Strategic Manufacturing Solutions for Accelerated Therapeutic Development

How Puresyn and Evolyra Therapeutics Reduced Development Timelines While Preserving Clinical Continuity

Executive Summary

The development of therapies for ultra-rare diseases demands a manufacturing strategy that balances speed, quality, and long-term program continuity. Delays in critical raw materials can significantly impact development timelines, downstream manufacturing activities, and ultimately the pace at which innovative therapies reach patients with urgent unmet medical needs.

When onboarding plasmids from Evolyra Therapeutics, Puresyn implemented a future-ready approach to hasten drug development. Prior to manufacturing ResearchReady plasmid DNA, an IND*Ready*® glycerol stock was prepared, establishing a source of continuity from nonclinical studies to future clinical manufacturing. This early investment aimed to reduce redevelopment activities and preserve program momentum as the therapy advances toward IND submission, while minimally impacting an accelerated timeline for delivery of the ResearchReady plasmid DNA.

Puresyn rapidly generated the company's critical starting material through and successfully delivered qualified ResearchReady plasmid DNA for Evolyra's first target within 24 days of receiving the starting material. A second target followed with qualified ResearchReady material ready for shipment within 24 days of starting material receipt.

These results demonstrate how strategic manufacturing planning, combined with operational execution and collaborative partnership, can significantly compress development timelines while maintaining rigorous quality standards and preserving future clinical flexibility.

The Challenge

Organizations developing therapies for ultra-rare diseases face a unique set of operational challenges. Limited patient populations, constrained development resources, and aggressive timelines create pressure to move quickly while maintaining scientific rigor and manufacturing quality.

For Evolyra Therapeutics, the challenge extended beyond obtaining plasmid DNA quickly. The company required a manufacturing partner capable of delivering high-quality material on accelerated timelines while establishing a foundation for future clinical development. A strategy that balanced speed, quality, and continuity would help reduce costs, minimize development risk, and preserve momentum as programs advanced.

Traditional manufacturing approaches often focus exclusively on immediate program needs. While effective in the short term, these approaches can create discontinuity between research and clinical development phases, resulting in duplicated activities, additional costs, and potential delays as programs advance toward regulatory milestones.

Evolyra sought a manufacturing strategy that would support immediate research objectives while simultaneously establishing a foundation for future clinical development activities.

The Puresyn Solution

Puresyn designed a manufacturing strategy focused on both near-term execution and long-term development continuity.

Rather than initiating production solely from a research-grade workflow, Puresyn first generated an IND*Ready*® glycerol stock before manufacturing ResearchReady plasmid DNA. This dual-batch strategy established a development pathway capable of supporting future clinical manufacturing activities while meeting immediate research requirements.

By creating the IND*Ready*® glycerol stock at the outset, Evolyra gained a qualified foundation for future manufacturing campaigns without requiring additional strain redevelopment or process re-establishment activities later in the program.

This approach provided several advantages:

- Accelerated delivery of ResearchReady material through streamlined manufacturing execution
- Preservation of development continuity across research and clinical stages
- Reduced risk associated with future manufacturing transitions
- Improved long-term supply chain planning
- Greater flexibility as development priorities evolve

The strategy reflects Puresyn's commitment to helping customers think beyond individual manufacturing campaigns and toward the broader lifecycle of therapeutic development.

Accelerated Execution

Speed was a critical component of the collaboration.

Following receipt of starting materials, Puresyn rapidly executed manufacturing, testing, quality review, and product release activities for Evolyra's first target. Qualified ResearchReady plasmid DNA was ready for shipment just 24 days after starting material receipt.

Building upon that success, Puresyn applied the same disciplined manufacturing approach to Evolyra's second plasmid, delivering qualified ResearchReady plasmid DNA within 24 days of receiving the starting material.

These timelines represent a significant acceleration compared with traditional plasmid DNA manufacturing schedules and enabled Evolyra to maintain momentum across key development activities.

Importantly, accelerated execution was achieved without compromising established quality systems, analytical testing requirements, or release review processes. Every manufacturing step remained subject to the same standards of process control, documentation, and quality oversight expected throughout the development lifecycle.

Partnership Beyond Manufacturing

The collaboration between Puresyn and Evolyra illustrates the value of a partnership-oriented manufacturing model.

Successful development programs require more than technical execution. They depend upon responsiveness, communication, strategic planning, and an understanding of broader program objectives.

Throughout the engagement, Puresyn worked closely with Evolyra to align manufacturing activities with development priorities, ensuring that both immediate needs and future considerations were incorporated into the production strategy.

This collaborative approach enabled manufacturing decisions to support broader program goals rather than simply fulfilling a transactional production request.

The result was a supply strategy designed to accelerate development while preserving flexibility for future clinical advancement.

Conclusion

The collaboration between Puresyn and Evolyra Therapeutics demonstrates how a thoughtful manufacturing strategy can accelerate therapeutic development while maintaining quality and future readiness.

Through the implementation of a dual-batch approach, beginning with the strategic creation of an IND*Ready*® glycerol stock that established continuity for future clinical manufacturing, followed by accelerated ResearchReady plasmid DNA production that was completed without extending delivery timelines.

Beyond the compressed timelines, the dual-batch strategy established continuity between research and future clinical development activities, helping preserve flexibility and reduce potential manufacturing challenges as the program advances.

As therapeutic developers continue to pursue treatments for rare and ultra-rare diseases, strategic manufacturing partnerships will play an increasingly important role in reducing development timelines, improving operational efficiency, and helping innovative therapies move more rapidly toward the patients who need them most.

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