

Envision™ Verification Case Study

Minimizing Drug Shortages of Life Promoting Medicine



The Challenge

An enzyme replacement therapy transforming the lives of recipients was in short supply across global hospitals, which created frustration for both patients and caregivers. In addition to the lost revenue associated with the high-value drug, the pharmaceutical manufacturer was also mindful of brand image damage. Because end of line drug rejects at the drug manufacturer were impacting the production yield and causing supply issues, the company partnered with West to initiate a project designed to increase the quantities of approved, finished drug.

The Considerations

Quick, cost effective changes were required to increase the yield. The team challenges a zero-defect specification in place at the drug manufacturer and replaced it with a new specification that fully evaluated patient risk. In parallel, the team conducted assessments for options for defect reduction without capital investment or time consuming regulatory filing changes.

The Solution

By adding Envision™ verification specifications to the approved Westar® RS stopper, the team was able to increase yield for the manufacturer. Working together, the team instituted changes within a six-month window – without a capital investment and with minimal regulatory impact. The result included a savings of several hundred thousand dollars per year and increasing supply – helping to restore a consistent patient drug supply to ease patient and caregiver frustration and restore the company's brand image.