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.

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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?