

Daikyo Crystal Zenith®

Case Study

Meeting the Challenge of Viral Vector Delivery



The Challenge

During a Phase III trial, a customer reached out to West to help overcome challenges associated with providing a unique therapy that was to be delivered by a viral vector, which required a containment system capable of -80°C cold storage. While the customer was using cryovials for storage during trials, they felt that the therapy – which treats a rare genetic disease – needed a traditional system that could maintain container closure integrity during cold storage to make the move to market.

Considerations

The use of a viral vectors can be an excellent choice to delivery gene therapies. However, recombinant Adeno-Associated Virus (AAV)-based vectors, which are currently the most widely used and show the greatest potential for delivery in gene therapy indications, can be difficult to package and store due to requirements for low temperature.

In order to ensure container closure integrity and the efficacy of the therapy, West Analytical Services' experts were engaged to perform CCI, extractables and leachables, and risk assessment testing for the drug product and its containment system.

The Solution

Using a Daikyo Crystal Zenith® vial combined with a NovaPure® FluroTec® stopper and customized Flip-Off® Seal, as well as the expertise of the West Analytical Services team, the customer was able to confirm that the containment system was the right choice for this therapy. Choosing a readily available Crystal Zenith system enabled the customer to overcome challenges associated with glass breakage and cold storage, and move the product to market quickly once Phase III trials were completed.