



\$2,000,000 Savings in Operating Efficiencies



Risk Reduction: Improving Product Integrity

QUALITY REMEDIATION

Medical Device Packaging Optimization,
Validation and Qualification

Client Needs

A medical device contract manufacturing company needed a viable packaging cost savings solution for a terminally sterilized Syringe Kit utilized for intravenous administration of CT contrast media.

Process

Delivered a phase zero assessment to:

- Determine the root cause analysis for a particular issue
- Mitigate an interim strategy
- Perform a regulatory gap assessment
- Develop a qualification strategy package solution
- Validate and verify a chosen concept
- Complete shelf-life stability and distribution performance testings to meet ISO 11607 compliant qualification needed for commercialization



Contact us for assistance with your packaging needs

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ENGINEERING PACKAGING EXCELLENCE