EL COSTO DE LA INTEGRIDAD DEL PACKAGING

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PACKAGING

Medical device manufacturers often struggle to satisfy packaging requirements. However, examining five key issues can help them avoid potential pitfalls.

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Many medical device manufacturers struggle to satisfy and maintain package integrity requirements while remaining cost-efficient. Such companies can save themselves time, money, and unnecessary headaches by examining key issues prior to developing their packaging.

Although manufacturers may still come upon engineering and logistical problems along the way, these issues will more than likely be relatively small and manageable. In the long run, those firms that address the potential pitfalls discussed in this article will be well positioned to meet package integrity requirements.

In a perfect world, every medical device manufacturer would have an engineer on staff with specialized knowledge about package design and all that it entails (e.g., package types, proper materials for specific situations, and validation testing). But in many cases, the task of designing a medical device's packaging is delegated to an engineer who is not familiar with packaging engineering and design.

Considering that many medical device manufacturers are currently experiencing a shortage (or even absence) of qualified personnel, they can take major steps toward avoiding headaches while remaining within their budgets by addressing the following five issues:

• Does the initial design of the packaging satisfy the needs of the specific device?

• Is the packaging material the best one for the product?

• Is the sample size sufficient to ensure adequate testing results?

• Can the testing decisions be sufficiently justified to the necessary government organization?

• Are the same testing parameters applied every time the same test is performed?

In reality, a few of these questions are rhetorical, and as such, the answer is unfortunately often a no. The recommendations presented here will help manufacturers anticipate and avoid potential problems before they occur.

Initial Design

Problem: Sometimes, packaging is poorly designed from the beginning. Every product that comes in a package, including medical devices, has trouble spots that must be addressed during the initial design phase. For example, catheters often have connectors or hubs with sharp edges. If the packaging is not designed properly, such edges could breach the package's integrity. A punctured package cannot ensure a product's sterility.

Solution: Design the most cost-effective packaging for the product that will satisfy ISO 11607 requirements.1 The sales and packaging engineers that represent material suppliers are experts in the field. Seek their advice and take advantage of their knowledge. It is also important to do research and ask questions. During the design phase, no question is a bad one. Don't be afraid to ask basic questions, such as the following:

• What are the options?

• Should a thick film be used for this application?

• Does this package need to include extra protection in trouble spots, or should an alternative packaging type be used?

• What is the worst-case scenario?

Material Selection

Problem: Choosing the proper packaging material for a product is often difficult. For example, no manufacturer wants to package sharp-edged or odd-shaped products in a flexible pouch only to find that they should have been put in a thermoformed tray.

Solution: The primary concern in choosing the proper material is maintaining the product's sterility. Medical devices come in all shapes and sizes. Accordingly, the packaging must be the correct strength, thickness, and size for the product.
Most device companies tend to resist changing their packaging. If a new device is designed, a manufacturer often tries to package it in the packaging used on its current product lines to save money. However, if a manufacturer fails to validate its old packaging for its new product, any savings are moot.

For example, imagine that Device A is a product currently packaged in a 5 × 9-in. polyethylene/Tyvek pouch. When placed in the shipper, the packaging has no creases or folds.

Now imagine Device B, the company's newer, smaller product. The manufacturer tries to use the same polyethylene/Tyvek pouch but must fold the pouches when placing them in the shipper. In this case, Device B's sterility may be compromised because the pouches are folded.

In this example, folding the Tyvek creates creases in the package. The creases raise the likelihood of package failure in integrity testing. This would be especially true after the package went through the accelerated aging process and distribution simulation testing. The company in this example should use a rigid material and package Device B in a formed tray.

Another option would be putting the pouches in a larger shipper and securing them with protective packaging. The larger shipper would allow the devices to be shipped in unfolded pouches. The bottom line is that manufacturers must ensure that the product and packaging work together to avoid delays for redesigning and revalidating the packaging.

It's also prudent to note that many companies tend to ship too many products in one shipper. There are several in-the-box protective packaging products that can add protection for a minimal cost—as low as a few cents. Manufacturers may want to consider using a large shipper with protective packaging.

Sample Size

Problem: Some manufacturers submit very few test samples to cut costs. Doing so can decrease the confidence level of the testing.

Solution: It is important that manufacturers choose a sample size that is appropriate for their particular product and package. Some companies do little testing up front to save money. This is often the case for start-up medical device firms that have limited resources. Instead of testing 30 samples, they might only test 10, for example.

There is a big difference between the confidence factor for 30 samples and for 10 samples. Testing 30 samples may result in a confidence factor of 90–95%, but the confidence level may drop to about 50% with a sample size of 10.2.

However, it should be noted that a sample size of 30 is not necessarily the proper choice for initial testing. As is mentioned above, manufacturers must do their own research to determine the correct sample size for their product. They must consider the confidence level they wish to achieve, the amount of money they can afford to spend, and what sample sizes FDA will accept.

It is also important to perform all the tests necessary to validate the package. Companies might decide to omit a strength test (seal strength or burst strength test) to save money.

But failing to do those tests could mean that the manufacturer will have to conduct the entire testing process again, because the packaging may not comply once it is in the field.

In addition, manufacturers need to validate their sealers. If a sealer is not properly validated, then the manufacturer cannot ensure consistent seals during production. The selected sample size from three different lots of product should be tested using one of two methods: the peel/seal test (described in ASTM F88-05)3 or the burst test (described in ASTM F1140-00).4 Samples should be tested on a regular basis during production to ensure that the sealer is operating within its tolerances.

Decision Justification

Problem: FDA requires that manufacturers justify the testing methods and sample sizes used for package validation. In some cases, a company cannot justify its package testing decisions sufficiently to satisfy the agency.

Solution: Manufacturers should make consistent decisions and should be prepared to defend their reasoning to FDA personnel. By choosing an appropriate sample size and justifying the decision to use particular test methods, manufacturers can avoid the cost of moving to conduct additional testing.

Manufacturers must also be consistent with the sample size throughout the packaging validation. For example, if a sample size is 30 for the package integrity baseline test after the sterilization process, then it is imperative to also assess 30 samples after accelerated aging and distribution simulation testing.

Manufacturers should also take into consideration the package they are validating. For example, a company might justify having a smaller sample size if the only change is that the company is extending a package's shelf life for an additional year. In addition, firms might justify their decisions by testing the worst-case scenario of their product package design—if the packaging passes the rigorous testing standards of ISO 11607, then the other packages in the product line should be able to withstand those same tests.

Testing Parameters

Problem: Many companies do not apply the same testing methods every time they do the same test. Often, manufacturers dislike changing their testing methods or have not kept up- to-date with the standards. In addition, engineers tend to stick with certain test standards with which they are familiar. If they go from one device manufacturer to another, many tend to use the same methods or standards to validate the new company's packaging.

Solution: The clearest solution to this problem is to follow the latest standards. For example, American Society for Testing and Materials (ASTM) standards are constantly updated. Manufacturers also should review revisions to ISO standards before packaging their product to ensure that the packaging satisfies international requirements.

If engineers are validating a product's packaging to increase its shelf life, for example, they must use the same test methods that were used on the original package. But if there are revisions to those methods, they must update their testing parameters to comply with the revisions.

If engineers choose to use a contract laboratory to perform integrity testing, the testing lab should be able to educate them on standards revisions.

Manufacturers can make sure that their supplier is up-to-date on the testing standards by asking the lab about the most recent revisions.

Choosing a testing protocol is also important. Engineers must consider the differences between those of the International Safe Transit Association (ISTA) and ASTM.

ISTA is a privately held, not-for-profit organization.5 All ISTA tests are preshipment test procedures (i.e., tests to compare or evaluate the effectiveness of protective packaging and a packaged product's ability to withstand the hazards of distribution). ISTA offers a variety of test protocols that give the user a choice of cost, complexity, and operator skill requirements.

ASTM is one of the largest voluntary standards-developing organizations in the world.6 ASTM is also a not-for-profit organization, and it has one performance test protocol that is intended to cover all situations. The protocol may be difficult to understand and use, but it can be effective if properly applied. However, it requires relatively expensive equipment and skilled operators. For example, the cost of the machinery is often more than the cost of outsourcing the testing services.

Engineers need to consider the big picture when choosing between performing an ASTM or an ISTA test regime. To properly choose the correct tests, engineers must also understand the differences between the two organizations. FDA recognizes and accepts both ISTA and ASTM testing standards; however, the EU only recognizes ASTM standards. So, to market overseas, a company must use ASTM test protocols.

Conclusion

Medical device manufacturers that are validating their packages' integrity should take advantage of all their resources. It is important to use the available experts, such as packaging suppliers, consultants, and testing providers. These resources can help

companies choose the correct design, materials, sample size, and testing methods to ensure a smooth process to product launch. It is important to be consistent and to be able to justify decisions and reasoning at every stage. Maintaining consistent sample sizes and test methods can help accomplish this. Proper planning and research will lead to a well- designed package the first time, thereby eliminating redesign and revalidation costs.

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