ReciBio Pharm

Revolutionizing xRNA Production: The Economic Case for Continuous Manufacturing

The development and manufacture of xRNA therapeutics and vaccines have long been hindered by high costs and lengthy timelines. ReciBioPharm is tackling these challenges with a continuous manufacturing platform that reduces production times from weeks to hours, dramatically lowers costs, and streamlines quality control. By shortening time to first-in-human trials and increasing efficiency, this approach is opening new opportunities for therapy developers and expanding global patient access to life-saving treatments.

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Addressing Pain Points in Conventional xRNA Manufacturing

The success of messenger RNA (mRNA) vaccines during the COVID-19 pandemic has sparked unprecedented investment in RNA-based therapeutics across a broad spectrum of diseases. Despite this progress, the journey from research to commercial production of xRNA products remains fraught with challenges — both in terms of process development and analytical requirements. The complexity is amplified by the wide variety of xRNA formats, including circular RNA (circRNA), self-amplifying RNA (saRNA), guide RNA (gRNA), and RNA interference (RNAi) products, each with different construct sizes, sequences, and modifications such as poly(A) tails.

One of the most pressing obstacles facing xRNA developers is the high cost of raw materials, a challenge that is expected to diminish as the field matures. However, another significant hurdle is the lengthy timeline to bring a new xRNA molecule from concept to clinical trial material. The current development process — spanning sequence identification, process and analytical method development, scale-up, and GMP production — can take anywhere from 10 to 14 months, presenting a substantial time burden for companies aiming to advance new therapies.

Even after the development phase, batch manufacturing remains a time-consuming endeavor. Once a process has been developed, it typically takes around 21 days to complete a single manufacturing batch, including an extended multi-day quality control hold. Each batch often requires separate cleanroom suites for critical unit operations, such as *in vitro* transcription (IVT), purification, lipid nanoparticle (LNP) formulation, and fill/finish. This reliance on multiple suites compounds operational inefficiencies and increases costs.

Adding to the complexity, RNA molecules are highly susceptible to degradation. They can be compromised by temperature fluctuations, shearing forces, and RNase enzymes that are pervasive in the environment. As a result, stringent process monitoring and precise control are critical at every step of manufacturing. Minimal handling and reduced processing times are essential to preserving RNA integrity and ensuring product quality.

These pain points underscore the urgent need for innovative manufacturing solutions that reduce costs, accelerate timelines, and improve process reliability — critical factors in making xRNA-based medicines more accessible to patients worldwide.

A Knowledge-Driven Approach to Continuous xRNA Production

To overcome the inefficiencies of traditional batch production, ReciBioPharm has developed a cutting-edge platform for the continuous manufacture of xRNA therapeutics. This modular platform offers the flexibility to support a wide array of xRNA formats — including mRNA, circRNA, and saRNA — regardless of size or structural complexity.

A critical differentiator of ReciBioPharm's approach is the seamless integration of process development, high-throughput screening, and manufacturing activities. The core to this approach is a knowledge hub that houses, consolidates, and analyzes data from every stage of development. Whether the xRNA constructs are created internally or provided by clients, all process data — ranging from enzyme selection for IVT to purification protocols — are fed into this centralized hub.

This knowledge hub functions as more than just a data repository. It powers an advanced online simulator that can predict optimal process conditions for new xRNA molecules. By leveraging this predictive model, ReciBioPharm significantly reduces the need for physical experimentation. Clients can quickly determine the best enzymes, purification strategies, and impurity profiles without enduring lengthy trial-and-error cycles in the lab.

The knowledge hub also incorporates a growing library of template DNA molecules, enzymes, and *in vitro* potency assay data. This extensive data set links specific xRNA molecules to their real-world performance metrics, further accelerating process optimization. As a result, ReciBioPharm's platform streamlines the journey from concept to clinical trial material, slashing timelines and ensuring that clients can bring innovative therapies to patients faster than ever before.

Bringing Quality Control to the Production Line

For continuous manufacturing to deliver on its promise of faster, more efficient xRNA production, real-time monitoring and control are essential. Recognizing this, ReciBioPharm has reimagined the role of quality control (QC) in biomanufacturing by integrating comprehensive process analytical technology (PAT) tools directly into its production processes. This approach shifts the traditional QC paradigm from offline lab testing to inline, real-time monitoring within the manufacturing environment.

At the core of this transformation are ReciBioPharm's PAT skids — customized systems that house a suite of advanced process analytical tools. These skids are positioned at, and between, unit operations along the continuous production line, allowing for constant assessment of process variables. By embedding QC directly into the manufacturing process, ReciBioPharm ensures that xRNA production remains consistent, reliable, and aligned with predefined quality standards.

This integration of QC into manufacturing not only reduces the need for lengthy offline testing but also enables faster batch releases and more efficient troubleshooting. The continuous flow of real-time data enables technicians to pinpoint exactly where a process might deviate or have a potential for improvement. As a result, ReciBioPharm's clients benefit from greater process control, faster turnaround times, and a higher likelihood of achieving first-time-right production runs

Maximizing Efficiency with Continuous Manufacturing

ReciBioPharm's continuous processing platforms are transforming xRNA manufacturing by drastically reducing time, resource requirements, and costs. The current system shortens production timelines from the traditional three-week batch process to just five days (Figure 1). Its successor, which will be available for services in the second half of 2025, pushes this advancement even further, enabling GMP-compliant xRNA production in under 24 hours within a single cleanroom suite. This streamlined approach covers all critical production steps, from IVT through purification, LNP formulation, and excipient addition.

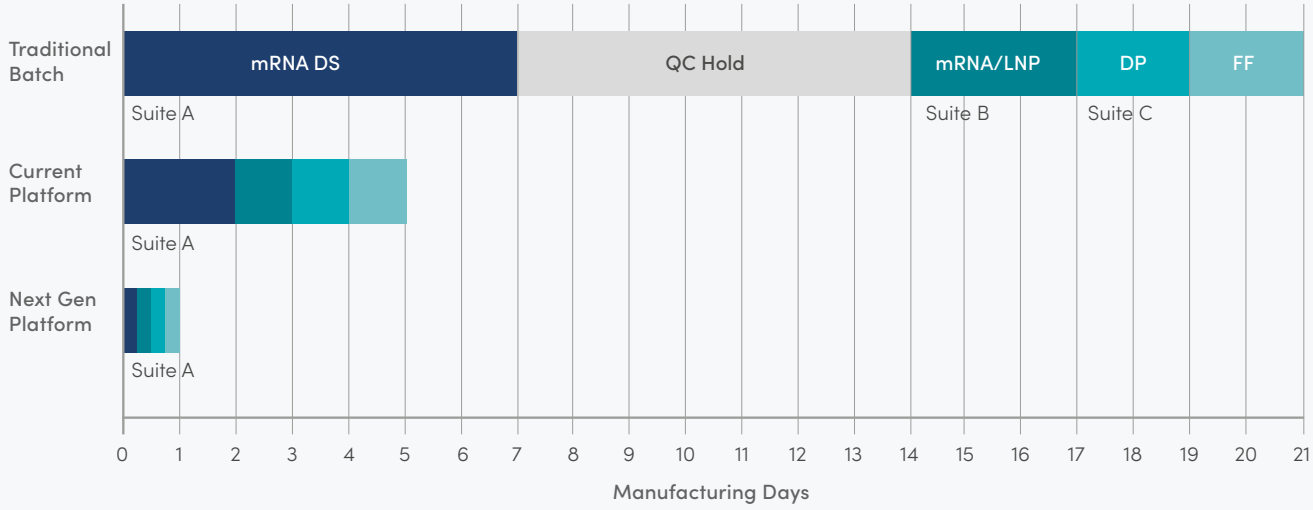

Figure 1. Comparison of timelines for batch manufacturing, ReciBioPharm's current continuous manufacturing platform, and the next-generation GMP platform in development.

These platforms integrate process development with real-time monitoring through advanced PAT tools, significantly accelerating timelines. What traditionally takes 10 to 14 months from construct to clinical trial material can now be achieved in as little as four months (Figure 2). This reduction is a game-changer for xRNA developers, allowing them to bring new therapies to market faster.

The benefits go beyond time savings. ReciBioPharm's continuous manufacturing approach reduces the number of full-time-equivalent (FTE) operators required from eight to just three per production run and enables the simultaneous production of four xRNA products in the space that previously supported only one batch. This increased efficiency translates directly into cost savings for clients.

mRNA products produced using ReciBioPharm's integrated continuous manufacturing platforms are anticipated to have a cost-per-dose at least three times lower than that of the current COVID-19 vaccines on the market. These savings could grow even further as enzyme and template DNA recycling processes are optimized.

Moreover, by shortening the timeline to GMP material, companies gain the flexibility to advance multiple constructs simultaneously for the same cost, effectively increasing their chances of developing more effective xRNA therapies. This approach lowers barriers to entry for new biotech firms, fostering innovation and competition in the field. The ultimate beneficiaries of these advancements are patients, who will gain faster access to potentially lifesaving therapies.

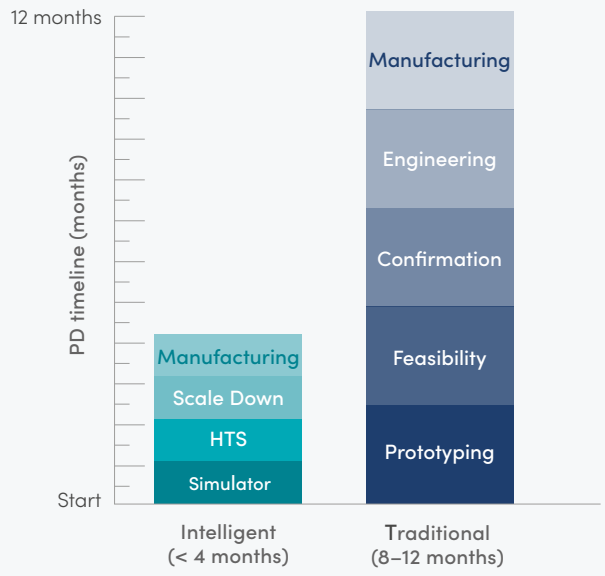

Figure 2. Comparison of process development timelines for ReciBioPharm's intelligent platform approach compared with traditional process development.

For ReciBioPharm, this paradigm shift dramatically increases its capacity to support a growing number of clients developing novel xRNA therapeutics and vaccines. The company's continuous manufacturing platforms ensure that clients meet critical milestones faster, enhance their valuations, and improve the overall economics of xRNA production — all while advancing the promise of accessible, cutting-edge medicines.

Driving Global Adoption of Continuous xRNA Manufacturing

ReciBioPharm's continuous manufacturing platforms offer significant time and cost advantages, the next hurdle lies in driving widespread adoption of this transformative approach. Despite support from regulatory agencies like the U.S. Food and Drug Administration (FDA), continuous bioprocessing remains underutilized in the biopharmaceutical industry. Encouraging manufacturers to embrace continuous manufacturing for xRNA production requires demonstrating its reliability, scalability, and global applicability.

The future GMP production system has the potential to revolutionize xRNA production on a global scale. Once deployed worldwide, it would enable drug developers to produce the same high-quality product with consistent specifications, regardless of location. This level of standardization is essential for ensuring that patients in every corner of the world have equitable access to advanced therapies.

ReciBioPharm is uniquely positioned to lead this charge, with manufacturing sites across four continents and well-established supply chains. However, achieving this vision will require more than technical capabilities; it calls for strategic partnerships and global coordination.

With support from a substantial grant provided by the Gates Foundation, ReciBioPharm is undertaking a demonstration of real-world mRNA vaccine production using our continuous manufacturing approach. Crucially, the grant will also support the validation of this technology by an independent organization, providing the third-party verification needed to build trust and drive adoption across the biopharma sector.

Through this grant, ReciBioPharm is taking the first steps toward deploying its GMP platform globally and ensuring that continuous manufacturing becomes a practical, effective solution for producing xRNA therapeutics and vaccines. This effort not only promises to lower costs and increase efficiency but also holds the potential to transform global healthcare by improving access to lifesaving medicines.

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.