REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Shelf Stability

Client

ASTM Internationaer.

Industry

Medical Devices

Business Challenge

Create a new design for a product to ensure a successful launch.

Background

A large medical products manufacturer was developing a new product to collect blood samples. Accelerated shelf age validation testing found that the protective sheath surrounding the needle in the device did not have adequate reseal characteristics. After aging, the sheath was not reliable in preventing leakage of blood after needle puncture

Challenge

The reseal failures came as a surprise since unaged test samples had not experienced failures. This led the program to fall behind schedule, and quickly finding a workable solution was considered critical to the success of the new product development.

RCA Approach

The material of construction was synthetic polyisoprene. Experiments were conducted employing alternative synthetic polyisoprene formulations, but in order to achieve the proper reseal, it was necessary to change the material to natural polyisoprene (natural rubber latex).

Results

Design verification and validation testing was completed, design review and design transfer were conducted, the design history file was updated, and ultimately the product was successfully launched employing the natural rubber latex sleeves.

"Finding a workable solution quickly was critical to the success of the new product"

References

1. ASTM International, “ASTM F1980-99, Standard Guide for Accelerated Aging of Sterile Medical Device Packages,” November 1, 1999.

2. FDA Code of Federal Regulations, Title 21, Part 820.30, Design Controls, April 1, 2010.