West
By your side
for a healthier world™

A Risk Mitigation Solution

West Envision™ Verification Process

Contamination. Defects. Particulates. These issues can be a source of variability for container closure systems for injectable drug products and can put quality, performance and patient safety at risk.

QUALITY EXPECTATIONS ARE RISING

Recent trends have focused on reducing variability in the quality of elastomer components and in particular, around loose and embedded particulate. Recent guidance describes the expectation that injectable drug products be essentially free of visible particles.[1]

WHAT YOU CAN'T SEE CAN HURT PATIENTS

Contamination and imperfections associated with elastomer components are a source of risk, especially for areas that are not visible when the component is positioned in the container. When a defect has not been detected, quality and patient confidence may be affected.

PRODUCT SPECIFICATIONS MAY NOT BE ENOUGH

Visual defects may result in costly line stoppages and end-of-line product rejections — not to mention increasing the risk of patient complaints or even product recalls. FDA data shows that nearly 25% of injectable drug recalls from 2008 to 2012 were due to particle-related issues.[2]

MAXIMIZING EFFICIENCY

You can optimize your manufacturing throughput to minimize end-of-line rejects, waste and loss of product while helping to ensure patient confidence. Select elastomer components that are 100 percent automatically vision verified.

ENVISION PATIENT CONFIDENCE AND SAFETY

Patients expect high-quality, effective drug products. West Envision verification provides a higher level of quality assurance, product consistency and control so that you can reduce your risk of returns and recalls, and ensure patient confidence and safety.

Talk to your West representative and choose the right option for your product, and ultimately, for your patients' health.

References: 1. General Chapter <790> visible particulates in injections. USP 37/NF 32; US Pharmacopeia: 2014. www.usp.org. Accessed September 29, 2015. XZCv Lynn S. Drug Defects. Presented at the 37th International Good Manufacturing Practices Conference; March 14, 2013; Athens, GA.

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West Envision™ 100% Automated Verification

A Risk Mitigation Solution

You Need to:

- Reduce product returns and recalls due to visible particulate and loss of sterility
- Reduce end-of-line product rejects caused by elastomeric:
  - Loose and embedded particles as specified
  - Defects caused by trimming and molding
  - Functionality issues, such as container closure integrity and leakage
- Maximize operational efficiency and throughput
- Reduce product waste and total cost of ownership due to:
  - Risks associated with poor quality closures
  - Manufacturing downtime and stoppages

Envision Provides:

- Consistency and control of critical quality defects of the closure components
- Components free of visible defects and contamination based on an existing defect library
- Sustainable product quality and consistency
- No regulatory filing impact
- A fully validated, ready-to-sterilize or ready-to-use product
- Confidence for patient safety

For more information, visit our website at **westpharma.com.**

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