



# RCA Case Study

Product  
Development

Shelf Stability

## 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, hence the program was behind schedule, and finding a workable solution quickly was considered critical to the success of the new product development .

## Approach

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

## Result

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

## References

1. ASTM F-1980-99, Standard Guide for accelerated aging of sterile medical device packages
2. Code of Federal Regulations (CFR) – Title 21, Parts 820.30 – Design Controls