

Bachem Innovates its Manufacturing Capabilities

Interest in oligonucleotide therapeutics has grown, as has the market demand, since their emergence as a new drug modality two decades ago. Initially focusing on rare diseases, oligonucleotide therapeutics are moving into more common chronic indications like asthma, diabetes, chronic renal failure, as well as cardiovascular and liver diseases.

The need for large-scale manufacturing to support market requirements for oligonucleotides has never been so high and is coupled by the emergence of new challenges related to scalability, sustainability and cost. Bachem is the leading CDMO for oligonucleotide and peptide manufacturing and has been rising to these challenges in a number of ways to support the best their customers in drug development and commercialization.

Bachem's new oligonucleotide manufacturing facility provides innovative solutions for large-scale oligonucleotide API (active pharmaceutical ingredient) production.

Customizations, such as in-line mixing of dichloroacetic acid (DCA) solution—enabling the right amount of DCA to be transferred and avoids side reactions, ensure a more efficient process and results in a high-quality crude API. The production line is also equipped with the first MCSGP (Multi-column countercurrent solvent gradient purification) equipment for large-scale continuous chromatography. This set-up brings significant benefits such as time optimization, cost-efficiency, and lower solvent consumption during the purification step.

A focus on Industry 4.0, the automation and digitalization of traditional industrial processes through smart technology and integration, is a key industry trend. Bachem sees digitalization as an enabler to meet



uncertain demands, compliance and ambitious timelines to deliver high-quality APIs. Within this concept, a “smart factory” is characterized by machines which are interconnected, and interoperable, and can process data autonomously. Such “smart factories” require only limited human decision-making or intervention and are therefore sometimes referred to as “intelligent automation”. Entering Industry 4.0 and developing the Bachem “smart factory” represents a big step forward in providing their customers with more flexibility, consistency and speed in manufacturing.

Bachem has primarily been focused on automating and digitaliz-

ing solid phase peptide synthesis (SPPS). This improves the reliability of the process, reproducibility of results and safety, while significantly increasing the cost-effectiveness of operations. Major innovations, such as a robot-operator, called BALU (Bachem Amino acid Loading Unit), and Process Analytical Technology (PAT) have recently been rolled out.

BALU was designed and programmed to support commercial scale of SPPS. The robot handles the containers with the amino acid powders and can perform the powder transfer into the activator vessels for Bachem's 150L SPPS reactors without the involvement of an operator. BALU can perform other critical tasks, such as cleaning the amino acid transfer port to prevent cross-contamination. A barcode scanner that reads the labels placed on the amino acid containers ensures correct handling.

PAT performs inline analytics after key steps. PAT removes the need for manual In-Process Controls (IPC) and provides a better control of Critical Process Parameters (CPP). Additionally, this automated process enables data recording and analytics as well as paper-free cGMP documentation. Implementing PAT to their process control decreases human contributions and cost of goods. Manual tasks

are no longer required, freeing resources for other tasks and projects. Furthermore, PAT leads to a higher reproducibility with minimized chemical side reactions.

Continuous innovation is key to transform oligonucleotide and peptide manufacturing and ensure a high-quality, sustainable, and cost-effective process. Investments in new production facilities and into automation of traditional processes enables companies to utilize assets more efficiently and streamline production scheduling for a higher capacity and flexibility. Bachem will continue to drive innovation, set high industry standards and expand their capabilities to help their customers in transforming patient's lives.



BACHEM

Bachem AG
 Hauptstrasse 144
 4416 Bubendorf
 Switzerland
 Tel.: +41 58 595 2020 (Sales department)
 sales.ch@bachem.com
 www.bachem.com