



## German CDMO Forms "Smart" U.S. Subsidiary

*Rentschler Biopharma's first facility outside Germany will focus on process innovation, production of designer biologics*

By **Gail Dutton** (<https://www.genengnews.com/author/gaildutton/>) - February 1, 2020

In the pharmaceutical industry, many products have been launched using well-established processes. But if new products are to reach greater heights, these processes must be improved. What's needed isn't rocket science, exactly, but something almost as challenging. What's needed is the boost that only smart, interconnected technologies and real-time analyses can deliver. That's the governing philosophy behind a facility that is being built by Rentschler Biopharma, a contract development and manufacturing organization (CDMO).

The facility is located near Boston in Milford, MA, and it is Germany-based Rentschler Biopharma's first manufacturing site in the United States. It is, the company indicates, committed to continuous innovation. "The Milford site isn't an extended workbench of the German site," declares Ralf Otto, PhD, COO of Rentschler Biopharma SE and president and CEO of Rentschler Biopharma, Inc. "Instead, it's both a CDMO and an innovation center."

The facility, which Rentschler purchased from Shire (now part of Takeda Pharmaceutical) early in 2019, currently manufactures the hemophilia A therapy Obizur® (antihemophilic factor [recombinant] porcine sequence) for Takeda. So, with a scientific and manufacturing staff already in place, Rentschler can focus on expanding the site's capabilities and footprint.

"We want to host clinical and commercial manufacturing programs in production process development," Otto says. "We will focus not only on standard proteins, but also on multispecific antibodies and other designer biologics. We always aim for a high proportion of designer biologics in our portfolio," favoring innovation over high throughput.

### Building the "facility of the future"

The smart, interconnected technologies being built into the Milford facility are integral to the vision Otto describes. "The current site," Otto emphasizes, "is built both as an existing facility and a 'facility of the future.'" To achieve these dual goals, Rentschler is investing in

process improvement. For example, the company "will reshape the labs with brand-new equipment, connecting them with digital solutions," Otto explains. "We call this PD Labs 4.0."



*When purifying proteins, Rentschler Biopharma uses technologies such as chromatographic separation (as indicated by this image), filtration and extraction, virus inactivation and removal, and protein modification.*

"The next layer is our ToxBox," he continues. Otto says this new concept features "extremely fast access to tox materials for tox studies." Then, for production, the facility's bioreactors work in parallel rather than singularly.

Rentschler is deploying and networking sensors throughout the production process. "We're building in real-time data analysis and providing clients access to it online," Otto points out. "By leveraging this data, our clients achieve faster optimization and higher yields. We also get feedback on the products once they are on the market and in use with patients, and we learn from that." This also means that clients needn't station a person "in plant" to gain real-time insights into production.

Rentschler's smart manufacturing approach accommodates built-for-purpose design solutions. "New concepts can shorten development time by removing bottlenecks and, therefore, time to clinic," Otto asserts.

This smart "facility of the future" is being built out next to the existing production facility, and it is expected to be in operation by the end of 2021. Currently, the new facility is preparing to take on new processes and products and is hiring additional personnel to build the skills needed to transfer projects from clinical to commercial status.

"Key steps include building up the process science and process development labs, and strengthening quality and manufacturing processes," Otto emphasizes. "The facility itself is flexible upstream and down." One 500-L disposable bioreactor was delivered last fall (2019) and is planned to be in GMP service this spring. Eventually, the facility may house up to four 1000–4000-L reactors. And by opting for prefabricated cleanrooms, the site gains the flexibility to move those modules throughout the facility as needs change.

One of the company's goals, Otto says, is for "Milford to be a strong, independent site that generates as much business as our Laupheim site" within the next few years. To that end, each client "is not just a contract," he insists. "We approach clients with very tailored solutions. We serve large, medium, and small companies, so it's important to offer the features individual clients value, such as flexible access, speed to clinic, reliability, and high-tech solutions." For example, the company can offer single-batch production and almost single-patient supply to meet the needs of rare disease clinical trials throughout the world. "One client," Otto notes, "has only 24 patients for one of its products, with 1 patient in China and 3 patients in Russia."



*Rentschler Biopharma's biomanufacturing services include upstream and downstream processing and quality control. In this image, company technicians are shown using an automated liquid chromatography system designed for process scale-up and large-scale biopharmaceutical manufacturing.*

The Boston area is the perfect location, says Otto, who used to live in California. (His previous position was partner at McKinsey & Company.) He recalls that when Rentschler was scouting locations, "We recognized that the services we offer are really needed here in

Boston. The area has a rapidly growing, dynamic biotech community, with more than 1200 biotech companies represented by the Massachusetts Biotechnology Council alone." Locating here enables co-development with world-class scientists and innovative companies in all stages of their growth. "And," he notes, "we are really welcome here."

### A fifth-generation family business

Rentschler's focus on innovation isn't new. Throughout its history, the company has consistently transformed itself. Formed 120 years ago as a pharmacy, it reformed in 1927 as a pharmaceutical manufacturer in Laupheim, Germany. It launched its biotech division in 1974. "Later, in 1997, it pioneered the biotech CDMO business," Otto adds, "and it began viral vector research earlier than others, too."

Reinvention, he explains, is fundamental to the company's strategy. He attributes this to owners who lead by example: "Our mindset is to turn challenges into opportunities. That frees people to take risks." Innovation and transformation ensue.



*Last year, Rentschler Biopharma acquired a manufacturing facility from Shire to establish a foothold in the United States. The facility, located near Boston in Milford, MA, is to serve as an "innovation center" focused on designer biologics.*

The Milford facility is an example. In the 10 months since closing the deal for the Milford facility, Rentschler ordered new equipment, broke ground to expand operations, and began filling key positions in the new organization. Notably, it retained most of the staff from the Shire facility. "I'm surprised at how enthusiastic the (inherited) workforce is about the new mission and vision," Otto admits. That comes back to mindset.

"We don't talk about integrating facilities or assimilating staff. Instead, we optimize," Otto says. "We aim for the best solution." Locating a new facility so far from headquarters brings fresh eyes and fresh thinking to issues. "Many new ideas will be tested here and then pushed to Laupheim," he predicts.

The challenge now is patience. "We are entering new areas, with new technologies and services, so the worst thing we could do is to go too fast," he maintains. Potential clients know Rentschler's reputation in Germany and are used to working with that site. To some, a new site is disconcerting. To erase their concerns, Rentschler has hosted an open house and an Oktoberfest celebration, inviting potential clients to get to know the new site and its position in the Rentschler network.

## Rentschler Biopharma

**Location:** 27 Maple Street, Milford, MA 01757

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**Principal:** Ralf Otto, PhD, CEO, Rentschler Biopharma, Inc. and COO of Rentschler Biopharma SE

**Number of Employees:** 100

**Focus:** Rentschler Biopharma, Inc., the U.S. subsidiary of Rentschler Biopharma SE, is a CDMO that specializes in developing novel biologics, including multispecific antibodies and other difficult-to-manufacture proteins in a state-of-the-art GMP facility.

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