ReciBio Pharm

Novel Integration of Process Analytical Technologies for Continuous Biomanufacturing

Integrated continuous processing can simplify and accelerate manufacturing of high-quality products, helping to make therapeutics and vaccines more accessible to patients worldwide. ReciBiopharm has developed Recimagine™— the next evolution of process insights and GMP manufacturing. The Recimagine suite includes CPS — a fully integrated, continuous manufacturing platform designed to accelerate and simplify the production of high-quality biomolecules, and PAT — advanced process analytical technologies (PAT) that enable real-time monitoring of critical quality attributes (CQAs), along with proprietary software systems that translate raw analytical data into actionable insights. This next-generation system combines real-time, multi-attribute analytical testing with advanced orchestration software and AI-driven predictive modeling. Mobile, configurable, and modality-agnostic, the platform enables continuous CQA monitoring at any scale. By replacing batch-based workflows with intelligent automation, it delivers improved yield and quality, reduces batch failures and waste, and significantly shortens timelines from development to delivery.

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Smarter, Leaner Bioprocessing for Next-Gen Therapies

Continuous processing brings significant advantages to pharmaceutical manufacturing, offering improvements in speed, cost-efficiency, product quality, and consistency. Unlike traditional batch manufacturing, continuous systems require less space, consume fewer resources, and produce less waste. Their inherent flexibility also allows manufacturers to scale production more easily in response to changing demand.

Equally important, continuous bioprocessing relies on real-time process monitoring and a high degree of automation. This combination helps maintain optimal steady-state conditions while minimizing human error during sampling and analysis. Real-time data collection enables seamless progression from one unit operation to the next, eliminating the need to pause production while awaiting offline analytical results — a key bottleneck in traditional workflows.

Recognizing these benefits, regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have increasingly supported the adoption of continuous manufacturing approaches for both small molecule and biologic drugs. The FDA has actively collaborated with innovators to help advance compliant, real-time solutions that improve manufacturing outcomes and reduce delays in drug delivery.

These benefits are especially compelling for RNA-based therapeutics. Because RNA processes are not yet fully established, they offer a natural entry point for the adoption of continuous manufacturing platforms. For products based on messenger RNA (mRNA), self-amplifying RNA (saRNA), circular RNA, guide RNA, and RNA interference, continuous processing enables the efficient production of high-quality material, helping to make these advanced therapies more accessible to patients around the world.

Building the Infrastructure for Real-Time, Scalable xRNA Manufacturing

Since 2023, ReciBioPharm has been developing a robust infrastructure to support the continuous manufacturing of RNA therapeutics at both the process development and GMP-compliant production scales. At the heart of this effort is the integration of Recimagine™ PAT — advanced process analytical technologies (PAT) that enable real-time monitoring of critical quality attributes (CQAs), along with proprietary software systems that translate raw analytical data into actionable insights. This infrastructure empowers operators to perform continuous trending analyses and predict outcomes in real time, enhancing control and efficiency across the manufacturing life cycle.

This work began with support from a joint grant from the FDA and the Massachusetts Institute of Technology (MIT) and led to the creation of two complementary systems. The current system is a non-GMP, lab-scale platform capable of producing approximately 0.5 grams of mRNA per day, designed for process development and proof-of-concept work. The next-gen system, by contrast, is a cGMP-grade platform that scales production up to 40 grams of mRNA per day and is built for commercial readiness. Both systems utilize the same foundational PAT architecture and software integration, ensuring continuity and scalability from lab bench to manufacturing floor.

In early 2025, ReciBioPharm received a three-year grant from The Gates Foundation to expand this platform globally. The funding supports not only broader deployment of the RNA continuous manufacturing system but also ongoing enhancement of the PAT toolkit, particularly for applications aimed at improving access to high-quality RNA therapeutics in low- and middle-income countries. The platform's modularity, real-time intelligence, and scalability make it ideally suited for flexible deployment across geographies and therapeutic modalities.

Simulating Success: Modeling Before Manufacturing

A foundational element of Recimagine CPS is its advanced simulator — a digital knowledge hub designed to accelerate development, reduce costs, and improve process understanding before any physical manufacturing begins.

Powered by historical run data and machine learning, the simulator evaluates a proposed process based on user-defined inputs, including raw material quantities, specific process equipment, reaction times, and desired outputs. It determines whether the target results are feasible and, if so, identifies the optimal process conditions. If the initial parameters don't yield the desired outcome, users can iteratively adjust the inputs to refine the strategy — all *in silico*.

The simulator can model both individual unit operations and full end-to-end continuous workflows. This makes it a powerful tool for developing design of experiments (DoE) studies and stress-testing processes virtually, before investing in costly lab-scale trials. In many cases, simulated runs can replace early-stage physical development altogether, helping save an estimated $150,000 – $250,000 per process development run by avoiding unnecessary material use and bench time.

Modular, Intelligent, and Inline: The Real-Time Analytics Engine

At the core of Recimagine is a modular PAT skid that brings together six real-time analytical technologies to measure critical quality attributes (CQAs) at any stage of the process. These include ultraviolet/visible spectroscopy, Raman spectroscopy, mid-infrared (mid-IR), near-infrared (near-IR), dynamic light scattering (DLS), multi-angle light scattering (MALS) and additional customizable modules. The system is fully compliant with 21 CFR Part 11, making it suitable for both process development and GMP manufacturing environments.

What sets the skid apart is its smart orchestration software, developed in-house to unify data collection, analysis, and process control. This software integrates outputs from all analytical instruments and manages recipe execution across unit operations. It can initiate or shut down instrument functions, adjust feed rates and temperature, and provide feedback control based on real-time CQA measurements — empowering continuous, autonomous operation from a central hub.

The hardware itself is built for adaptability. The skid's stackable, plug-and-play design allows it to be easily reconfigured to match the specific CQA requirements of a given process. New instruments or technologies can be integrated as needed, without overhauling the system. This forward-compatible architecture has earned ReciBioPharm multiple patents and distinguishes the platform from traditional setups, where disparate tools are often added piecemeal and require separate interfaces.

Crucially, every analytical technique embedded in Recimagine PAT is validated against offline methods to ensure consistency and regulatory reliability. Real-time models are only accepted once strong correlation with offline reference data has been established, supporting compliance and confidence in in-process decisions.

Predict, Adapt, Improve: Real-Time Analytics in Action

A cornerstone of Recimagine CPS is its tightly integrated data analytics and automation framework. At the heart of the system is a centralized command hub that aggregates data from all process operations, enabling real-time control, visualization, and decision-making.

The platform uses predictive models developed from prior continuous runs, built through principal component analysis and advanced artificial intelligence algorithms. These models are not static; they evolve and improve with every additional run, incorporating new data to become increasingly accurate and robust over time. This iterative learning process enables increasingly precise forecasting of CQAs and process outcomes.

Together, the automation and AI layers provide continuous monitoring, trending, and predictive analytics across the manufacturing workflow. The system delivers key insights, such as reaction kinetics, raw material consumption, product formation rates, and potential process deviations, feeding back into process controls to optimize performance in real time. As additional capabilities are layered in, such as soft sensors to monitor hard-to-measure impurities, the platform moves closer to enabling fully autonomous, intelligent manufacturing.

By transforming raw data into actionable insights, this digital infrastructure allows ReciBioPharm to achieve greater consistency, efficiency, and quality in RNA production while also laying the groundwork for real-time release and future-ready manufacturing operations.

Built for mRNA — Ready for Anything

Recimagine CPS was initially developed and validated for mRNA manufacturing, serving as a proof of concept for real-time, end-to-end RNA production. Building on this foundation, the team is now expanding its application to other RNA constructs — beginning with saRNA, which shares similar chemistry but has a longer sequence length. Because the platform was designed with flexibility in mind, only minimal adjustments to the models, simulator, and digital twin environment are required to accommodate saRNA and related molecules.

Importantly, the system was engineered from the outset to be modality agnostic. Beyond RNA therapeutics, ReciBioPharm is actively preparing the platform for application to mAbs, antibody–drug conjugates (ADCs), and even small molecule APIs. The core hardware and orchestration software remain the same; only the CQAs, measurement techniques, and predictive models need to be tailored for each new modality.

Thanks to this modular, plug-and-play architecture, the transition to other therapeutic classes is straightforward. Technologies already incorporated in the platform — such as Raman and IR spectroscopy — can capture a wide range of spectral signals, enabling model adaptation rather than wholesale redesign. As new modalities emerge or evolve, ReciBioPharm's flexible system is already equipped to support their continuous manufacturing needs.

Compliance by Design: Built with FDA Insight

Close collaboration with the FDA has been instrumental in the development of Recimagine CPS. Through monthly meetings and onsite interactions, the FDA has remained closely informed on the project's progress, providing valuable input without issuing formal endorsements. These ongoing dialogues have helped ReciBioPharm proactively address regulatory expectations, refine its approach, and validate key elements of the system in real time.

Rather than serving as a traditional oversight body, the FDA has acted as a development partner, offering insights that shaped both the technical execution and regulatory strategy of the platform. This deep familiarity has even led the agency to explore the use of ReciBioPharm's framework as a potential training tool for broader industry education on continuous processing and real-time analytics.

The result is a platform not only built for GMP compliance, but one developed in alignment with the evolving priorities of global regulators — positioning it for broader acceptance and faster adoption across therapeutic categories.

Accelerating Access: Smarter Manufacturing for a Faster Path to Patients

Recimagine CPS combines regulatory-compliant, multi-attribute, inline testing with real-time orchestration software and AI-driven predictive modeling. Designed to be mobile, configurable, and modality-agnostic, the platform enables continuous monitoring of CQAs at any scale. By replacing traditional batch-based workflows with a fully integrated, automated system, the platform improves yield and quality, reduces batch failures and material waste, and significantly shortens production timelines

Using the current system in development settings, ReciBioPharm has already demonstrated that mRNA production timelines can be cut from 21 days to just five by eliminating bottlenecks associated with offline analytics, and using the bespoke production system currently being fabricated, ReciBioPharm will soon be able to cut that to a single day. The platform is currently in its prelaunch phase, with full GMP release — including software and hardware — scheduled for early 2026.

Ongoing enhancements are being supported by a three-year grant from The Gates Foundation, which aims to improve access to high-quality RNA therapeutics in low- and middle-income countries. Planned upgrades include the addition of soft sensors for real-time impurity analysis, new PAT tools to support broader modality use, and refinements to the human–machine interface. Miniaturization efforts are also underway, along with a redesigned enclosure to support greater portability and adaptability in diverse settings.

The vision is clear: to bring this next-generation manufacturing solution to the global market. With growing interest from regulatory agencies and biopharma clients alike, ReciBioPharm is well-positioned to support faster, more flexible, and more equitable access to advanced therapeutics — helping to bring innovative medicines to patients around the world more efficiently than ever before.

About us

ReciBioPharm, a division of Recipharm, is a contract development and manufacturing organization (CDMO) specifically established to focus on serving companies seeking to develop and commercialize advanced therapy medicinal products (ATMPs). ReciBioPharm's specialized CDMO capabilities include pre-clinical to clinical and commercial development and manufacture for new biological modalities encompassing technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production. Led by a management team and technical experts with a proven track record in both process development and contract manufacturing, ReciBioPharm offers the knowledge and resources necessary to help customers develop and manufacture promising new therapies to meet the needs of patients across the world.

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