Published on *chemanager-online.com* (https://www.chemanager-online.com)

19.02.2020

Outsourcing Services: from Gene to Patient

Rentschler’s Contribution to the Development and Global Availability of Innovative Biopharmaceuticals

Rentschler Biopharma SE, headquartered in Laupheim, Germany, is a leading, family-owned, full-service biopharma CDMO. Owing to agile decision making and efficient processes, Rentschler Biopharma is the preferred outsourcing partner for bioprocess development, cGMP manufacturing, as well as elaboration of product approval strategies for over 150 clients worldwide. With about 1000 employees, the company has set its sights on highly ambitious goals. Michael Reubold asked CEO Dr. Frank Mathias to elaborate on the development plans for the company and the market trends underlying the strategy.

CHEManager: Since its beginnings almost a century ago, Rentschler has been active in biotechnology and has made a name for itself with the development of various interferon products. How do you assess the general conditions (and how they change over time) for biotechnological production in Germany?

Frank Mathias: Germany was and remains an important player in the global biotechnological landscape, as reflected by the 11.7% increase in domestic revenue generated by biopharmaceuticals last year. Details are presented in the Biotech-Report 2019 provided by Boston Consulting Group for vfa bio. With each passing year, the complexity of manufactured biopharmaceuticals is increasing, we are constantly moving from simpler to so called designer molecules. Hence, developing an innovative biopharmaceutical product demands substantial time (up to 10 years) and resources (more than $1 billion). To confidently make an investment of this scale, pharma and biotech companies need a reliable framework that enables innovation and fuels advancement. In this respect, Germany currently lags behind countries such as Singapore, South Korea, or even European neighbors such as Austria and Ireland.

In order to get back in the lead, the German framework supporting the cycle of innovation, comprising of research, development and manufacturing needs to be strengthened. This translates to working on three levels.

Firstly, Germany must be positioned internationally as an attractive healthcare hub. Modernizing education and training, embracing Industry 4.0, fostering favorable conditions for innovation, optimizing approval authority timelines, promoting the translation of scientific ideas to products via funding programs, incubators and startup initiatives, are the immediate steps to be taken in this direction.

Secondly, more innovation capital needs be mobilized for research within Germany.

Introducing research tax incentives, boosting venture capital via additional investors, mobilizing equity capital, drawing inspiration from best practice national venture capital case studies, providing a robust legal framework for investment is indispensable to this objective.

Thirdly, we must make the most of all opportunities for better healthcare and work towards a holistic patient-centered approach. Improving inpatient diagnosis via reimbursement regulations, encouraging registry data acceptance, safeguarding physician autonomy and therapeutic diversity, advancing digitalization in health care and further strengthening the stakeholder network in the healthcare system are essential in this regard.

The German Government has set up initiatives such as the “High-Tech Strategy 2025”, “Agenda “*Von der Biologie zur Innovation*” (from Biology to Innovation), “National Decade Against Cancer”, “Agentur für Sprunginnovation” (Federal agency for the promotion of disruptive technologies). If run effectively and sustainably, these could contribute greatly to make Germany fit for the future.

Germany has long since lost its position as the "pharmacy of the world". New drugs and therapies are increasingly based on biological molecules. How competitive is Germany in the global biopharmaceutical market?

F. Mathias: Indeed, Germany once enjoyed the well-earned reputation as the world’s pharmacy, boasting of big domestic players like Bayer, BASF and Hoechst. Today, Germany is Europe’s largest and the world’s fourth-largest pharmaceuticals market. The country may have lost its top international ranking but is still very much relevant and significant on the global scene. Germany is the European leader in clinical trials and ranks second only to the USA on the global front. The German pharmaceutical sector has enjoyed market stability and benefited from being at the

leading edge of research, with proven excellency in production and optimum market access. These factors play to Germany’s advantage as reflected in the fact that it is the world’s second largest producer of biopharmaceuticals. We are known the world over for being the best in API manufacture. “Made in Germany” is not just a stamp, it is a promise, a guarantee of the highest quality. In order to sustain and improve our international standing, we must immediately commit to investing in and strengthening the supportive framework that I elucidated in my previous answer.

The development of new drugs has also changed considerably. Contract development and manufacturing organizations such as Rentschler Biopharma have become an elementary part of the pharmaceutical value chain and compete for profitable projects. How do you position Rentschler Biopharma in this highly competitive market?

F. Mathias: Our Strategy 2025 gives us a head start in today’s volatile and highly competitive biopharmaceutical CDMO landscape. What sets Rentschler Biopharma apart is our guarantee for providing high-quality premium solutions for even the most complex challenges. We have successfully manufactured over 100 varied formats; spanning fusion proteins, recombinant enzymes and multi-specific antibodies. Our unrivaled expertise, founded on more than 40 years of biotech experience, ensures success through early stage development as well as clinical and commercial manufacturing. We see our clients as partners, and our best-in-class services as an extension of their operations. Owing to this client centric approach our consulting support, be it project management or regulatory support is difficult to surpass. Quality excellence is a mindset at Rentschler Biopharma, and our international top talent drive our vision forward every single day keeping us and our clients ahead of the curve in this rapidly changing landscape.

In its Strategy 2025, Rentschler Biopharma's management has formulated where the company's journey will take it in the coming years. Can you briefly outline the plans and goals?

F. Mathias: Strategy 2025 maps our journey to the Rentschler Biopharma of tomorrow, and what we want to achieve in order to continuously offer our clients premium CDMO services in the near future and beyond. In order to design our place in the future, we extensively analyzed 12 megatrends that will shape society and industry in 2025. We then distilled their implications for the biopharmaceutical industry, and what that specifically meant for us as a CDMO. Based on these insights we plan to concentrate on three strategic dimensions.

The first of these is growth through geographical expansion. Our American clients, accounting for about a third of our revenue, requested for a regional site. We met this need by the acquisition of a 93,000 square foot biopharma facility in Milford, Massachusetts in early 2019. In October 2019, we intensified our longstanding collaboration in the Asian market with Summit Pharmaceuticals International Corporation , a wholly owned subsidiary of the Sumitomo Corporation. We can hence offer our outstanding services from early stage development through clinical and commercial production for an increasing number of clients worldwide.

Our second strategic dimension is strong client-partnering. We are aware that retaining our position as a premium contract service partner means providing superior quality, simplified processes and transparent communication to nurture close strategic collaborations with our clients. We see our clients as true partners and we will work even more closely with them at every step to plan, develop and implement best-fit solutions for their next generation biologics.

Best-in-class innovative services is the third dimension that we plan to concentrate on. We are a highly experienced CDMO with more than 40 years of experience in the business. We are a forerunner that has successfully produced more than 100 formats and about 300 molecules, but we choose to not rest on these laurels. We are investing in three directions: firstly, by advancing conventional biopharmaceutical development and manufacturing; secondly, by fostering know-how in the field of designer molecules such as bispecific antibodies; and lastly, by looking into innovative therapeutic modalities such as viral vectors for gene and cell therapies. The primary goal of Strategy 2025 is to embrace the future through a comprehensive transformational process that will give us and our clients a competitive advantage in the everchanging biopharmaceutical landscape.

Just over a year ago you acquired a development and production site in Milford near Boston, USA, which you are now expanding. What plans do you have for your first US biotech hub?

F. Mathias: Our first U.S. subsidiary, located in Milford, MA within the Boston Biotech Hub is on its way to being developed into a center of excellence: a multiproduct production site to fulfill the demand for high-quality biopharmaceuticals in North America. The fully FDA-audited facility in Milford possesses a consistently favorable inspection history (FDA, EMA, and Health Canada) and offers flexible cleanroom capacity with capabilities to expand within the current footprint and 93,000 square foot site. We have embarked on our expansion plans by putting a 500 L single-use reactor as part of the state-of-the-art

GMP facility suite concept in operation. The bioreactor and downstream processing train is currently being prepared for technology transfer and will be operational in mid-2020. Another building for large-scale single-use manufacturing with bioreactor capacities up to 2,000 L will be added shortly thereafter. Our new site will be dedicated to the exploration of new technologies and innovative solutions, parallel to ongoing client projects. Rentschler Biopharma will be able to leverage its client-centric approach and expertise in advanced technologies to facilitate the robust and scalable production of complex biopharmaceuticals.

Today, the USA is the most innovative and lucrative market for pharmaceuticals, especially biopharmaceuticals. How do you intend to exploit the opportunities there in the future?

F. Mathias: Our U.S. presence allows us to better serve our clients across the Atlantic because of an even closer collaboration and exchange. In addition to that, we plan to make the most of the access to innovation and newest technologies that this geographical presence offers us. The proximity to the Boston Biotech Hub translates into the availability of a large and diverse talent pool and the opportunity to spar with leading experts from industry and academia. This will help us constantly push the envelope and offer even better services to our global client-partners from early-stage development through clinical and commercial production.

In order to establish yourself as a full-service solution provider, you also use technology partnerships such as the one with LEUKOCARE AG in the area of formulation development. Are you planning further such additions?

F. Mathias: Our technology alliances are a key component and integral part of our 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, 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. Indeed, a great example is our alliance with LEUKOCARE AG, 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.

What role does technological competence in process development and production play for your clients?

F. Mathias: Technology goes hand in hand with the development and production of high-quality biopharmaceuticals. We ensure outstanding solutions for difficult to manufacture proteins of all formats by leveraging our state-of-the-art facilities. Our experts bring a blend of scientific acumen, technological leadership and established experience that is second to none in the industry. We are strongly anchored in science and technology as we employ scientific talent across all processes ranging from business development to the in-lab analytical departments. I would not be exaggerating when I say that we always find the best solution of the highest quality for every client product, however complex it might be. This is a claim that not many CDMOs can make today.

Do your clients expect above all reliability in project execution or also an innovative contribution?

F. Mathias: We deliver our clients a combination of both. Allow me to elaborate. Rentschler Biopharma is synonymous with best-in-class project management across the industry, because we reliably guarantee budget and timeline adherence, leading to minimal plan amendments for our clients. In addition to that, we are innovation leaders. This might not be expected from a CDMO that is 100% dedicated to the client’s pipeline. However, at Rentschler Biopharma, we strive to continuously improve our offering, our process, ourselves every single day. Our clients expect us to implement trends and to make the newest technologies available to them. For example, the trend digitalization. We have embraced digitalization at all levels within our organization making our processes transparent and boosting efficiency. This benefit has been further extended to our clients by making project related information and analyses readily available to them. To remain at the forefront of market innovations, we have established an innovation strategy to continuously evaluate novel advances, and elevate our services. We have very exciting projects in our pipeline, and I look forward to sharing these with you in the near future. We don’t limit our innovation to ‘just’ superior process development and

manufacturing, but also excellent project management and regulatory compliance. This takes the services that we offer our clients to a whole new level.

What are the advantages of a family-run medium-sized CDMO in this market, and where do you see disadvantages due to your size?

F. Mathias: Rentschler Biopharma is a family-owned company in the 5th generation, renowned for its company culture and quality of leadership. This reflects in our vision, our strong work ethics, passion and commitment towards clients and employees alike. As a medium-sized company, we cannot invest as rapidly as larger companies, but we plan more sustainably. Our framework gives us the independence and freedom to plan a future, which is not exclusively driven by short-term financial gains. We see that this approach is paying off. In 2019, Rentschler Biopharma was featured for a second year in a row on the annual list of Germany's best employers, published by the F.A.Z. Institute. The analysis evaluates the largest German companies from over 150 different sectors for their reputation as employers. Of the 10,000 companies included, 503 were recognized as top employers. Rentschler Biopharma once again ranked number two in the biotechnology sector. In October 2019, Prof. Dr. Nikolaus F. Rentschler, chairman of the board, and I were jointly named "Entrepreneur of the Year" in the category "Industry" by Ernst & Young. These achievements are a clear reflection of our dedicated employees, committed to providing high-quality best-fit solutions for our client-partners and reinforce our belief in our business model, and hence we choose to remain independent and privately owned.

Personal Profile
Frank Mathias studied pharmacy at Paris VI University, where he received his doctorate in immunology in 1991. He started his professional career at Hoechst before working as managing director at Servier and Amgen in Germany. He then moved to Medigene, where he was initially COO and from 2009 CEO. Mathias has been CEO of Rentschler Biopharma since 2016. As Chairman of the Board of the Interest Group for Biotechnology (vfa bio), the native Frenchman is a member of the Executive Committee of the Association of Research-Based Pharmaceutical Companies (vfa).

Autor(en)

Interview with Frank Mathias, CEO, Rentschler Biopharma

Kontaktieren

Rentschler Biotechnologie GmbH
Erwin-Rentschler-Str. 21
88471 Laupheim
Germany
Telefon: +49 7392 701555
Telefax: +49 7392 701521