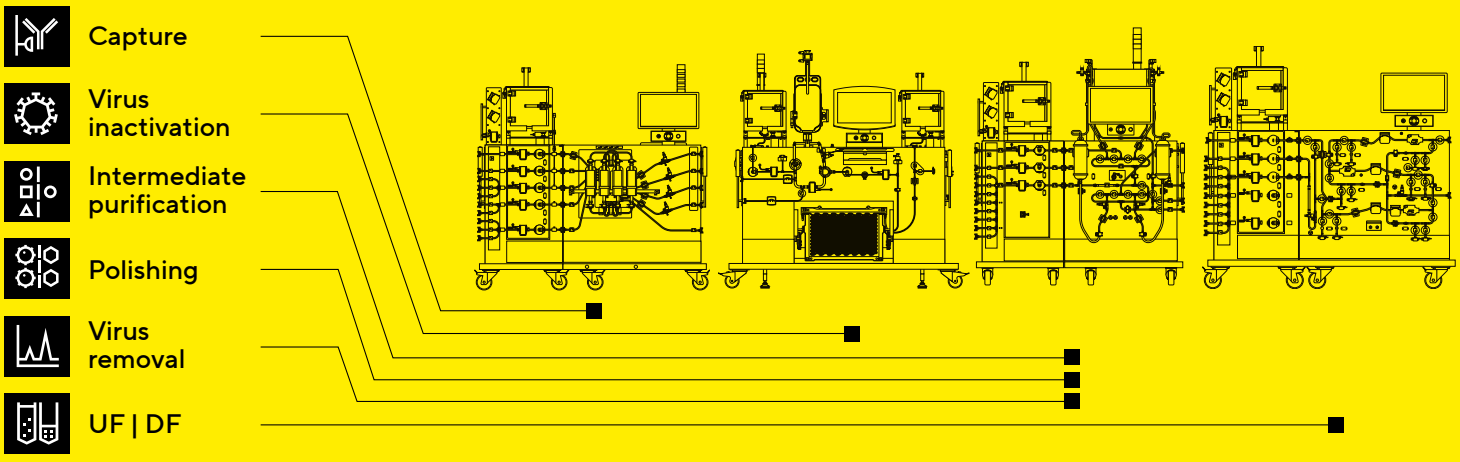


Figure 2: Modular continuous biomanufacturing with Pionic®



Pionic® Spin: The next generation of continuous low-pH virus inactivation

Pionic® Spin streamlines the low-pH virus inactivation process for mAbs with predefined strategies and automated exception handling, marking a significant advancement in downstream bioprocessing. It features an incubator, versatile recirculation loop, 3D biocontainers, and an innovative flow kit, forming an autonomous aseptic closed-unit operation. This setup transforms low-pH virus inactivation workflows, providing exceptional flexibility and control from clinical to commercial production.

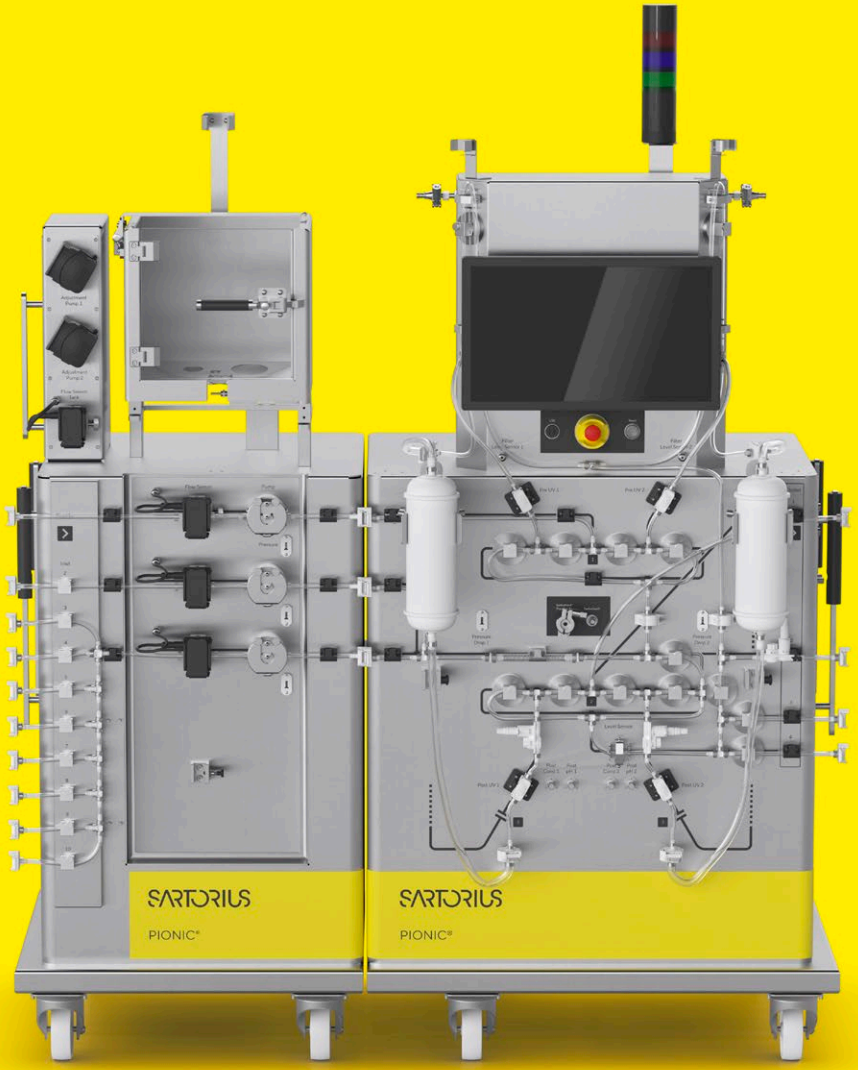
- **Efficient virus inactivation:** Pionic® Spin offers high-performance inactivation that minimizes process risks and enhances efficiency. It allows universal integration into existing infrastructures and delivers scalable results with an adjustable incubation flow rate of 1 – 22 L/h.

- **Improved product quality:** Pionic® Spin's gentle and time-effective approach minimizes the risk of protein aggregation and product degradation common in traditional batch methods. The tight residence time distribution and absence of static product hold time ensure minimal overexposure while achieving effective viral log reduction.

Pionic® Dual: The fully flexible module for continuous chromatography and filtration

Pionic® Dual streamlines continuous filtration and chromatography with a flexible design that allows users to select between distinct applications. The system ensures efficiency and precision while delivering fully automated processing with Biobrain® automation. Designed for aseptic operations, it accommodates flowrates from 1 to 150 L/h, supporting extended process durations of 28 days for integrated continuous biomanufacturing of monoclonal antibodies (mAbs) at clinical and commercial scales.

- **Dual filtration and chromatography:** Pionic® Dual offers intensified filtration and chromatography, minimizing process risks and enhancing efficiency. It integrates seamlessly into existing infrastructures and delivers scalable results, processing volumes from 50 – 2,000 L/day.
- **Unmatched process flexibility:** Pionic® Dual's adaptable configuration across filtration and chromatography steps allows manufacturers to tailor processes to diverse molecule types and production scales, ensuring consistent product quality and efficient operations.

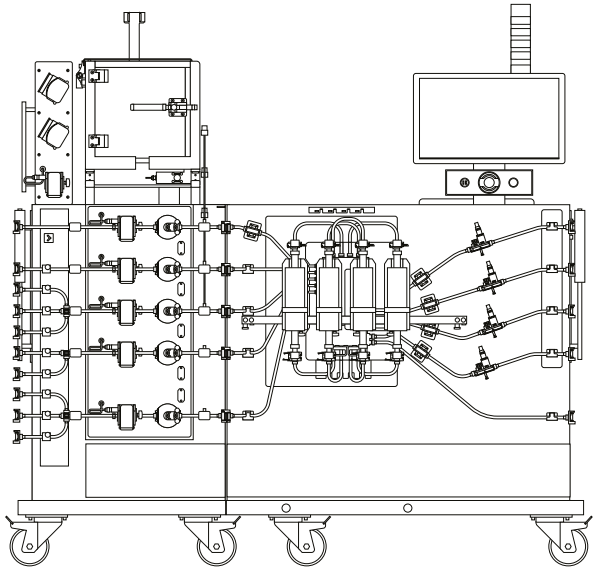


Pionic® Quad: The high-performance solution for all chromatography steps

Pionic® Quad is a single-use chromatography solution capable of processing up to four columns or membrane devices. It is engineered to optimize the performance and flexibility of Pionic® processes, particularly with high (or changing) bioreactor titers. As a fully automated, user-friendly GMP system, Pionic® Quad supports aseptic operations for processes ranging from 1 to 150 L/h. Its adaptability makes it an invaluable tool for integration with process scales from 50 to 2,000 L.

A notable feature of Pionic® Quad is its fluid path architecture. As a dedicated chromatography system, it integrates key process and column valves into a single component, thereby minimizing the risk of errors and reducing assembly time for the single-use flow kit. Pionic® Quad is designed to seamlessly integrate with the fluidic delivery module of Pionic®, Pionic® Flow. These modules can be configured to accommodate various fluidic configurations and enable advanced process functionalities such as inline buffer dilution and precise fluid management, enhancing efficiency and control in continuous downstream processing.

- **Streamlined single-use operation:** Pionic® Quad's integrated fluid path architecture and consolidated valve design minimize assembly steps, reduce error risk, and enable fast, intuitive setup — delivering true plug-and-play chromatography in GMP environments.
- **Versatile performance across all chromatography steps:** Pionic® Quad delivers cost, time, and throughput benefits across any chromatography process, with a scalable and configurable design that supports efficient operation from development to large scale manufacturing.



Pionic® Flow: The standardized modular flow manager

Pionic® Flow is the specialized pumping module designed for Pionic® Dual, Pionic® Quad, and Pionic® Cross systems. It facilitates advanced process functionalities, including inline buffer dilution and precise fluid management, maximizing efficiency and control in continuous downstream processing. This module is repeatedly utilized across the connected and continuous downstream processes, standardizing the installation and deinstallation of the flow kit and minimizing the risk of operator errors.

Pionic® Cross: The versatile single pass tangential flow filtration system for enhanced efficiency

Pionic® Cross is designed to support single-pass tangential flow filtration (SPTFF) applications across various downstream process steps. It can execute UF1, DF, UF2, and intermediate TFF steps in a single pass, ensuring effective purification and concentration of bioproducts.

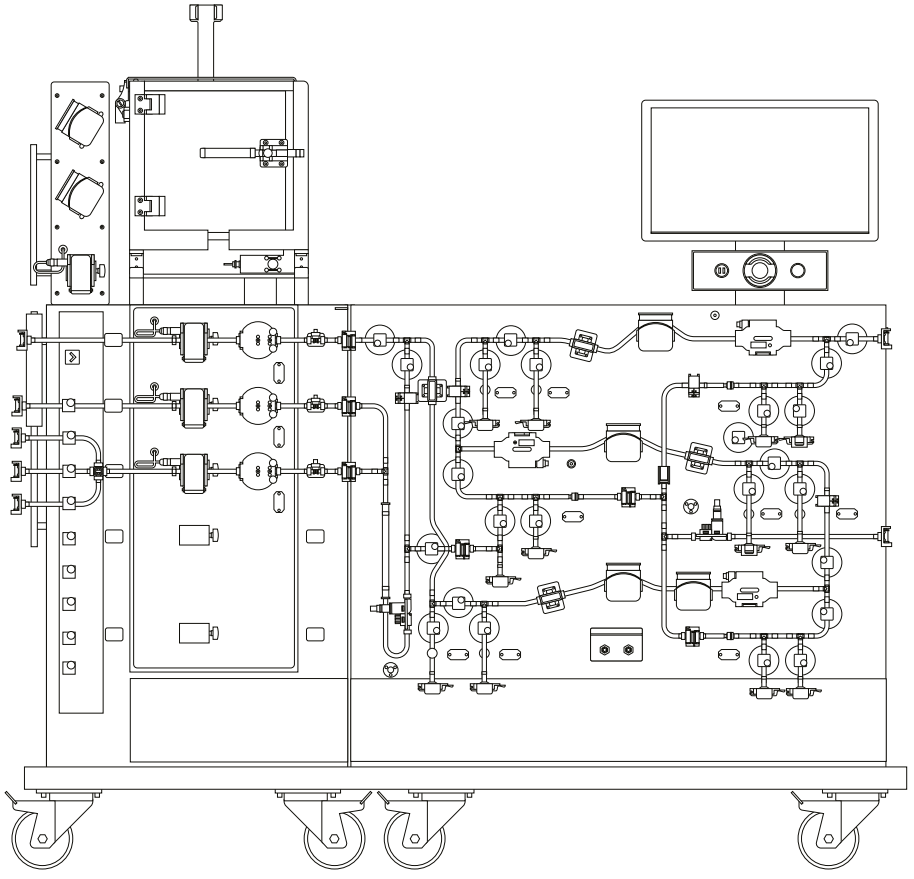
Biobrain® software delivers full process automation with embedded template-based process know-how to streamline implementation, minimize operator input, and provide real-time process monitoring throughout the production cycle. The system features a flexible design that accommodates multiple use cases with simple flow kit changes. These flow kits are available in different variants to suit specific process needs, such as only for the intermediate concentration or buffer exchange step, or for the final UF | DF step, optimizing operational expenditure (OPEX) and enhancing efficiency.

When combined with Pionic® Flow, Pionic® Cross offers additional functionality, such as inline dilution and fluid adjustment of the incoming product in the integrated intermediate surge tank.

Support for multiple consumable types makes Pionic® Cross a versatile member of the platform, suitable for a range of biomanufacturing requirements while maintaining high product quality and reducing time to market.

- **Process flexibility and coverage:** Improved time utilization allows Pionic® Cross to effectively replace two conventional TFF system sizes with one versatile SPTFF unit. It can be deployed at multiple points within the downstream process and unifies three unit operations, broadening process coverage and enabling flexible integration into existing workflows.

- **Controlled product concentration and quality:** Pionic® Cross enables precise control of product concentration, supporting consistent quality and reducing variability across downstream processing steps.



Biobrain® automation software—built for bioprocessing flexibility

Pionic® Platform is built on Biobrain®, a modular digital ecosystem and automation platform purpose-built for biopharmaceutical manufacturing. It pairs robust industrial hardware with configurable software, enabling rapid adaptation to evolving process requirements. Biobrain® integrates equipment-level automation and centralized process orchestration with the Umetrics® portfolio for advanced data analytics, delivering synchronized, high-performance operations from process development through commercial manufacturing (Figure 3).

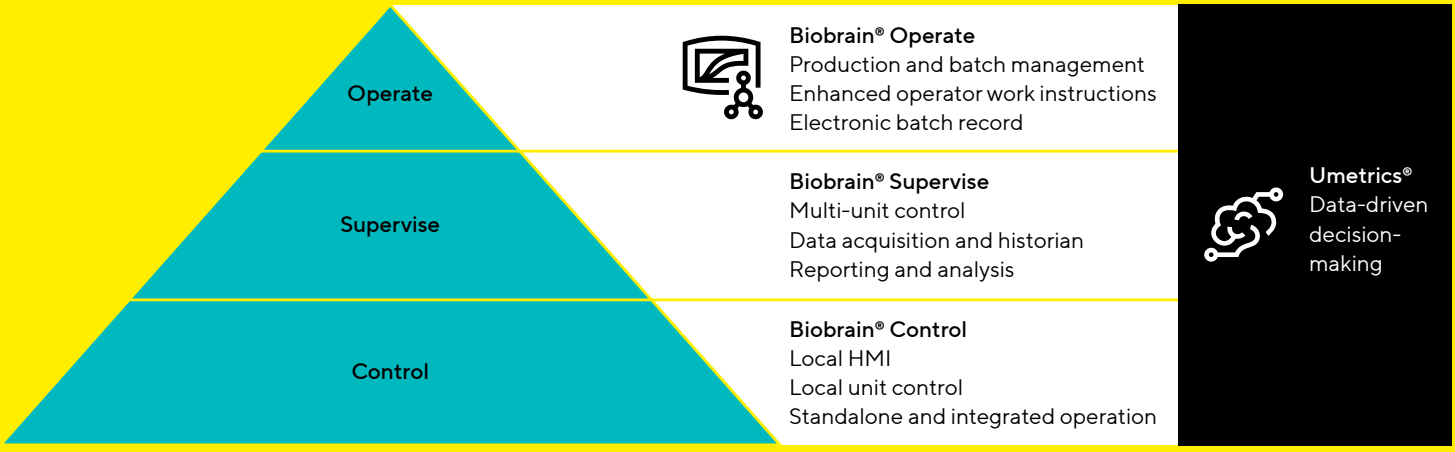
The Biobrain® Control layer delivers real-time, local automation for individual Pionic® unit operations. It can function autonomously or integrate seamlessly with broader control environments (e.g., DCS). Designed for robust process control, it ensures precise regulation of critical parameters and supports both batch and continuous operations.

The Biobrain® Supervise layer aggregates data across equipment and systems, enabling centralized process monitoring, alarm management, and performance visualization. It serves as an information hub, ensuring traceability, historical data availability, and process transparency across units and runs.

Biobrain® Supervise also includes complete process orchestration capabilities designed specifically for intensification processes, providing out-of-the-box rule sets required for the reliable execution of continuous operations. These include decision matrices that define equipment behavior in response to various scenarios, such as flow interruptions, step transitions, or upstream | downstream mismatches, ensuring all connected operations remain synchronized and resilient in dynamic environments. This orchestration logic eliminates the need for custom-coded scripting, reduces engineering effort, and reflects best practices validated across numerous intensified manufacturing setups.

The Biobrain® digital ecosystem was designed to meet the integration needs of the biopharmaceutical industry. Each layer can communicate seamlessly with external DCS | MES, third-party equipment, data historians, and SCADA systems. The architecture uses standard protocols like OPC UA to enable stepwise deployment. Manufacturers can begin by automating a single step, then add orchestration, analytics, or MES integration as needs evolve. Sartorius can also provide validated process templates and automation libraries, enabling customers to adopt pre-configured logic based on real-world best practices, dramatically reducing commissioning time, engineering effort, and project risk.

Figure 3: Automation and analytics platforms from Sartorius



Platform Highlights

Pionic® is the first modular, end-to-end platform for continuous and intensified downstream processing, offering unmatched flexibility for various processes and modalities.

Pionic® supports smooth and consistent material flow, combining several steps into a single, simplified process. This approach uses less raw material and energy, boosts productivity, and cuts waste. The platform also offers high configurability for flexible bioprocessing.

Flexible, modular design
Pionic® performs all essential downstream unit operations, allowing each to be intensified individually or connected for continuous processing. The system's hardware, flow kits, and control software can be reconfigured to meet specific production needs, enabling faster changeovers, simplified qualification, and broader process coverage across various volumes and titers.

Simplified automation and orchestration
Pionic® represents a unique out-of-the-box automation solution for continuous downstream processing, integrated with robust analytics to enable tight process control. Its automation framework encompasses both process operations and equipment management, reducing the need for custom engineering and qualification activities, shortening implementation timelines by several months while mitigating operational and validation risks.

Designed for long process durations
Ready-for-use systems and disposable flow kits are designed for use in closed and aseptic processing lasting up to 28 days. Each flow kit supports the full duration of a perfusion process or multiple batches of the same fed-batch product, optimizing resource use and reducing OPEX.

Key Benefits

Significant time savings and increased throughput
Pionic® enables continuous manufacturing, allowing the complete downstream process to be performed in just a few days, compared to weeks in traditional fed-batch scenarios. This efficiency significantly boosts throughput, achieving up to threefold productivity and enabling more batches per year.

Lower costs and smaller facility footprint
Continuous manufacturing with Pionic® enables the use of smaller equipment and chromatography columns compared to traditional setups. This reduction in size decreases the cost of goods to less than $50 per gram and achieves a 50 – 70% reduction in footprint in many cases compared with traditional DSP, leading to lower electricity and water usage. It also reduces both CAPEX and OPEX requirements for cleanrooms.

Reduced environmental impact
The compact, modular setup of Pionic® consumes less raw material and energy, reducing waste. It minimizes HVAC and WFI costs and lowers CO_2 emissions, contributing to a more sustainable manufacturing process.

Reduced labor through flexible manufacturing
The versatility of Pionic® allows the platform to accommodate a wide range of USP conditions, including variations in volume, titers, and production types such as fed-batch and perfusion. This flexibility makes the platform ideal for CDMOs or multi-product facilities, allowing them to handle different processes, batch numbers, and product throughput with minimal human intervention. Continuous 24/7 operation enables up to a twofold increase in labor productivity compared with a traditional DSP line.

For more information, visit
sartorius.com/pionic

Frequently Asked Questions

What is continuous manufacturing in the pharmaceutical industry?
Continuous manufacturing refers to the production of pharmaceutical products in a constant flow in which raw materials are fed and products are produced continuously rather than in batches.

How does the continuous manufacturing process differ from traditional batch processes?
In batch processes, all steps are carried out in distinct, time-separated units. In continuous processes, all steps occur in a connected, real-time flow, reducing downtime and increasing efficiency.

What challenges are associated with continuous manufacturing?
The key challenges include risk aversion, resistance to change due to a lack of data references, resource-intensive modification of existing infrastructure, product quality concerns, and complex processing.

What are the advantages of continuous downstream processing vs. traditional methods?
Continuous manufacturing enables the use of smaller equipment and chromatography columns compared to traditional setups. This reduction in size decreases the cost of goods and minimizes the footprint. The downstream process is also executed more quickly, increasing throughput and enabling a higher number of batches per year.

Another significant benefit of improved time management is the ability to expand process coverage, allowing the same continuous downstream line to accommodate more upstream process cases.

How does integrated bioprocessing contribute to sustainability in biomanufacturing?
Integrated bioprocessing helps minimize resource consumption (water, energy, and materials), reduces waste, supports the efficient use of components through single-use, modular systems. It also improves yield, minimizes failed batches, and lowers the carbon footprint via streamlined operations.

Is my upstream strategy | bioreactor compatible with continuous manufacturing?
Continuous manufacturing is a DSP strategy that is compatible with many upstream approaches, including traditional fed-batch, concentrated fed-batch, N-1 perfusion and dynamic perfusion. For example, a 2,000 L fed-batch bioreactor can be processed in one or two days in a continuous process.

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