

Case Study

Seamless Scale-Up of Lyophilized Vial Products



The Challenge To scale-up three different products from our PDS lab unit to our GMP 7m² system while maintaining consistency.

The Solution The first product contained a recombinant protein, and as is common practice in lyophilized formulations of pharmaceutical proteins, a surfactant agent was included. This protected against surface-induced denaturation, minimized risk of aggregates in the final rehydrated product, and provided protection during rehydration.

The second product was a suspension of an oligopeptide formulated in a mixture of water and ethanol. Co-solvent systems were employed to increase the sublimation rate, resulting in decreased drying time.

The third product was a monoclonal antibody formulated in a buffer.

The Outcome The batch-to-batch consistency was excellent for all three products. All key product analytical properties, especially those sensitive to lyophilization, were maintained in the scale-up.

