## Daikyo Crystal Zenith® Solutions

# Case Study

# Avoid Delamination in Reconstituted Drug Products

### The Challenge

Once a lyophilized drug has been reconstituted, it may have a shelf life of days or just hours. In the case of drugs indicated for pulmonary arterial hypertension, once reconstitution has occurred, the drug must be used within a few short hours or be discarded, proving costly to manufacturers and end-users alike.

### Considerations

An approach to extending the shelf life after reconstitution is to change the drug's diluent. In this case, the manufacturer's new diluent had a higher pH, which in turn caused glass delamination, or flaking, of the glass primary containment system. Delamination occurs when thin layers of glass (lamellae) separate from a glass container and float within the reconstituted drug product. This can not only result in costly recalls for the drug manufacturer, but also may put patients at risk.

### The Solution

High pH solutions benefit from an engineered polymer containment system that ensures that the drug, once reconstituted, will not interact with its container. By choosing a Daikyo Crystal Zenith® vial or syringe as a primary container, drug manufacturers can extend the shelf life of reconstituted drugs without the risk of delamination. In this case, the drug manufacturer employed a Crystal Zenith® 50 mL vial for the new diluent, enabling the reconstituted drug to achieve a shelf life of days vs. hours, helping to reduce cost for the manufacturer and mitigate risk for the patient.



#10193a • 08/17