

# Envision™ Verification Case Study



## Taking Container Closure Integrity (CCI) to the next level

### The Challenge

A pharmaceutical company challenged itself to prove container closure integrity (CCI) once a vial of highly valuable drug was stoppered and sealed. As the study design evolved, the company needed to determine how a problem would be detected if the stopper detrimentally affected CCI. Since the vial was already sealed – making the stopper all but invisible – this posed a significant problem for the company.

### The Considerations

Using acceptable quality levels (AQL) to release primary packaging components onto the production line is a well-established and accepted method of quality control. The impact to drug sterility could, theoretically, be compromised if a defective closure that did not meet AQL slipped into production. This theoretical question around sterility resulted in the formation of a team to investigate further.

### The Solution

Working together, West experts and the pharmaceutical manufacturer determine that the only way to ensure total reassurance around sterility was to implement a move to 100% vision inspection in addition to AQL. West's Envision™ verification process provided that reassurance as an add-on service to the already approved stopper. With Envision verification in place at numerous global facilities, including that of the existing stopper production facility, the use of Envision verification was validated, seamless and gratefully received.

