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Diosynth biotechnologies

From Innovator to Partners in Cell Therapy Development: Our Evolution into a CDMO

Source: FUJIFILM Diosynth Biotechnologies

Our history as an innovator company gives us a unique ability to assist our partners as they advance their own cell and gene therapy programs today. Having once been in their position, we understand firsthand the requirements and challenges associated with developing innovative therapies. This inside-out perspective allows us to fully support and guide our clients at every stage of the product lifecycle.

In this short article, we will share insights from our leadership team about the challenges we encountered as an innovator company working with external organizations. We will also discuss how these experiences have shaped our current practices and our vision for the evolving relationship with CDMOs in the future.

Lesson Learned as an Innovator Company

In our previous role as an innovator company, our teams were dedicated to a singular program pipeline and worked with multiple CDMOs and contract testing labs, as well as vendors and suppliers across the globe. Our team members have taken on the roles of primary points of contact, persons-in-plant, and cross-functional team leaders working and collaborating with selected external partners trying to meet our pipeline goals. During this time, we encountered several challenges when partnering with third-party providers, these challenges included program prioritization changes, vendor management confusion, differing regulatory interpretations, decision making/ownership confusion, a lack of timely, clear, or purposeful communication, lack of clarity in definitions and needs, and of course, production challenges. Throughout our history, we have learned that every partnership faced similar challenges, and our experience in identifying and responding to such hurdles has influenced our operations today.

“It’s a complex business that we're in—whether you're manufacturing cell therapies in-house or outsourcing to a third party. There’s variability in the process and inevitably things do go wrong. I think what matters most is how you react when you get unexpected results and that's where some CDMOs struggle. They fail to react and communicate appropriately in response to unexpected roadblocks and challenges.”

Dave Bolish, Cell Therapy Site Head, Thousand Oaks, California

A Value Proposition Defined

It was important to find a partner who we could trust, who would act in our best interest, and be invested in our product’s success. Unfortunately, in certain cases, we experienced delays in project timelines due to communication gaps and misaligned expectations that resulted from unforeseen obstacles. One might notice that at the heart of all the challenges we faced, communication was a prominent element. With some introspection and honest ‘lessons learned’ sessions, it became clear that defining success in the form of clear, measurable, and attainable goals was absent in many partnerships. Each side of the relationship was interpreting and assigning intention without collaboration. Sometimes the team was lucky, and we landed on the same page, and at other times it was clear we were not even in the same chapter.

We’ve learned the importance of timely and proactive communication, early engagement, transparency, and willingness to problem-solve in a successful partnership with a CDMO. Our mission is to embody these qualities now and provide support and partnership that goes beyond transactional services. We understand, empathize with, and are committed to our clients’ success.

Developing CDMO Best Practices

What makes us unique and sets us apart from traditional CDMOs is the knowledge we’ve acquired about how to develop advanced therapies. We understand our clients’ perspective and are well-positioned to help them navigate their own products towards market approval.

Customer-Centric Approach

Our experience taught us the importance of putting the client first and building strong, collaborative partnerships. With transparency and timeliness in our communications as essential components of our operations, we can better pre-empt shifting requirements, evolving requests, and priority changes. This enables our teams to provide better options and solutions for our customers. Openness builds better trust, trust that is critical as we work to provide feedback that not only helps educate our clients but sets realistic expectations for the path forward. Our customer-service mindset as a CDMO is focused on delighting the customer and forming a culture of partnership.

"When a client trusts us with their programs, we don't take the responsibility lightly! We want to execute at the highest level of quality and compliance because we value the trust our clients place in us."

Cindy Colon, Head of Manufacturing, Cell Therapy

Relationships with Vendors

Drawing from our past challenges with third-party providers, we invest in building strong, long-term relationships with vendors to support smooth operations and mutual success. We foster a culture of continuous improvement and adopt inventory management strategies to prevent supply chain issues that could delay our clients. One key strategy is engaging in periodic reviews with our vendors to assess performance metrics, discuss areas for improvement, and address any gaps, which contributes to cost efficiency and better outcomes.

Holistic Development Perspective

Your goals, your strategy, and your risk tolerance are all critical elements to the success of your program, and our teams understand the importance of alignment and clarity on how you define success. Whether that is your next company milestone, clinical end point, or preclinical models, a true partner works alongside you to enable those goals. Our experience can be leveraged to avoid the delays and quagmires associated with a new industry and evolving regulatory expectations. Our comprehensive understanding of the entire product development cycle gives us line of sight to anticipate potential future challenges and identify areas for improvement to streamline process optimization and ensure product delivery—whether it's additional process development (PD), characterization work, or robustness studies that are needed to get the process appropriately compliant.

Historical Experience & Resources

We have experts across quality and regulatory compliance, supply chain, manufacturing, process engineering, validation, development, and tech transfer, who bring invaluable historical experience and cross-functional competencies. This ensures successful collaboration across departments and with clients. Access to the right SMEs at the right time allows us to proactively engage with clients, align priorities, and troubleshoot as needed across every stage, whether a project is in early Phase I, Phase III, or is in post-approval commercialization. Our team and facility have also successfully navigated regulatory visits, including two successful Pre-Approval Inspections (PAIs) by the European Medicines Agency (EMA) in 2022 and 2024.

Solution-Building Culture

The challenging nature of a young industry like cell therapy is made more intense due to the inherently variable nature of growing human cells. Prompt and transparent communication is invaluable when unexpected results are observed. When good communication is partnered with truly collaborative problem solving, innovation is all but guaranteed; therefore, innovation and problem-solving are attributes we carry forward today. The solutions-building culture is evident at every level of the organization, which enables us to drive to the optimal solution for our clients, so they can overcome obstacles and deliver lifesaving therapies to patients.

"At the end of the day, coming from an innovator company, we all have a passion for getting effective drugs to the patients in need, and we carry that same drive and attitude with us as a CDMO. Having that patient focus is still with us today."

Steven Tan, Head of Supply Chain, Cell Therapy

Looking into the Future: The Evolving Relationship with CDMOs

As the landscape of cell therapy evolves, earlier-line collaborations between innovators and CDMOs are becoming more commonplace. Because smaller companies may lack the facilities, resources, or expertise for in-house manufacturing, industry partnerships can bridge the gap and help advance new therapeutic candidates to first-in-human trials. There are also new opportunities and a willingness to engage in industry-wide collaboration, which will help drive forward progress that benefits all stakeholders.

We recognize the wealth of cutting-edge research occurring across startups, academia, and medical centers, so staying informed about emerging technologies and even participating in their development enables us to proactively ensure future readiness. Our teams are engaged in industry focus groups, literature reviews, and attend relevant conferences to ensure we are continuing to learn as the science advances.

Empowering Clients with Global Expertise and Patient-Focused Solutions

When clients partner with us, they gain access to the comprehensive resources of the entire FUJIFILM Diosynth Biotechnologies network with capabilities across various modalities and technologies at different sites. Harmonization of quality systems and standards across the global network ensures our clients' experiences remain consistent regardless of the location. Our ***Partners for Life*** mindset means we're dedicated to our clients' success from start to finish with a shared goal to bring life-changing therapies to patients around the globe.

About FUJIFILM Diosynth Biotechnologies

FUJIFILM Diosynth Biotechnologies, a subsidiary of FUJIFILM Corporation, is a world-leading contract development and manufacturing organization (CDMO) for the development and manufacture of biologics, advanced therapies, and vaccines. The company operates a global network with major locations in the Unites States of America, the United Kingdom and Denmark, offering end-to-end services including drug substance, drug product, and finished goods services. It is also building a new manufacturing site in Holly Springs, North Carolina, USA, scheduled to be operational in 2025. FUJIFILM Diosynth Biotechnologies has over thirty years of experience in developing and manufacturing drug substance of recombinant proteins, monoclonal antibodies, vaccines, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. We have drug product filling capabilities to support both clinical and commercial demands. Our finished goods services, supported by more than 15 years of experience, can accommodate commercial products for more than 65 countries around the world. The company offers a comprehensive list of services from cell line development using its proprietary pAVEway™ microbial and Apollo™X cell line systems to process development, analytical development, clinical and FDA-approved commercial manufacturing. For more information, go to: www.fujifilmdiosynth.com.