Simplifying Progress

Continuous Downstream Process Orchestration in Pionic® Platform

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Introduction

Biopharmaceutical companies are under constant pressure to reduce costs, time, footprint, and resource use while improving yield, quality, and productivity. However, regulatory constraints, risk aversion, and legacy infrastructure often slow the adoption of new technologies. Pionic® Platform breaks through these barriers with a modular, ready-for-use modules for chromatography, filtration, virus inactivation, and ultrafiltration | diafiltration (UF | DF). This poster shows how Pionic® modules can be orchestrated using Sartorius software.

Pionic® Platform and Software

1. Bridging the gap in downstream process intensification

Process intensification is widely recognized as a key strategy for improving productivity, resource efficiency, and facility utilization in biomanufacturing. While upstream operations have advanced substantially through approaches such as intensified seed trains, high-cell-density cultures, and dynamic perfusion, adoption in downstream processing has remained comparatively limited. Major barriers include the capital-intensive modification of existing manufacturing infrastructure, concerns regarding process robustness and product quality attributes, as well as the perceived operational risks associated with transitioning from established batch-based workflows to intensified continuous or semi-continuous processing platforms.

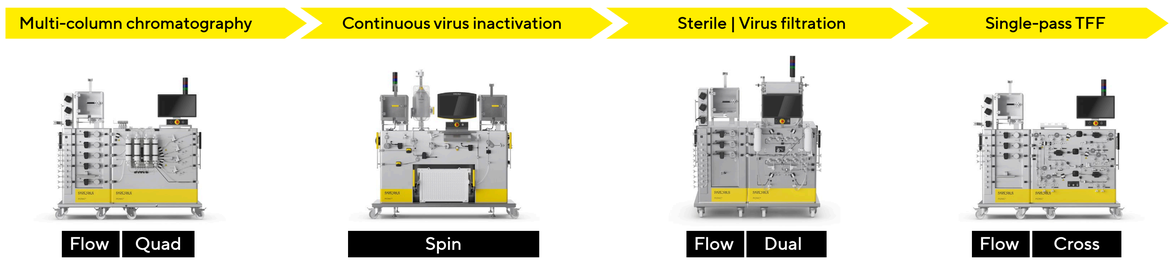

Figure 1: *Pionic® modules capable of performing chromatography, filtration, virus inactivation, and UF | DF on a single platform.*

Flow
- Modular (3 or 5 pumps)
- Connected to Dual, Quad, and Cross
- In-line dilution capability
- Product conditioning in surge tank

Dual
- Dual filters or dual chromatography
- Dynamic loading
- Aseptic venting

Quad
- 4 chromatography devices
- In parallel or sequential process
- Ease installation with valve cassette

Cross
- Single-pass tangential flow filtration (TFF)
- Combines both UF and DF steps
- Up to 3 steps in one system (UF1 | DF | UF2)

Spin
- Low-pH viral inactivation
- Unique incubation chamber
- Acidification, incubation, and neutralization

2. Biobrain® software structure

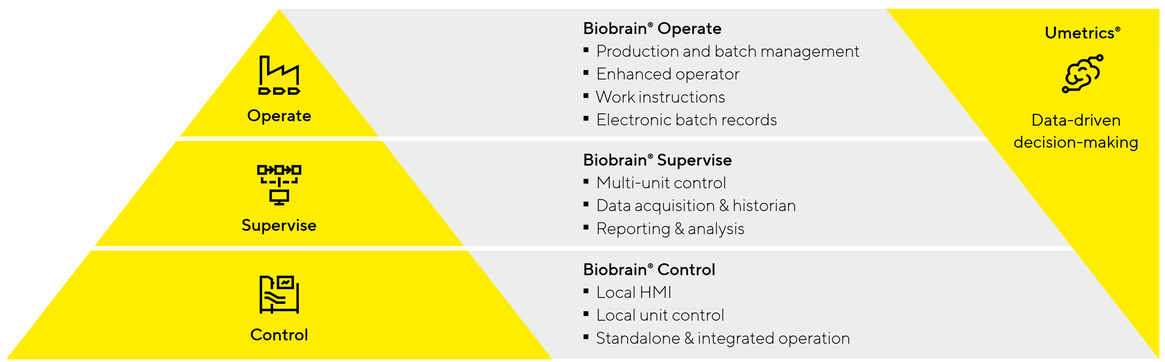

Figure 2: *Automation and analytics platforms from Sartorius*

3. Integration infrastructure for Biobrain® software

Pionic® Platform is designed to overcome barriers with a modular, ready-for-use modules that fit both new and existing facilities. It enables manufacturers to adopt intensification strategies step by step—connecting selected unit operations to ease bottlenecks, improve productivity, and build toward a fully continuous downstream process.

In the example below, several unit operations are connected, physically and digitally to increase productivity and remove bottlenecks in existing facilities. The orchestration layer transfers data bi-directionally across equipment "islands", and process commands can be sent at the equipment phase level, enabling true integration and automated coordination without custom engineering.

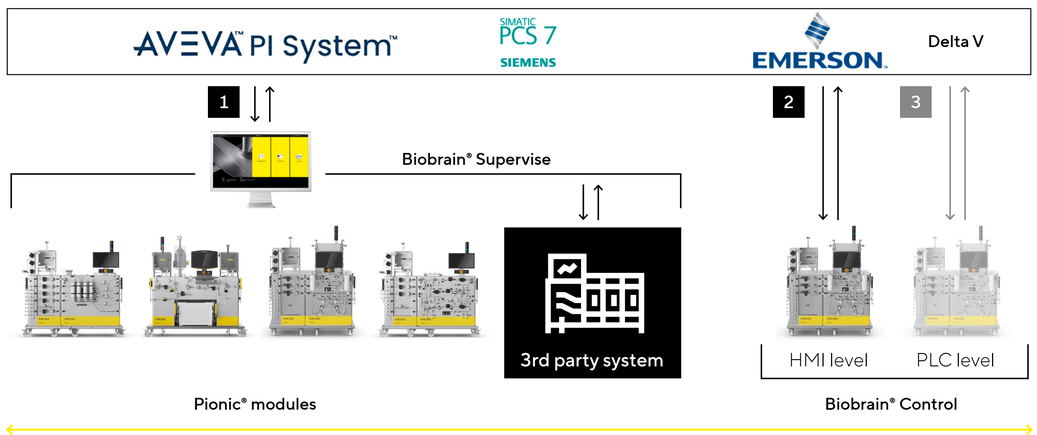

Figure 3: *Pionic® modules with an example of two types of automation integration.*
***(1)** SCADA-Level integration — Benefit from all Sartorius-provided content including process recipes | logic*
***(2)** HMI-Level integration — Benefit from all Sartorius-provided content including unit recipes*
***(3)** PLC-Level integration — Benefit from full flexibility in production scale*

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Orchestration concept

1. General concept

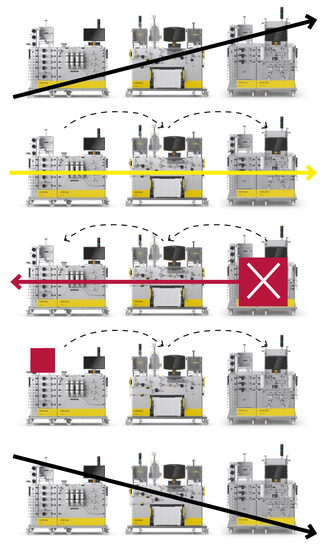
Sequential ramp-up for continuous processing:
- Staggered starting of unit operations based on real-time process values

Dynamic flow setpoint control:
- Real-time surge tank level automated flow setpoints adjustment of connected modules

Exception management and interlock logic:
- Max. surge tank reached
- Downstream modules are automatically paused
- Chromatography operations can be paused in a safe state, e.g., before the next loading phase begins.
- Resumption can be automatic (once safe levels are restored) or manual (requiring operator validation).

Cross-module calculations:
- Biobrain® Supervise can calculate and display derived parameters in real time using data from multiple modules.
- Example: Mass flow integration, surge tank residence time estimation.

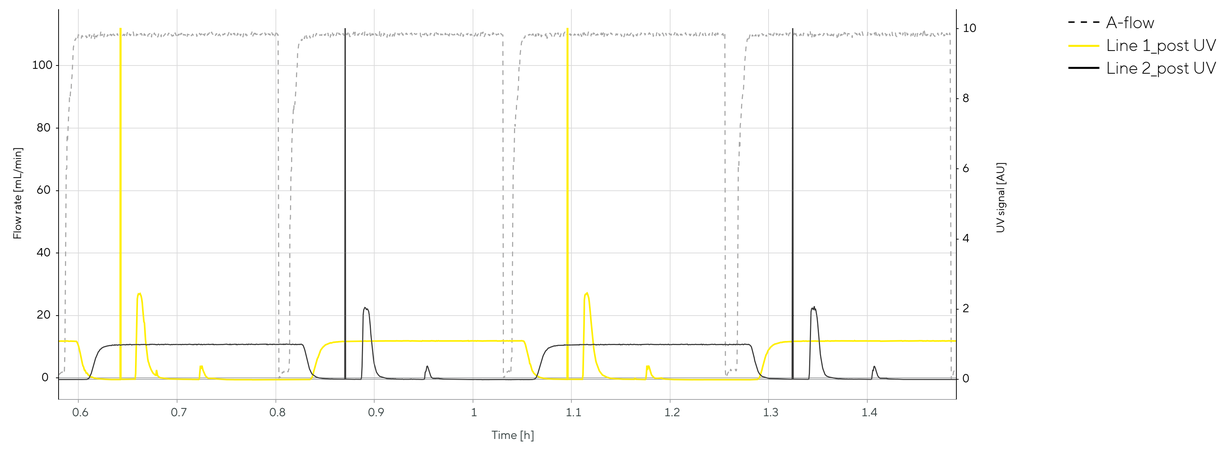
Sequential ramp-down for continuous processing:
- Staggered starting of unit operations based on real-time process values



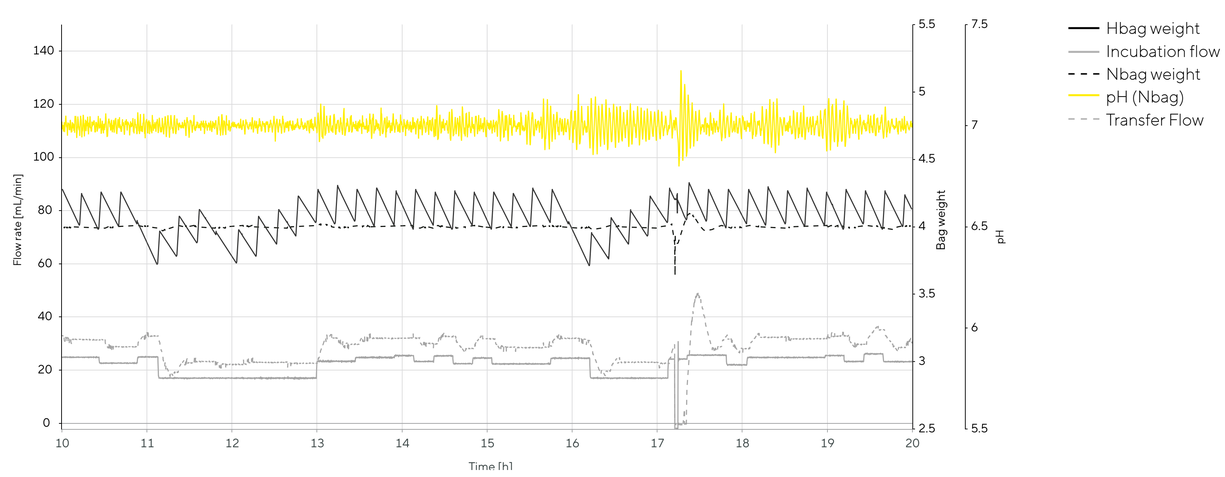
2. Orchestrated flow rates across multiple systems

Below experimental data from a fully continuous downstream processing setup comprising the chromatography (bind-and-elute), virus inactivation, and sterile filtration. The individual unit operations were integrated using the presented orchestration approach, enabling coordinated control of flow rates and tank levels across all unit operations. Experiments were conducted using an antibody solution and operated continuously over a period of four days.

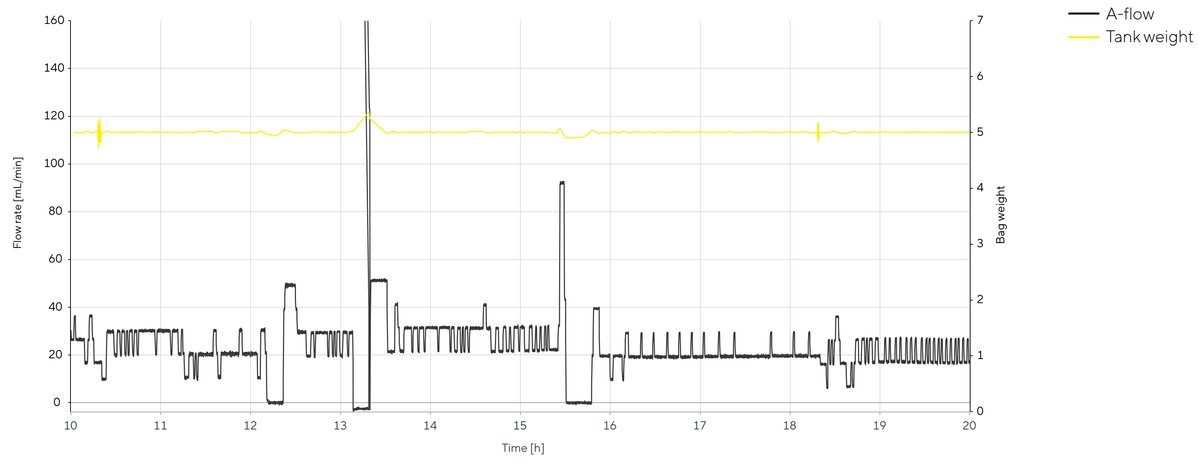
Pionic® Dual: Bind-and-elute chromatography



Pionic® Spin: Continuous virus inactivation



Pionic® Dual: Sterile filtration



Summary and Conclusion

Pionic® Platform enables stepwise downstream process intensification through modular integration of different unit operations, including chromatography (single column and multi-column), virus inactivation, single-pass TFF and normal flow filtration.

Using an orchestration layer, multiple unit operations are physically and digitally connected, allowing real-time control of flow rates, synchronized operation, and automated exception handling. This approach removes bottlenecks, ensures stable integration, and provides a scalable pathway toward fully continuous downstream processing.