HOUSTON, WE HAVE A COMPLEX BIOPHARMA MARKET!

TAKING OFF WITH THE RIGHT CDMO

Rentschler Biopharma

NAVIGATING THE COMPLEXITIES

In the biopharmaceutical industry, companies face a complex journey as they strive to transform groundbreaking ideas into life-saving therapeutics. The process is fraught with challenges, also driven by current geopolitical changes, that demand for a suitable and reliable Contract Development and Manufacturing Organization (CDMO) partner.

The demand for scalable, high-quality biologics manufacturing solutions is immense, with market projections indicating a potential valuation of $1.37 trillion* by 2033. However, in today's highly dynamic biopharmaceutical landscape, companies face significant challenges not only in developing and manufacturing complex molecules like multispecific antibodies and other therapeutic proteins but also in navigating external factors such as evolving regulations, geopolitical shifts, and trade intricacies.

Transforming innovative ideas into viable, life-saving biopharmaceuticals necessitates a reliable partner who can adeptly facilitate this journey. Firstly, companies should look for CDMOs that maintain a steadfast commitment to technological and scientific excellence, quality and adaptability, and have global market presence. And there are more factors to consider.

Rentschler Biopharma offers dedicated teams and facilities in Europe and the U.S., which collaborate closely with companies to understand their unique challenges and deliver customized solutions. Don't miss the case study "What it takes to be first to market – 12 months to PPQ" at the end of this article.

*BioSpace, Biologics Market Size to Hit Around USD 1.37 Trillion By 2033

FINDING THE RIGHT CDMO PARTNER

When selecting a CDMO partner, consider the following key factors:

1 Experience and Stability

Opt for a seasoned CDMO with a long-standing market presence, experienced in adeptly handling market fluctuations. If they have production facilities across multiple countries or continents this will help minimize risks related to regulatory changes or supply chain disruptions.

2 Partnership and Communication

Choose a CDMO that emphasizes strong client relationships and open communication, acting as a true partner by offering ongoing support and collaboration throughout the project lifecycle.

3 Customization and Flexibility

Look for a CDMO that offers tailored solutions and is willing to adapt services to fit the unique requirements of each project, recognizing that one size does not fit all.

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FINDING THE RIGHT CDMO PARTNER

4 Quality and Regulatory Experise

When selecting a CDMO partner, the importance of quality and regulatory expertise cannot be overstated. Ensure that the CDMO possesses a robust quality management system that not only adheres to industry standards but also demonstrates a commitment to continuous improvement and excellence.

5 Speed and Efficiency

Consider whether the CDMO can meet project timelines and deliver results efficiently without compromising quality, particularly for projects with tight deadlines.

6 Proven Approval Track Record

Look for a CDMO with a proven track record of meeting regulatory standards across various markets, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other international regulatory bodies. This involves not only successfully obtaining approvals for past projects but also staying abreast of evolving regulatory requirements and guidance.

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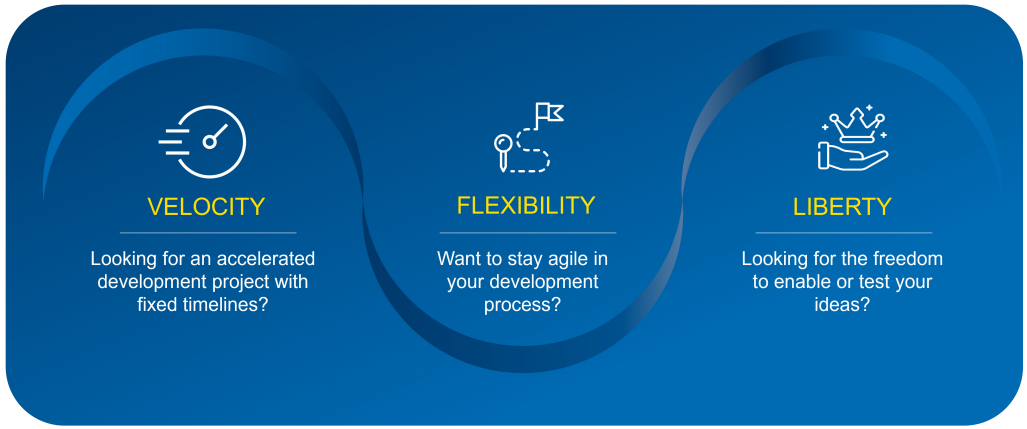
TAILORED DEVELOPMENT SERVICES

Rentschler Biopharma's comprehensive service portfolio encompasses all steps from concept to market, including Analytical Development, Process Development, Cell Line Development, Formulation Development, cGMP Manufacturing, Quality Assurance, and Regulatory Affairs Consulting. Each client project undertaken is unique, with varying needs and demands. Recognizing that one size does not fit all, the **Rentschler Development Services** are designed to cater to the unique needs of each company, whether they are startups or established players:



Velocity

For companies needing rapid progress, this fast-track service offers fixed timelines, fixed prices, and standardized processes, ensuring timely delivery for clinical Phase I/II projects.

Flexibility

Ideal for companies facing shifting priorities or unforeseen challenges, this service allows them to pivot as necessary without compromising quality, regardless of the clinical phase.

Liberty

For companies who thrive on experimentation and innovation, this service offers standalone activities and work packages, enabling rapid iteration and hypothesis testing without the obligation of commissioning a full development project.

Click to find out more about the Rentschler Development Services

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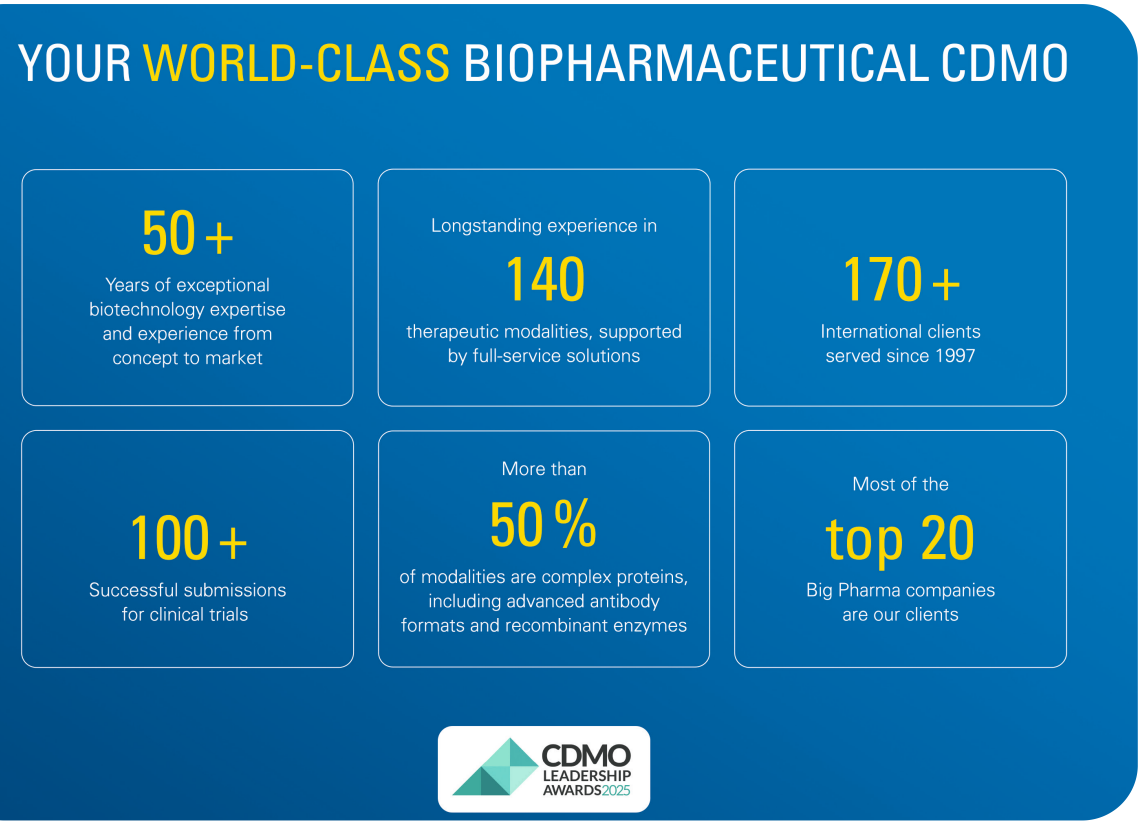
A TRUSTED PARTNER IN BIOPHARMA SUCCESS



Rentschler Biopharma's impressive track record underscores its reliability and expertise. The CDMO with headquarters in Germany and a facility in the U.S., has experience with over 140 therapeutic modalities and more than 100 successful submissions for clinical trials under its belt.

Clients value its over 50 years of success in biopharma. In 1983, the company became a pioneer with the world's first market approval of a native interferon-ß (Fiblaferon). Since then, Rentschler Biopharma has consistently supported numerous modalities from concept to market, regularly contributing to biopharmaceuticals reaching market approval. In 2023 alone, Rentschler Biopharma contributed to nearly 25% of all FDA-approved biologics, highlighting its role as a trusted partner in the industry.

Selecting the right CDMO involves finding a partner who understands one's vision, shares a commitment to quality and innovation, and remains supportive throughout the development journey. Rentschler Biopharma embodies these qualities, making it an invaluable partner in the pursuit of biopharmaceutical success.

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CASE STUDY:
WHAT IT TAKES TO BE FIRST TO MARKET – IN 12 MONTHS TO PPQ

Rentschler Biopharma's ability to deliver on its promises is best illustrated through its success in helping a client achieve first-to-market status. The company condensed the development timeline from Good Manufacturing Practice (GMP) to Process Performance Qualification (PPQ) into just 12 months, a feat that underscores its strategic approach and robust infrastructure across its sites in Germany and the U.S.. Achieving first-to-market status offers substantial advantages to biopharmaceutical companies, including brand recognition, market share optimization, and maximized patent exclusivity. However, the journey from GMP to PPQ is fraught with challenges, requiring significant resources and expertise. In this case study, find out how the Rentschler Biopharma team helped a client to be first to market.

KEY FACTORS IN RAPID DEVELOPMENT

Global Expertise and Collaboration

Rentschler Biopharma's Laupheim, Germany, facility, with its extensive experience in late-stage development, played a crucial role in the project's success. The Milford, Massachusetts, facility successfully executed the initial GMP run and the final PPQ, showcasing the company's capability to meet demanding industry standards.

Robust Process Development

The development of scalable and robust processes was essential to support commercialization. Rentschler Biopharma's team focused on optimizing various parameters, including pH, conductivity, loading range, residence time, and peak cut criteria, to ensure reproducibility and high-quality product output.

Effective Communication and Teamwork

Clear communication and close collaboration between Rentschler Biopharma and its client were pivotal. The teams worked together to author and review documents, plan activities, and solve problems, ensuring all timelines were met.

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CASE STUDY: WHAT IT TAKES TO BE FIRST TO MARKET – IN 12 MONTHS TO PPQ

THE RESULT

Rentschler Biopharma's Milford site successfully completed its PPQ, with all batches meeting the defined acceptance criteria. This achievement led to the approval of the Biologics License Application (BLA) ahead of schedule, allowing the client to be the first to market.

This accelerated timeline not only provided a competitive edge but also helped the client realize its vision of enhancing patient care by making life-changing therapies available more quickly.

Click to download the case study

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Rentschler Biopharma is a leading contract development and manufacturing organization (CDMO) focused exclusively on client projects. The company offers process development and manufacturing of biopharmaceuticals as well as related consulting activities, project management and regulatory support.

Rentschler Biopharma's high quality is proven by its long-standing experience and excellence as a solution partner for its clients. A high-level quality management system, a well-established operational excellence philosophy and advanced technologies ensure product quality and productivity at each development and manufacturing step.

Rentschler Biopharma is a family-owned company with about 1,400 employees, headquartered in Laupheim, Germany, with operations in Milford, MA, U.S..

In 2024, the company joined the United Nations Global Compact, emphasizing Rentschler Biopharma's focus on sustainability.

www.rentschler-biopharma.com

Laupheim, Germany (HQ) | Milford, USA

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