Envision™ Verification
Case Study

Mitigating the Risk of Drug Recall

The Challenge
The manufacturer of a pediatric oncology medicine was issued an FDA warning letter for foreign contamination. The drug was already in short supply around the globe and, being a "last attempt" treatment, could not be pulled from the market. The concern around contamination created greater risk to patients who were already exceedingly ill. The pharmaceutical company was at risk of losing their global drug production licenses and experienced detrimental loss of reputation. A zero-defect specification at end-of-line inspection had been applied to production, which in turn had forced drug shortages of this "last attempt" medicine, as well as increased production costs.

The Considerations
Unfortunately, capacity for the active pharmaceutical ingredient production had been limited, with only one global site producing this potentially life-saving drug product. The pharmaceutical company's regulatory team raced to show the FDA a plethora of improvement activities; none of which could further decrease production capacity or overly rely on the in-house end-of-line inspection process. Upstream changes were rapidly required and a project team of West experts came together to investigate options.

The Solution
While the pharmaceutical company's original request of zero defects was beyond the limits of the Envision™ verification specification, a modified, very tight specification was evaluated to reassure the company that loose contamination and dispersion limits would meet the FDA's expectations. The evidence used with the FDA showed Envision verification to be a quick, cost-effective process change that made a significant impact to the overall reduction of contamination risk.

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