DRIVING INNOVATION TO SUPPORT STRATEGIC CLIENT PARTNERSHIPS

→ BY **FEDERICO POLLANO,** RENTSCHLER BIOPHARMA SE

Patients have been benefiting from the innovative nature of the pharmaceutical industry for over a century. With an increased reliance on outsourcing, contract development and manufacturing organizations focused on bringing cutting-edge solutions to the market have a distinct competitive advantage, and Rentschler Biopharma has been at the forefront of biologic development and manufacturing for over 40 years. Innovation remains central to all our activities and enables us to provide optimum support for our strategic client partners, from idea to market and ultimately to patients.

MODULAR ONE-STOP SHOP

Rentschler Biopharma's value chain comprises the whole process from gene to vial and from concept to market. As a full-service provider, our partners have one primary contact, sign only one contract and deal with just one quality system for all phases of the development cycle. As a solution provider, we help clients transition a project from genetic engineering all the way through fill and finish. Projects are supported by analytical method development and validation, formulation development and the elaboration of optimal global regulatory approval strategies from clinical studies to market approval.

CLIENT-FIRST MINDSET

As a mid-sized family-owned contract development and manufacturing organization (CDMO), Rentschler Biopharma has the ability to make decisions based on the long-term value we can provide to our clients. We have a client-first mindset and "live our clients' products." We appreciate the challenges our clients face and value every client and project, regardless of size.

We seek to partner with our clients to develop effective solutions for their complex products and processes. We are the ideal partner for both biotech and pharma companies in need of support for projects with challenging requirements, such as designer biologics.

Rentschler Biopharma works with large biopharma companies that appreciate our long track record and reputation for reliability and trustworthiness. We also complement smaller and mid-sized firms seeking a sustainable and reliable CDMO for process development and manufacturing that will satisfy future licensing partners.

Our client partners benefit from Rentschler Biopharma's continual investment in high-end technologies (i.e., advanced analytical and process development capabilities) that increase efficiency and productivity to reduce time to the clinic and the market. We also offer more than just capacity and product output; we serve as a consultant, advising our clients and advocating for solutions that provide the best products for patients.

THE ACQUISITION OF THE FACILITY ANSWERS OUR U.S. CLIENTS' STRONG REQUEST TO BRING OUR INNOVATION AND TECHNOLOGY **TO THEIR DOORSTEP AND UNDERSCORES OUR DEEP COMMITMENT TO MEETING THEIR UNIQUE MARKET NEEDS.**

LONG HISTORY OF INNOVATION

Innovation is deeply embedded in Rentschler Biopharma's culture. We are a biopharma pioneer committed to the development and application of advanced technologies and innovation leadership. We think strategically and invest in innovation for the long-term success of both the company and our biopharma partners. We think globally, yet focus exclusively on our partners' current projects and future needs.

Rentschler Biopharma has been producing biopharmaceuticals via mammalian cell culture since 1974 and working with recombinant cell lines since 1979. The first market approval for a natural interferon, and one of the first for a recombinant interferon, were awarded to Rentschler Biopharma in 1983 and 1989, respectively. Rentschler Biopharma also pioneered the use of disposable technology for bioprocessing and was the first company to install a 1000-L single-use bioreactor.

In 2012, Rentschler Biopharma won the Facility of the Year Award (FOYA) sponsored by the International Society for Pharmaceutical Engineering (ISPE), INTERPHEX, and *Pharmaceutical Processing* in the category Equipment Innovation, in recognition of our flexible, multiproduct manufacturing facility designed to minimize manufacturing costs and product cycle times.

In 1997, Rentschler Biopharma became one of the first CDMOs focusing on biologics. Since then, we have been a 100% dedicated CDMO committed to providing development, manufacturing and consulting support to our client partners.

Since 1997, Rentschler Biopharma has produced 90 different therapeutic proteins under cGMP conditions, including monoclonal and multispecific antibodies, fusion proteins and challenging recombinant proteins. Overall, we have worked with approximately 280 molecules in manufacturing and/or aseptic filling, with 23 of them reaching the market, 42 at phase III, 183 at phase I and 29 at the preclinical stage.

These development and manufacturing efforts have included the preparation of 80 complete dossiers for regulatory submission, including 25 for submission of market approval. Our facility in Laupheim, Germany has undergone 46 authority audits (EMA, U.S. FDA, Health Canada and various other country agencies) since 2000 and is subjected to approximately 40 client audits per year.

BUILDING STRATEGIC PARTNERSHIPS

Since 1997, Rentschler Biopharma has worked with approximately 140 different partners, including small and medium-sized biotech firms as well as 18 of the top 20 biopharma companies. Over one-third of our clients have been partners for more than five years, and about half work with Rentschler Biopharma on more than one project.

Our goal is to establish collaborative, long-term, win-win strategic relationships with our clients. With our flexibility, commitment to innovation and room to expand capacities and capabilities, we are ideally positioned to support clients from early phase development to commercial launch and beyond. We work closely with our partners to help them plan, build and implement long-term strategies for their candidate pipelines, including complex and next-generation biologic molecules for the treatment of severe and orphan diseases.

DRIVING INNOVATION THROUGH STRATEGIC ALLIANCES

In order to complement our offering along the entire biopharmaceutical value chain, we seek out strategic alliances with other organizations that have best-in-class capabilities. Their offerings are integrated seamlessly into Rentschler Biopharma's business processes, allowing our clients

access to a single service provider. Rentschler Biopharma manages the entire process, ensuring that all parts of the project are aligned. As a result, clients not only benefit from outstanding services, but their time to market is also reduced significantly.

Our alliance partners also continue to have their own business interactions and further develop their knowledge and offerings, which often benefit Rentschler Biopharma as well. With this approach, these alliances extend the high level of services that Rentschler Biopharma can offer while driving further innovation within the company.

Rentschler Biopharma currently has two important strategic alliances. Leukocare AG is the exclusive formulation developer for Rentschler Biopharma, offering its patented SPS® Formulation Technology for protein stabilization. Rentschler Fill Solutions provides access to a brand new, state-of-the-art fill/finish facility for the production of clinical and commercial biologic drug products, including liquid and lyophilized formulations.

Rentschler Biopharma will be expanding its strategic alliances going forward.

OPENING DOORS TO INNOVATION WITH A NEW U.S. SITE

In response to requests from North American client partners to bring our expertise, full-service CDMO offerings and passion for performance and innovation closer to them, Rentschler Biopharma acquired a state-of-the art facility strategically located in the Boston metro area.

The fully FDA-audited facility with a consistently favorable inspection history (FDA, EMA, Health Canada) currently supplies a recombinant hemophilia A product for Shire. In the future, it will be qualified as a multi-product production site to accommodate the growing biologics market. It has flexible cleanroom capacity with capability to expand within the current footprint and site.

The facility currently has capability to provide process development support. A 500-L bioreactor and downstream processing train will be operational in mid-2020, and additional single-use bioreactors up to 2000-L will be added shortly thereafter. We will, therefore, be able to support partner projects from early stage development through clinical and commercial production. An integration management team comprising experts from both Laupheim and Milford, Massachusetts ensures that the administration, quality, technical operations and other systems are aligned across both sites.

The Milford facility not only increases Rentschler Biopharma's flexibility and manufacturing capacity, but is also located in close proximity to many biotech startups, large pharmaceutical companies, incubator sites, world-class universities and biotech-focused research institutions. As a result, we will be able to strengthen our important U.S. partnerships and forge new ones, further elevate our technological capabilities and tap into the region's wide pool of expert talent.

Indeed, we expect the Milford facility to become a driver for innovation, both in manufacturing and partnerships. One further advantage of the site is access to a building dedicated to the exploration of new technologies and innovative products and separate from ongoing partner projects.

INNOVATING FOR THE FUTURE

To head up our innovation efforts going forward, Rentschler Biopharma recently hired Dr. Jesús Zurdo, previously Senior Director of Strategic Innovation at Lonza Pharma & Biotech, as Senior Vice President of Process Science and Innovation. Jesús will provide scientific leadership for development and manufacturing services from cell line development through to final product manufacturing. He will also be responsible for managing key strategic collaborations so that Rentschler Biopharma remains at the forefront of innovation and technology.

A new dedicated training facility enables Rentschler Biopharma to provide both initial training and retraining of internal staff and partner representatives in GMP operations, working under aseptic conditions, quality awareness and much more. The new facility will also serve as a site for the testing of new equipment, technologies and standards.

In addition, we continue to develop our Strategy 2025 initiative to ensure investment in innovation that can be directly translated into long-term client value. The strategy focuses on two types of innovation. The first involves innovations within cell culture to enhance our core business, including technologies that not only improve efficiency and productivity but also enhance interactions with clients and partners and enable them to participate more in the development process. The second addresses innovative therapy areas that rely on technologies other than mammalian cell culture. With input from external consultants, client partners, academicians and patients, we are considering all options before selecting the right business models to successfully take Rentschler Biopharma and our partners forward. In the future, we will provide full service beyond recombinant proteins to support whatever our clients have in their pipelines. P

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Federico Pollano is Senior Vice President at Rentschler Biopharma, located in Laupheim, Germany. He has nearly 30 years of experience in pharmaceuticals and biopharmaceuticals, mainly in senior and executive positions at the following companies: Polpharma Biologics, Richter-Helm BioTec, Helm, BioGeneriX, Glaxo Wellcome and Zambon. Pollano studied biology at Bielefeld University in Germany, and at the German Primate Center, Göttingen, Germany.

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