REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Product Cleaning Endotoxin Control

Client

Medical Device Manufacturer.

Industry

Medical Device

Business Challenge

Design new cleaninging equpment as well as devlop and coordinate controled testing of product.

Background

A medical device manufacturer was experiencing occurrences of unacceptable endotoxin levels on finished, cleaned surgical needles, and an FDA 483 observation was received for nonconformances to certain procedures related to the needle cleaning process and endotoxin control.

Challenge

RCA was requested to analyze the process used to clean the needles, develop a protocol for evaluating cleaning efficacy, and recommend improvements to the process and specifications.

RCA Approach

Regulatory Compliance Associates® Inc. developed and coordinated controlled testing using a "worst case" product example inoculated at a target level of approximately 300 EU/device, with the final goal being endotoxin levels at below 2.15EU/device after cleaning. Test results showed a gradual buildup of bioburden in the cleaning water from one batch of needles to the next. RCA also assisted the client in the design and build of new cleaning equipment. The final cleaning system was replaced with the automated system, a clean compressed air system was installed, vacuum driers were installed, the equipment and process was validated, a clean room behavior SOP was developed, and training was performed. Additionally, a sampling plan with action and alert levels for product endotoxin levels was established.

Result

Product endotoxin levels were substantially reduced, and the risk of nonconforming product reaching customers was effectively addressed and documented through process validation and improved process control.

"RCA also assisted in the design and build of new cleaning equipment."

References

1. U.S. Pharmacopoeia, Chapter 161, Transfusion and Infusion Assemblies and Similar Medical Devices.

2. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, “Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices,” December 1987.