Pharmaceuticals

Rationalized Analytical Methods to Support Regulatory Compliance



RJ Lee Group is an ISO-compliant, FDA-registered laboratory with a well-established quality system. Our experts use and develop validated protocols and execute them in a cGMP-level environment to investigate your problem and provide resolution.

In addition to investigating your particulate matter, we provide pharmaceutical failure analysis and design a program for future contamination control based on your profess. Industrial hygiene, containment, and toxicology services are also available. We work closely with our clients to understand the issues surrounding each unique situation.

Services

- Foreign Particulate Matter Analysis
- Contamination Identification
- Root Cause Analysis
- Source Determination
- Surface Defect Analysis
- Particular Morphology Evaluation
- USP Testing
- Toxicology Services

Case Study

INDUSTRY: Pharmaceutical

Shatter-prone glass syringes pose any number of risks — to patients and health care workers — and costly, potentially dangerous waste. One well-known medical device manufacturer wanted reliable data on why syringes from an overseas manufacturer would shatter upon loading.

Our team examined failed and unused syringes, and reconstructed a failed syringe, which had shattered into several hundred spiral-shaped shards. Microscopic examination revealed the gross pattern of failure, and the location of failure origin. A more detailed microscopic examination of that spot revealed forming defects — the glass had not completely formed and healed during the rolling process, resulting in a weak point that ultimately caused the failure.

Data translated to corrective action — a meeting of the minds between the supplier and medical device maker, with RJ Lee Group's report used to illustrate the failure. The material failure analysis showed that folds developing during the glass forming process generated the defects in the syringes. As a result, RJ Lee Group included the following suggestions for corrective action: (1) increase the process temperature, (2) slow down the process, or (3) flame polish the item at the conclusion of the process to strengthen the glass.

RJ Lee Group continues to be involved in providing subsequent quality assurance and quality control services for this medical device manufacturer.

CONNECT WITH AN EXPERT
724.519.9069 | WWW.RJLEEGROUP.COM

RJ LEE GROUP
DELIVERING SCIENTIFIC RESOLUTION