Creating a Verification Process, not an Inspection Process

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Introduction
Vision inspection of rubber components brings an understanding of the manufacturing processes creating a verification process and not an inspection process. Component suppliers should not place emphasis on the end of line product sorting. Helping to reduce customers’ end-of-line rejections is a major benefit of 100% vision inspection of rubber components. When vision inspection is utilized, it leads to improved patient safety.

The trend in aseptic processing of parenteral drug containers to reject those showing evidence of contamination with visible foreign material. Biopharmaceutical drug products in particular are scrutinized for particles.

Packaging components are an important subset of this process. Component manufacturers can contribute to reducing particulate matter in finished drug products by supplying closures with reduced embedded and adhered particles. Vision inspecting components leads to improved upstream quality in the closure manufacturing process; verification of this improvement provides a lower risk of rejecting the final drug product for particulate and foreign material.

Case Study #1
Figure 1 shows that the trend for detection of foreign matter (FM) defects has increased. The most commonly identified defects were submitted as complaints for investigation. West identifies complaints as product concerns, which meet the specification, and product discrepancies, which do not meet the specification. To address the foreign matter discrepancies, West has implemented various process improvements to reduce the contribution of foreign matter during the elastomer production process; examples include gowning, cleanroom best practices and ISO 8 manufacturing area.

Have you chosen the correct component to align with the drug product and critical quality attributes? It is typical that customers provide a component specification that evaluates the elastomer at incoming for specific attributes including but not limited to foreign matter defects.

Case Study #2
Examples of the direct impact that automated vision inspection is having on the acceptance of incoming release and final reject rates are shown below. In both examples (Figures 3 and 4) the plungers of incoming release and final reject rates are shown. In both examples (Figures 3 and 4) the plungers of incoming release and final reject rates are shown. In both examples (Figures 3 and 4) the plungers of incoming release and final reject rates are shown.

Case Study #3
Automated vision inspection of components was used to gain product and process understanding, and resulted in improvements to the upstream process. Before the vision inspection process was implemented, the focus was on verification of assuring patient safety by using the highest quality components. Figures 5 and 6 are examples of defects seen during vision inspection that are further evaluated in the upstream manufacturing process as described in Figure 7.

Conclusion:
Driving quality and product understanding upstream to the component manufacturer may improve the finished goods production process. Helping to reduce customers’ end-of-line rejects is a major benefit of 100% vision inspection of rubber components.

Citations:
(1) U.S. Pharmacopeia USP32/NF27, General Chapter <112>
(2) European Commission EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Volume 4, Annex 1, 2008