

# Daikyo Crystal Zenith®

## Case Study

### Solving Breakage for High-Volume Delivery



#### The Challenge

Delivering a large volume drug is not easy – challenges include how to fill, deliver and scale-up production for commercialization. When an oncology-focused biopharmaceutical needed a solution to ensure stability and reduce the chance of breakage for a large-volume drug, they looked to West and Daikyo for help.

#### Considerations

The company was concerned that vials for a 100 mL drug volume would be difficult to fill and run on a filling line without breaking. Movement of such a large amount of material can be a challenge, so in order to ease concerns over breakage, the company and its CMO filling partner reached out to West to alleviate potential road blocks. Working together, the three companies gained a better understanding of the manufacturing requirements needed for proper filling, scale-up and commercialization. The team then collaborated to ensure that the filling line set-up and process would minimize the risk of breakage.

#### The Solution

Together, the partners determined that Daikyo Crystal Zenith® vials would solve issues and risk associated with breakage for the large fill volume. In addition, a Daikyo Westar® Ready-to-Sterilize stopper helped to ensure that internal processing at the CMO would run smoothly. Under West's guidance, the customer and its CMO achieved a strong solution that alleviated breakage concerns, and maintained project timelines to help ensure a smooth scale-up and ease the transition to market.