Emphasis on Testing: How to Work SuccessfullyWith a Package Testing Lab

Many medical device packaging manufacturers struggle to understand what they need to do to test and certify their packages. Here are 10 tips to help you work efficiently and effectively with a third-party package testing lab in order to satisfy your package testing expectations and regulatory requirements.

By Patrick J. Nolan

BEFORE TESTING

Tip #1: Define objectives

What do you want to achieve from your medical device package testing? Do you want to recreate damage or do you want to simulate the actual transportation and storage environment for compliance to regulatory requirements such as ISO 11607 and/or FDA? These are the two main concepts used in laboratory package testing. The first concept uses the tools of the laboratory to recreate the type and levels of product or package damage observed in actual shipments. In this concept, the test inputs are adjusted to a level that causes similar damage as that seen in actual shipments. Having recreated the same product or package damage in the lab allows subsequent testing at those test levels on product and/or package design variables. This concept is most effectively used for initial design. The second concept, simulating the actual environment in the lab, is most effectively used for validating or certifying a medical device package's ability to withstand realistic environmental inputs. In this testing concept, published standards such as ASTM D 4169 or ISTA Procedures are used to simulate the effects of shipping and handling on the packaged product. These tests are recommended in Annex B of the ISO 11607 standard as acceptable methods for transportation simulation of packaged products. It's important to understand your basic needs and objectives. Is the main objective design evaluation or feasibility testing, or is it validation of a medical device package design to protect the product through the hazards of the transportation environment and for regulatory compliance?

Tip #2: Define criteria and key deliverables

An important key to completing a successful testing project is to define the acceptance criteria. The ASTM Test Standard D 4169, "Standard Practice for Performance Testing of Shipping Containers and Systems," which is a performance test or validation test, devotes a section on defining "acceptance criteria" and indicates the importance it has on test results. Since this standard applies to many different types of packages and products, it cannot be very specific in the description of what constitutes acceptance.

For each project or product, there should be some detail that indicates where the test failed. For medical device packages, the ultimate indicator of acceptance is if the package integrity is maintained and the product remains sterile at the point of end use.

Tip #3: Match lab's capabilities to your testing needs

During your search for a test lab, you will want to match your objectives with the laboratory's capabilities and expertise. You also will want to evaluate its credibility by the accreditations, registrations, and certifications it holds as well as the participation of its staff in technical activities such as AAMI, ASTM, and other professional associations. You will need to find out if the lab is ISO 9001 registered. Unless the lab has a registration number from a "notified body" such as BSI, the lab is not registered but may claim to be in compliance with ISO 9001. In other words, it has not gone through the rigorous auditing procedures required for true registration.

Similarly, labs registered to the ISO 17025 standard must have been audited by a "notified body" to be truly in compliance with the provisions of those standards. Other registrations may be obtained from associations such as ISTA through a process of auditing lab equipment for proper operation and calibration. In addition, DOT certifies labs as Third-Party Testing Agencies through a similar process of validating proper equipment and staff expertise. These registrations provide significant evidence that the laboratory is operating under quality standards and produces credible, precise, professional test data.

Some testing labs provide a Test Request Form that the customer submits with general package information and intended testing objectives. This gives advanced notice to the lab that a test project is coming and provides an opportunity to establish and set expectations for both parties. A confidentiality agreement may be essential. Notice to all lab personnel is required so that the customer's products and test items are kept in confidence.

DURING TESTING

Tip #4: Witness testing in person

On-site viewing of testing may be insightful as first-hand observation is usually much more valuable than the details of test results described in a test report. When on-site observation is not possible, some labs have installed webcams in the test labs so that observation of the testing can occur over an Internet link. Another important method of communication with customers who are not able to be on-site is frequent status reports on the testing, using digital photography or digital video. These can be easily e-mailed to customers for observation of test procedures and results.

Tip #5: Be prepared to make on-the-spot decisions and use advanced techniques

To keep the project and approval process on track, fast and sometimes instantaneous decisions regarding packaging problems or failures are essential. Because packaging development is often part of the critical path to product approval and introduction into the marketplace, timely validation of the packaging process is critical and must stay on track and on schedule.

Tip #6: Document clearly

Critical to the entire project is documenting the details and events that occur during testing. Data can be recorded on pre-designed worksheets for each test type, or data can be recorded in standard laboratory notebooks. There must be approval of the data by a project manager after testing is completed. There also must be pre-approval of the worksheet to ensure that the test plan matches the protocol.

AFTER TESTING

Tip #7: Read and analyze the report as soon as it's received

Most of the tasks for creating a successful interaction with a testing laboratory have been performed by this point, but a pile of data sitting on a desk somewhere does not result in a solution to a problem, a reduction in packaging costs, or a successful process validation. These will not be accomplished without analysis of the data and decisions based on that data.

The laboratory should help reduce the data or summarize it so that it is easy to see what the results may portend for the project. This can be done through tables summarizing test results and through root cause analysis in the event of a package or product failure.

Tip #8: Clarify and revise as required

When all objectives are met, a final test report will be provided that details all test results, procedures, and events that took place during testing. This test report should be concise and professional with copious use of photography to demonstrate test procedures and results.

Tip #9: Authorize additional testing if indicated

Sometimes the original objectives of the project are not met by the testing protocol developed or sometimes something unexpected happens during testing that causes a change in the objectives. Consequently, a new series of tests may be required to glean more information about the product or package design.

Tip #10: Make decisions based on objectives

Remember your objectives and determine if the test results met those objectives. If not, either re-evaluate your objectives and retest or make design changes to the package and then revalidate.

Patrick J. Nolan *is chief operating officer and technical director of DDL Inc., which maintains full service testing labs in Minnesota and California. Nolan has 25 years of*

experience in the testing and analysis of packages and products for shock and vibration hazards inherent in the distribution system. He is the Division II chairman of ASTM Committee D10 on Packaging and a member of the medical packaging subcommittee of ASTM Committee F02 on Flexible Barrier Materials. DDL offers product testing, package testing, and material testing services including shock testing, vibration testing, tensile testing, leak testing, and validation. Nolan can be reached by calling 800-229-4235.

ONLINE

For additional information on the advice discussed in this article, see *Medical Design Technology* online at www.mdtmag.com or DDL Inc. at www.TestedandProven.com [1].

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