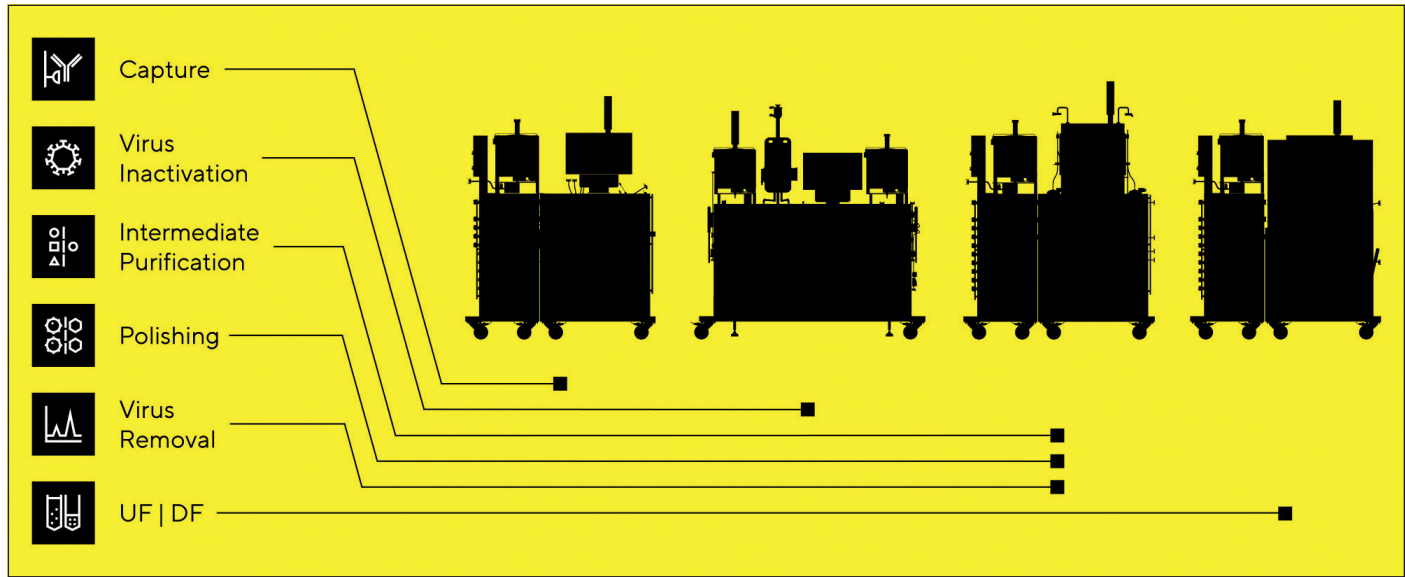




Modular process intensification

DEFINING THE NEXT DECADE

The biopharmaceutical manufacturing industry is under increasing pressure as drug development costs rise and profit margins shrink, driving a shift away from conventional batch-based production toward intensified approaches. Over recent decades, single-use technologies have become widely adopted, delivering flexibility, lower capital investment, and reduced contamination risks. Today, process intensification, built on automation, integration, and modularity, is emerging as the next paradigm for efficient, sustainable biomanufacturing.

Sartorius sees process intensification as a strategic imperative for our partners to enable the development of new and better therapies and more affordable medicine. To help drive the shift toward faster, smarter, and simplified biomanufacturing,

Jan Schäfer and Dr. Geert Lissens, Sartorius Stedim Biotech explain how modular process intensification will define the next decade.

Sartorius developed Pionic®, the latest innovation for process intensification.

CONTINUOUS MANUFACTURING

For more than a decade, bioprocessing experts have promoted the benefits of continuous and intensified processing: reduced cost of goods, shorter timelines, smaller footprints, and better scalability. Yet adoption has remained limited, especially downstream, due in part to technological fragmentation and the difficulty of integrating individual components into a compliant, reliable system.

As a fully modular ready-for-use platform for intensified downstream bioprocessing, Pionic addresses this challenge.

Pionic was designed with automated, system-level intensification as the primary goal.

MODULARITY WITH A PURPOSE

Flexible manufacturing is paramount in modern biopharmaceutical production. Changing demands, scales, and formats affect both traditional protein-based processes and newer, more advanced modalities. We designed Pionic to be modular at every level to help biomanufacturers navigate uncertainties and meet evolving requirements.

Pionic is designed to allow customers to adapt the system—not their process—to their goals. For example, a contract development manufacturing

organisation (CDMO) might choose to gradually intensify the capture chromatography step first by switching from 1 column to 2 columns using conventional resins or by transitioning from resins to membrane adsorbers initially. At a later stage they could gradually expand to include continuous virus inactivation and polishing. In this case the CDMO only needs two Pionic hardware systems as visualised below (one system for capture & polishing and one system for virus inactivation) and gets flexibility through the different ready-for-use flowkit designs. Another customer might use Pionic to debottleneck a single step in an otherwise batch-based process (e.g. the capture or polishing step). In both cases, the same Pionic hardware supports multiple operating modes for one or more unit operations without requiring reinvestment or revalidation.

CO-DEVELOPMENT WITH INDUSTRY LEADERS

Pionic wasn't developed in isolation. Partnerships provided real-world conditions, such as processing unpurified monoclonal antibodies for 30+ days continuously in our labs, and invaluable feedback on system architecture, automation, and regulatory considerations.

DIGITAL FOUNDATIONS FOR A PREDICTIVE FUTURE

Leveraging the full benefits of process intensification requires robust control systems for its orchestration. In current manufacturing processes, the orchestration of the unit operations requires users to manually integrate hardware systems from various suppliers which run on different software platforms, control modules and components. This adds risk, slows implementation, and limits scalability.

Digital capabilities enhance usability, enable advanced process analytics, and support real-time release. Pionic is designed to serve as a bridge, helping manufacturers transition from manual workflows to smart, self-optimising systems with predictive control and data-driven operations—capabilities that will be essential to meet future manufacturing demands.

SUPPORTING THE FULL LIFECYCLE

The journey towards process intensification is not a one-size-fits-all operation. Early-stage innovators need agile, small-scale systems to establish concepts and de-risk transitions. Established manufacturers may require larger systems that integrate into existing infrastructure while scaling efficiently.

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The current Pionic platform—designed for flow rates up to 150 L/h—is ideal for pilot-scale and early commercial applications, and is already helping advanced users scale up their continuous strategies. Meanwhile, the future smaller Pionic platform will support development- and clinical-scale applications where speed and confidence are critical; the upcoming larger platform variant will address high-volume facilities operating with multiple 2,000 L bioreactors.

This lifecycle-spanning approach ensures Pionic is accessible, adaptable, and scalable across all stages of development.

ACCELERATING INNOVATION IN EMERGING MODALITIES

While monoclonal antibodies remain the largest application area for process intensification, emerging modalities—from novel protein scaffolds to RNA and viral vectors—are likely to achieve even more substantial benefits. These newer therapies often lack standardised workflows, making them ideal candidates for modular, reconfigurable platforms.

We see particular promise in the future smaller Pionic platform as a tool for rapid development and technology transfer in these spaces. By enabling fast, flexible experimentation in a controlled,

digitally enabled environment, Pionic can help compress timelines and bring novel therapies to patients faster.

A PHILOSOPHY OF PARTNERSHIP

Sartorius acts as a strategic partner, working alongside our partners to help define the right intensification strategy for their specific goals. Through tools like the Expert Chromatography Intensifier Tool (ExCIT), we help quantify the time, cost, and throughput benefits of process intensification scenarios and guide decision-making with real data.

Our global team of field application specialists, digital solutions architects, and regulatory experts ensures that customers are supported not only during implementation, but across their full product lifecycle. This is especially important in multi-product facilities like CDMOs, where the ability to

seamlessly switch between modes and molecules can be a key competitive advantage.

CONCLUSION

Pionic enables flexible and modular downstream process intensification. Each unit operation can be intensified individually or connected to enable continuous processing. System hardware, ready-for-use flow kits, control, and orchestration software can also be reconfigured to suit specific production requirements. This flexibility supports faster changeovers, simplified qualification, and a broader process coverage across volumes and titers.

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