Visual Inspection in Biosimilar Manufacturing

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ABSTRACT

Visual inspection of injectable products is critical for ensuring that these drug products meet the required standards of quality. Additionally, production speeds increments and more complex processes presents other challenges for quality.

Visual Inspection is the most critical areas in the biosimilar industry. Having control of the inspection process will help increase the product quality as well as the control of the filling processes. Controlled Visual Inspection Technique means that all areas of the units were covered during the execution of visual inspection technique. The inspection should be done under suitable and controlled conditions of illumination and background. Container closure integrity shall be inspected using unit/container dimensions. Methodology should be consistent between inspectors, following inspection steps. Visual inspection should not be considered a controlled technique and using the most effective defect kit for the inspector certification.

Using controlled technique the efficiency of the visual inspection increases as well as the quality of the product.

RESULTS OF DETECTABILITY

Theoretical percentage values of stains on Syringe Plunger Stopper during detectability study using controlled and uncontrolled (UC) visual inspection technique (50 units)

- Based on companies detectability studies performed previously the results summarized on this paper demonstrated the following:
  - Quality increase if a controlled technique is used for visual inspection
  - The quantity of complaints related to defects decrease proportionally with the increase in quality
  - The process of the controlled visual inspection compared with uncontrolled visual inspection techniques
  - The detectability of defects is lower if a good defect panel is used to verify the inspectors.
  - Finally the visual inspection process must be organized and structured.

METHODS

- Visual Inspection Methodology – Controlled Technique after Remediation.
  - Robust Technique – All areas of the units were covered during the execution of visual inspection technique. The inspection should be done under suitable and controlled conditions of illumination and background.
  - Container closure integrity should be inspected using unit/container dimensions.
  - Methodology should be consistent between inspectors, following inspection steps. Visual inspection steps for consider a controlled technique and using the most effective defect kit for the inspector certification.
  - Defect Library should have defined minimum and maximum % defects in the challenge set for inspector.
  - At least all defects based on PDA report No. 43 must be included in the defect kit.

BACKGROUND

Visual inspection of injectable products is critical for ensuring that these drug products meet the required standards of quality. Additionally, production speeds increments and more complex processes presents other challenges for quality.

Parenteral manufacturers are facing increasingly strict quality standards that require them to produce products free of visible particles, reduce process/product variation, and minimize rejects.

Visual Inspection is the most critical areas in the biosimilar industry. Having control of the inspection process will help increase the product quality as well as the control of the filling processes. In order to have control of the visual inspection mostly the inspectors have the great responsibility. In some cases is the training the issue and sometimes the system.

Most of the biosimilar industries uses manual visual inspection and other uses the automatic process but both required a high level of understanding, training, and also defect standards to challenge both processes. Controlled visual inspection will increase quality.

This paper information is based on different detectability studies performed, by Syrviatek Corp., on different pharmaceutical industries remediation plan of visual inspection processes.

CONCLUSIONS

- The results of a controlled visual inspection process.
  - High Quality – Low Complaints
  - High detectability of filling problems and/or supplier defects.
  - Knowledge of the common problems with high detectability and deviations reduction

RESULTS

The results of a controlled visual inspection process.

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INSPECTION PROCESS IS THE HEART OF A BIOSIMILAR STERILE FACILITY