

Bringing a Biosimilar for Oncology to Market Case Study

Journey from Early Development to Commercialization

The Challenge

A large Indian biopharmaceuticals company contacted West for a packaging recommendation while in their early stage development of a monoclonal antibody biosimilar for oncology treatment. The manufacturing of biosimilars is a complex process, requiring extensive controls to ensure not only that the products being developed are high quality, but that they are also similar to the innovator's biologic drug. The company needed a stopper that they could rely on to maintain the high-quality standards needed for the success of their biosimilar and pipeline of future biosimilar products.



The Considerations

The company wanted to use packaging for its oncology biosimilar that closely resembled what the innovator was using in terms of quality, performance and appearance. The organization's overall strategy was to bring biosimilars to regulated markets, such as the US and EU, after launching first in emerging regions. Since developed markets often have tighter regulatory scrutiny for approvals, the customer recognized the importance of maintaining the highest quality standards for their drug treatments, which included decisions around their manufacturing process and selection of their packaging needs.

As the company was in early stage development work, they only needed very small quantities of premium quality stoppers to support their operations. Additionally, they were looking for a supplier they could rely on for: providing technical expertise in biologics packaging and guiding them through the development process; delivering orders quickly; and working closely together to support a successful commercial launch.

The Solution

The company selected NovaPure® stoppers from the West's Ready Pack® component system. West's Ready Pack system includes ready-to-use stoppers, seals and vials designed to work together as an integrated system with proven container closure integrity, offered in small quantities for quick delivery. Customers have the flexibility to order the entire containment system or only the components that they need. This customer's primary need was for a high-quality stopper.

The Ready Pack system includes the NovaPure stoppers, West's premium line of elastomers, designed specifically for the use of biologics and biosimilars. NovaPure components were developed using Quality by Design principles, an approach recommended by many regulatory agencies for drug and packaging manufacturers when developing products to minimize risks and ensure patient safety. NovaPure stoppers are ready-to-use and fully vision verified, resulting in a consistent high-quality component with the tightest particulate specification of all West components. NovaPure stoppers are produced with FluroTec® barrier film, which is designed to maintain drug purity by reducing the risk of degradation and aggregation development. The use of FluroTec film in the biologics market is highly valued for its exceptional barrier properties, with over 65 of approved biologics and biosimilars¹, such as Monoclonal Antibodies and Proteins, using a FluroTec film-coated stopper.

As the company was initially focused on R&D activities, they only needed small volumes of components with a fast delivery to accommodate their timelines and key milestones. West's Ready Pack system was a perfect choice, offered in both serum and Iyo designs and in 13mm and 20mm dimensions in ready-to-use small packs, delivered quickly to customers from strategic stock held by West.

Another key benefit of West's Ready Pack system is the ease of transitioning the customer's drug product from clinical development through product launch. The customer transitioned from small scale volume of NovaPure stoppers via West's Ready Pack system to higher volumes needed post commercialization with no additional regulatory requirements. West partners with you on supplying larger volumes from our global manufacturing network as you transition through commercial launch, enabling your biosimilar and its packaging to maintain a consistent profile throughout the drug development cycle.

The company launched its biosimilar for oncology treatment with the NovaPure stopper in India and several other markets and went on to pursue approval of its biosimilar in the US. After launching a second biosimilar and focusing on increased development of new biosimilars, they made the strategic decision to transition to a platform strategy. They are now using NovaPure stoppers for their two marketed biosimilars, as well as pipeline programs for biosimilars and innovative biologics. The selection of West's Ready Pack system and NovaPure stoppers was an ideal choice for this customer, providing them with the assurance of:

- Protection of their sensitive biosimilars and biologics
- Confidence that the products they provide to patients are contained with packaging of the highest quality
- Compliance needed to meet stringent regulatory requirements for developed markets
- A packaging solution to accommodate all phases of the development timeline and successfully support a launch