Manufacturing Complex Peptide APIs

There is more to creating APIs for generics than simply following a recipe. The support and services around the molecules are critical. Customers need to be able to rely on passion and expertise to offer all the ingredients for a successful API supply experience and successful launch, and make generics accessible and affordable to patients all over the world.

Going the extra mile helps to stand out in the competitive generics landscape. Customers can focus on their masterpiece, while CDMOs like us are taking care of the rest!

Read the interview from Sergey to learn more on what's behind the manufacturing of complex APIs.

The generics space is a very dynamic and growing market. What are the challenges that face the generics landscape?

“The main challenges that generics companies face are to deliver the right products, at the right time, and at the right cost while thoroughly monitoring product safety. Therefore, it is of the utmost importance that you find the right partner to help your business to successfully deliver the generic masterpiece. It is well known, that it needs more to create active pharmaceutical ingredients (APIs) for generics than than simply following a recipe, especially for complex APIs. The expertise and support services around the molecule are critical to ensure a successful launch. Having this in mind customers need to be accompanied throughout the whole process from manufacturing to regulatory and delivery.”

What does a CDMO like Bachem offer to meet these challenges?

“These challenges aren’t typically solved by a single service offering, but through a multidisciplinary approach, which enhances commercial success through innovation and operational excellence and manages risk, regulatory, and compliance issues. With more than 50 years of experience, we have built outstanding regulatory expertise to provide a complete generic API package to meet your needs. Innovation is imperative to continuously improve our processes, and thus their efficiency. Exploring new technologies to meet emerging generic API opportunities at high quality, minimized lead time, and the right cost.

Providing customers with a full package for generic APIs to answer their needs

- Extensive and evolving catalog
- Comprehensive documentation
- Regulatory know-how
- The right scale for you – with reliable timely delivery from mg to tonnes
- Some of our starting materials are manufactured internally

Understanding this and going the extra mile to offer comprehensive services and an all-around positive experience for customers is key.”

Among the complex peptide API portfolio, GLP-1 analogs like liraglutide or semaglutide are currently of high interest in the generics market. How do you ensure an efficient and high-quality production of these molecules?

“Originally, liraglutide and semaglutide are produced at industrial scale using genetically modified organisms – the so-called recombinant method. With decades of experience in peptide synthesis, we were able to develop a robust and scalable commercial GMP process to manufacture them synthetically via solid-phase peptide synthesis (SPPS).

This process combined with quality by design approach and efficient purification methods, we obtain these APIs with high purity and minimized batch-to-batch variations. With this, ensuring a strict control of every individual impurity and aggregation behaviour. Then, the sameness of the generic API with the original drug substance is proved with a combination of multiple sophisticated orthogonal analytical methods. It allows making a detailed comparison with the reference listed drugs followed by immunogenicity and toxicological studies for individual impurities.”

https://youtu.be/OsTX1mg0f5M

Sergey Malashikhin on generic active pharmaceutical ingredients such as liraglutide and other GLP-1 analogues

What part has innovation in the generic development?

“Innovation is a strategic pillar at Bachem. Innovation enables us to keep a technological leadership and offer customers world-class products and services. Being future-oriented is also what will help customers to remain competitive in the generic world.

So, we are constantly assessing and developing 2nd generation processes for our generics. We are increasing process efficiency, implementing the latest manufacturing and purification technologies to deliver large-scale quantities at a competitive price, yet without jeopardizing product quality and continuing to stay in line with the strictest regulatory guidelines.

Your product quality and patient safety always comes first.”

With more and more stringent requirements from authorities, how does Bachem ensure the successful filing of generics APIs?

“The FDA has issued very demanding guidelines for the development of certain highly purified synthetic peptides. To ensure compliance, a unique in-house expertise is a key asset in the complex APIs development.

As explained earlier, we are in the very good position where we can offer GMP material of excellent quality and no signs of aggregation behaviour, especially the latter being a common issue with GLP-1 analogues. You can select a full package of services around the generic API and there are more than 80 DMFs available worldwide.

The regulatory affairs experts are highly experienced and communicate with authorities on a regular basis. We do everything to ensure a smooth registration process for your final drug product.”