How Science Helps Manufacturing Evolve To Meet The Complex Challenges Of Drug Development

In 2022, the worlds of technology and science will continue to merge at an unprecedented rate, allowing for the faster development and delivery of novel patient-centric treatments, such as cell and gene therapies. But novelty is naturally accompanied by risk. It is critical that biopharma companies collaborate with innovative manufacturing partners in this evolving environment.

Agility and flexibility are the keys to a successful manufacturing system. Almost two decades ago, the US FDA set out its Pharmaceutical Quality for the 21st Century initiative to support a successful, agile and flexible global manufacturing system. While substantial improvements have been made over time, the COVID-19 pandemic has given rise to a unique period of growth and innovation.

Mitigating Risks Through Scientific And Technological Expertise

Rentschler Biopharma SE is supporting clients as they seek efficient and innovative manufacturing approaches for novel drugs. Dr. Christian Schetter, Rentschler Biopharma's chief scientific officer, highlighted two different kinds of risk to mitigate in order to avoid the costs of failure. "One is a technological risk, which often you cannot avoid because success is determined by trial and error of new modalities or therapies. There is usually no alternative to go through a well-thought clinical development program to ascertain the proper questions to ask. Dr. Schetter noted that execution risks were often the most prominent reason why great ideas fail early in the process, but these can be minimized by expertise. By collaborating with the right partners at the outset, companies are able to focus on where they want to be at the end and develop robust processes for manufacturing.

This is where Rentschler Biopharma sees its role in the industry. The company has built strong foundations based on incorporating technological and scientific innovations into its processes. Assessing the current and future industry outlook, Rentschler Biopharma has integrated digital technologies, single-use manufacturing and flexible production to handle the challenges of today's biopharmaceutical developers. Tailored processes in bioprocess development and cGMP manufacturing, flanked by strategic expansion, result in optimal timelines while achieving and maintaining high productivity.

Well-versed in combining science and technology for manufacturing success, Rentschler Biopharma is able to minimize risk for clients, as well as assist its partners in asking the right questions at the right time.

There has been a shift in the industry to focus on therapies that require more advanced manufacturing. To remain the partner of choice, Rentschler Biopharma's commitment to staying at the cutting-edge of science means it has noticed significant benefits, such as gains in speed and reliability in processes. Dr. Schetter noted that often clients came to Rentschler Biopharma because of its ability to rapidly develop products. All drug developers are seeking ways to speed up R&D – to get a product from bench to patient faster and in a more cost-efficient manner. COVID-19 vaccines are a prime example of how R&D timelines can be reduced significantly through technology and close collaboration. Dr. Schetter highlighted Rentschler Biopharma's expertise in the manufacture of complex molecules, an expanding area of importance for the innovative drug development sector is it grows away from small molecules toward biologicals and modalities that can be selected and personalized to the appropriate therapy for a patient.

Shaping The Technological Horizon

For the rapid development of groundbreaking therapeutic approaches, standardization within both bioprocess development and manufacturing plays a central role. As the evolution of the biopharma market continues, with a focus on complex molecules, Dr. Schetter saw the greater use of technologies "which digitalize both the production and distribution processes."

The steps can be incremental, such as going paperless and digitizing lab testing records. Besides the initial benefits, "new advances in equipment connectivity allow direct transcription of thousands of data points without any manual data transcription or reviews, and this is clearly reducing the source of manual errors and variability, as well as allowing much faster and effective resolution of problems."

Furthermore, Rentschler Biopharma aims to offer its clients the best technology and solutions along the entire value chain by collaborating with strategic partners that provide complementary services. This sense of collaboration has been an integral part of the company's strategy – as demonstrated in its partnerships with Vetter and Leukocare – and is a growing trend across the life sciences industry. During the pandemic, the life sciences sector saw a number of new collaborations, pairing up big pharma, CDMOs, government and regulators in a new way. Industry leaders have expressed a desire to see this greater collaboration and newly effected lines of communication stay active after the pandemic subsides.

Meeting The Evolving Needs Of Biopharmaceutical Production

Rentschler Biopharma continues to grow in response to the market's increasing demands, by expanding cGMP manufacturing capacity. In August 2021, the CDMO announced a significant expansion of its existing U.S. production site within the Greater Boston area. A new production facility, the Rentschler Biopharma Manufacturing Center US (RBMC US), will add 22,000 square feet to the existing footprint and include four 2,000l single-use bioreactors for easy clinical to commercial scale-up capabilities. The RBMC US has been designed specifically to accommodate future scalability and capacity needs and is due to be operational in 2023.

Looking ahead, Rentschler Biopharma is also evaluating and exploring new modalities with the formation of Rentschler ATMP Ltd. located in the UK. Dr. Schetter explained that this facility is "preparing for cGMP, small scale manufacturing of Adeno-associated virus (AAV), as a means for providing cGMP viral vectors to our clients for gene therapy." A key bottleneck that has previously affected the speed of development and manufacture for gene therapy companies.

Considering innovations in technology and science that will be beneficial to the manufacturing sector, Dr. Schetter offered key insights. He specifically pointed out that the right blend of scientific advancements into technology is necessary to be able to effectively use a modular and flexible manufacturing design. "I think the continuous increase of online and inline monitoring capabilities, in combination with computational modeling, is just a fascinating field which is leading towards a better understanding of how technical limitations may potentially interfere with product quality." As this field continues to grow, product quality can be modeled to minimize material waste and time consumption, which are major advantages. Also, as a standard, Dr. Schetter suggested that constantly increasing product titers and quality with the application of next generation cell line development platforms, in combination with new process formats like intensified or fed batch or continuous manufacturing via perfusion, will be the new standard.

Overall, the biopharmaceutical industry is working hard and working together with expert partners to raise known standards while meeting the complex challenges of next-generation drug development.

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