

Daikyo Crystal Zenith[®] PFS

Case Study

Seeking a Commercially Ready Delivery System



The Challenge

When drugs come off patent, generic manufacturers need to move quickly to gain a strong share of the market. Many generics manufacturers seek containment solutions that mimic the drug product's original packaging. In the case of a radionuclide imaging therapy, a ready-to-use engineered polymer prefilled syringe was needed to compete with the innovator's product.

Considerations

Seeking a commercially available equivalent to an innovator's containment system can be a challenge for any generic manufacturer. In this case, the customer needed a commercially ready system to meet critical launch timelines. There were challenges with many industry offerings not having a required updated Drug Master File and validated Ready to Use sterilization attributes. In addition, changes to fill-finish regulations meant loss of time and potential compliance issues.

The Solution

With the Daikyo Crystal Zenith[®] prefilled syringe, West was able to provide a commercially available engineered polymer solution that ensured compliance with the new regulations, and enabled the customer to move to market quickly.