Three Testing Tips for Medical Device Packages

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Sterile medical device package testing produces the data necessary for compliance to ISO 11607 "Packaging for Terminally Sterilized Medical Devices", Part 1: Requirements for materials, sterile barrier systems and packaging systems and Part 2: Validation requirements for forming, sealing and assembly processes.

The following are some key tips for ensuring that your medical package system is evaluated and ultimately validated with the most appropriate, relevant testing protocols for validation of sterile barrier integrity and overall package and product safety and efficacy.

Testing Tip #1:
Define the testing objectives and required testing outcomes
- Is the testing exploratory or design feasibility testing? Define what you want to learn. Be honest regarding what is known about the performance of your package design. Is the packaging system ready for prime time?
- Is the testing considered validation for a regulatory submission and compliance for the relevant industry standard(s)? This requires expertise in interpreting compliance to the standard(s).
    - Invest the time into reviewing and interpreting the relevant industry packaging standards (example ISO 11607 parts 1 and 2 and the ANSI/AAMI/ISO TIR16775, "Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2"). Seek guidance and expertise, prior to executing testing.

Testing Tip #2:
Determine the value proposition for in-sourcing vs. outsourcing the testing activities
- Review internal test capabilities versus the project goals
    - Is the appropriate test equipment in-house?
    - Is there expertise to correctly run the test equipment in-house?
    - What is the lead time and availability of equipment and staff to meet the project timeline?
- Evaluate external providers
    - Assure depth of expertise of outsourced testing provider
        - Evaluate the testing lab's industry experience and knowledge.
        - Can the testing services provider speak with authority on package materials and designs and the relevant testing methods for package validation? Can the testing provider suggest test methods to help you explore your package design?
        - Does the testing provider hold any relevant industry certifications?

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Testing Tip #3
Define the testing protocol with appropriate test methods and acceptance criteria

- A good starting point as a reference guide for design and evaluation of flexible primary packaging is ASTM F 2097, "Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products". This document provides guidance on the following areas: safety, barrier, durability, package integrity and seal strength, visibility and appearance, processing and printed ink.
- Define statistically relevant test sample sizes based on your testing objectives and your company's risk management policy and statistical rationale. Define pass/fail criteria.
- <u>Test methods must be validated</u>. This includes your business internal procedures and the contract testing laboratory.
- If outsourcing your package testing, request a detailed testing quote.
    - Can the outsourced testing provider provide full protocol and report development services?
- Seek review and approval of testing protocol from company functional experts.
- Stay involved with the testing process and review test results and report for accuracy.
- Prepare in advance, a contingency plan, to address test results that fail to meet acceptance criteria.