

# A VISION FOR ACHIEVING WORLDWIDE BIOPHARMACEUTICAL CDMO LEADERSHIP

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With the biopharmaceutical industry undergoing significant transformation, it is essential that CDMOs evolve to meet the changing needs of their clients. As a privately owned company with a long-term view and a commitment to building a sustainable business, Rentschler Biopharma SE has taken the time to gather external insights into trends and issues in the biopharmaceutical industry that will impact how the company should operate in the future. Strategy 2025 is a vision that addresses innovation, growth, and partnering needs that Rentschler must fulfill to establish formidable competitive advantage and create greater value for its clients.



## LONG-TERM VISION

Rentschler Biopharma is a fifth-generation family-owned company that has been developing bioprocesses and producing biopharmaceuticals since 1974. As a privately owned firm, Rentschler Biopharma is able to rapidly make difficult decisions, implement innovative programs, and build a business that is sustainable for the long term.

The innovative spirit of our leadership has enabled Rentschler Biopharma to be positioned at the forefront of new developments in the biopharma industry. We received the first marketing approval for interferon- $\beta$  in 1983 and were the first company to install 1000-L single-use (SU) bioreactors and produce commercial batches in a 2000-L SU bioreactor. We have hence been an expert provider of drug substance manufacturing for more than 40 years with proven experience exceeding 100 formats, including difficult-to-manufacture proteins.

Our employees are our main assets and the key to realizing the long-term vision of the company. For two years in a row, Rentschler Biopharma has been recognized as one of “Germany’s most attractive employers” according to the F.A.Z. Institute, ranking number two in the biotechnology sector. On behalf of all of our employees, Chairman of the Board Prof. Nikolaus F. Rentschler and myself also received Ernst and Young’s “Entrepreneur of the Year Award 2019” in the “Industry” category as the result of the dedicated contribution of many hands and many minds to meet the needs of our clients in bioprocess development and manufacturing all over the world.

Today, we have more than 140 clients, and we have worked as a dedicated CDMO with more than 280 different biomolecules, including monoclonal and bispecific antibodies, fusion proteins, enzymes, blood factors, cytokines, and growth factors. Over 20 products have reached the market, and many more are

progressing through preclinical to phase III clinical development.

## A UNIQUE APPROACH TO STRATEGY PLANNING

In 2016, I was approached by Prof. Rentschler to take over the helm as CEO of Rentschler Biopharma. I had been a member of the Supervisory Board since 2013, and this transition meant a direct role reversal for the both of us. While handing over the reins, he requested me to develop a long-term strategy for Rentschler Biopharma, a vision that would carry us into the future. I found myself becoming very aware of both the exciting possibilities and daunting responsibility that this task brought with it. Bracing myself, I took the time to reflect. The sustainability of a promising long-term vision cannot be governed by financial KPIs alone. No, we had to catapult ourselves into the future. We had to gather insights on what the world, the society, and the industry of tomorrow would look

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like, in order to chart our path into the future. I was convinced that, if we followed the right approach, financial success was bound to follow. What followed next was a fantastic adventure around the world together with my team, which laid the foundation for what was to become our “Strategy 2025.”

Long-term commitment to growth and innovation is reflected in this “Strategy 2025,” a vision for our company that itself was developed over an extended period to ensure input from many diverse and valuable sources. The goal was to define what the company should look like in 2025 given the megatrends that will shape society, and hence the industry of tomorrow.

Unlike most strategy planning initiatives, which are completed in a few weeks, the process for developing Rentschler Biopharma’s Strategy 2025 took 18 months. Both internal and external experts were consulted to gather as many insights as possible to establish the principles on which our vision is anchored.

External sources included companies outside of the pharmaceutical industry, physicians from renowned hospitals, academics, and patients. Venture capitalists were interviewed, because their expectation of a return on investment in 5-7 years gives them a good sense of where technology is headed. Headhunters provided insights on the new generation of people entering the workforce and what leadership might look like in the future. Clients and non-clients alike provided information on what they like about Rentschler Biopharma and what they think should be changed.

#### KEY TRENDS ANALYSIS

During the development of Strategy 2025, the key trends in the biopharmaceutical industry were identified and evaluated based on the input gained from these experts. A vast data pool was generated for in-depth analysis, giving us a solid platform from which to determine the path that the company should follow going forward.

Key questions we addressed included: What will the treatment of severe and rare diseases look like in 10-20 years? Will mAbs continue to be the major therapies of choice, or will the importance of cell and gene therapies increase even further?

Indeed, one key trend is the shift in the market to personalized medicine, particularly cell and gene therapies. The aging of the global population is another, particularly when combined with the fact that people today expect to remain active even during retirement. Meanwhile, the approach to health care by younger people is changing, because this group wants to remain healthy and prevent ever becoming ill in the first place. Finally, the increasing reliance on outsourcing by drug makers is particularly relevant for us as a CDMO.

#### THREE MAIN INNOVATION PILLARS

With the biopharmaceutical industry undergoing these significant transformations, Rentschler Biopharma recognizes the necessity of evolving to meet the changing needs of our clients. Strategy 2025 addresses all aspects of our development and manufacturing activities, from the platform technologies we need, to how our people will work in the future

and what our clients will expect from a company like Rentschler Biopharma.

When it comes to innovation, we are focusing on three main horizons to position Rentschler Biopharma as a partner of choice and add long-term client value: improving conventional biopharmaceutical development and production processes, building capabilities for designer biomolecules, such as bispecifics, and meeting the needs for new therapeutic modalities.

We are continually working to improve our processes so they help our clients reduce their time to market, including fit-for-purpose process solutions 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.

We are developing standardized platform processes that are pre-validated and pre-qualified, or at a minimum offer a simpler, streamlined pathway, minimizing risk and affording reduced development timelines. Integrated design and development are also combined with improved workflow strategies and approaches for streamlining unit operations, including automation and process intensification.

Our second priority is the further enhancement of our capabilities for producing more complex, designer molecules, including the capability to produce customized expression hosts and supporting bioprocesses in optimized integrated solutions that allow efficient assembly and stabilization of biomolecules with complex architectures. Our “smart” bioprocessing approach enables the creation of optimized, robust, and reproducible cGMP-ready bioprocesses from the start, leading to reduced costs, time, and effort.

Strategy 2025 also addresses innovative therapy areas that rely on technologies other than mammalian cell culture, most notably viral vectors for the production of gene and cell therapies. Further down the road, we may enter additional new fields through collaborations with companies that have similar management approaches and that fit well with Rentschler Biopharma.

Through our Strategy 2025, we have identified the steps that must be taken for us to remain a worldwide, indepen-

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dent, family-owned, and 100% dedicated CDMO offering flexible solutions and exceeding client expectations. We will be broadening our substantial knowledge of complex molecular entities into new biomolecules and modalities and expanding into regions where Rentschler Biopharma has not been very active in the past.

#### BETTER SERVING OUR CLIENT-PARTNERS

As part of our research on industry trends, we also learned that the main factors driving the selection of contract service providers – apart from quality – are close collaboration in strategic partnerships, as well as transparent communication. These attributes are seen as essential to facilitating further innovation along the value chain. Clients want to be partners with CDMOs that can provide support from concept to market.

This is why Rentschler Biopharma seeks to partner with our clients to develop optimal solutions for their complex and challenging products and processes. 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 rare diseases.

Enhancing the depth of this collaboration with clients is a fundamental aspect of Strategy 2025, which will lead to improvement of our relationships with our clients and the ability to provide stronger portfolio management support.

#### GROWTH THROUGH EXPANSION

In addition to identifying new areas for innovation and ways to improve client interactions, the Strategy 2025 planning process provided numerous insights into the organization of Rentschler Biopharma and identified opportunities for significant growth.

A key request of our North American clients was to establish a local site in the region. With about a third of revenue generated in the United States, we elected to acquire a site in that country. Early in 2019, we closed on a biopharma facility in Milford, Massachusetts near the renowned Boston biotech hub, giving us access to new technologies, a large talent pool, and the opportunity to exchange ideas with leading industry and academic experts.

The facility is FDA, EMA and Health Canada licensed. It currently supplies a market product for Shire/Takeda, and investments are underway to enable us to qualify it as a multi-product production site. Notably, it has flexible cleanroom capacity capable of expanding within the current footprint. A 500 L bioreactor and downstream processing train will be operational in mid-2020, and additional SU 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. Further expansion planning includes another building for large-scale SU manufacturing and lab capacity for new modalities.

In addition to the United States, Rentschler Biopharma is also experiencing significant growth in Asia, notably in Japan. In late 2019, we expanded our existing collaboration in Japan with Summit Pharmaceuticals International Corporation (SPI), a wholly owned subsidiary of Sumitomo Corporation. Through strong collaboration with SPI, Rentschler Biopharma has secured new contracts with Japanese pharmaceutical companies. We are working with SPI and Japanese clients to outline projects from early clinical stage up to commercial launch and ensure optimal service. Japanese pharmaceutical companies are playing an important and expanding role in the global healthcare market, and we are delighted to be continuing this productive collaboration as we grow our client base in Japan.

#### LEVERAGING STRATEGIC ALLIANCES

Strategy 2025 is also supported by Rentschler Biopharma's technology alliances, which are a key component of our innovation strategy. Our main goal is to offer our clients the best-available and best-fit solution possible. Hence, we seek out strategic alliances with other organizations that have best-in-class capabilities. Their offerings are integrated seamlessly into our business processes. 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; their time to market is reduced significantly.

Our alliance partners also continue to conduct their own business interactions and further develop their knowledge and offerings, which often benefits us 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.

One example is our alliance with LEUKOCARE, which is the exclusive formulation developer for Rentschler Biopharma, offering a database-driven approach with maximum design space for antibody stabilization. We have had 10-12 clients in just the last few months benefit from more effective formulation development through this collaboration, providing them tremendous commercial advantage.

We fully expect to expand our strategic alliances going forward. Potential areas

of opportunity include partnerships in early discovery, cell-line development, modification and bioconjugation of antibodies, and the packaging and logistics of finished products. A significant goal is to position Rentschler Biopharma as a CDMO that can support our client-partners with services from gene to patient.

#### DEVELOPING COMPETITIVE ADVANTAGE

Rentschler Biopharma's Strategy 2025 is our manual to develop further competitive advantages as we grow the company into a leading biopharmaceutical CDMO. We will continue building strategic capacity to meet the needs of emerging life-saving therapies. We will also continue investing in our partners to develop mutually successful alliances so that together we can drive supply excellence for reliable delivery to the patient.

We will become highly agile, simplify our interactions with clients, reduce time to market for the highest-quality biologics – from conventional proteins to highly complex biomolecules and viral vectors – and establish ever stronger partnerships with our clients. Our business models, services, and talent will continue to rapidly drive client projects from concept to market execution. As a result, Rentschler Biopharma will be highly sought by companies looking for a premium outsourcing partner to convert medical research into outstanding treatments. ■

#### ABOUT THE AUTHOR



#### Frank Mathias, Ph.D.

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In 1991, **Dr. Frank Mathias**, a freshly graduated French pharmacist of the Paris VI University, entered the German pharmaceutical industry, the largest at the time. Since then, he was able to experience different corporate and leadership cultures in multiple management positions: from then global giant Hoechst AG, via family-owned French Servier, followed by American top Biotech Amgen, to publicly listed German Medigene AG — leading him to Rentschler Biopharma SE as CEO in 2016. As Chairman of vfa bio, he is representing German biotech industry interests. Frank champions long-term strategic growth in the biopharmaceutical industry.

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