

## Six Pitfalls of Medical Device Packaging Development

Bill Limmer

**A device's packaging is a critical component as it can protect it, keep it sterile, and help prevent tampering. However, for medical device designers, it is easy to overlook this aspect of the device and either come up short on what's needed or over do it and use too much packaging. This article looks at six items to avoid in packaging development so as to create exactly what's needed.**

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Developing practical and efficient packaging for medical products can be a challenging process. There are lots of things that can and do go wrong. Just knowing the right questions to ask can make the difference between success and failure. There are also a number of common misperceptions about medical packaging that almost guarantee increased costs and development time.

### **Pitfall #1; Most packaging problems stem from not asking the right questions**



This directly relates to the nastiest package surprise of all; error by omission. The person making the selection did not know that the package had to perform to a certain level.

Here are a few of the basic product/package questions that need to be answered in detail. While these may seem obvious, it is surprising how often this kind of basic information is overlooked.

- Who is the user?
- What is the product used for?

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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- How is it used?

## **Pitfall #2; "It worked for them, so lets do that!"**

The push for a cookie-cutter solution is driven by an attempt to gain speed to market. While this works sometimes, most of the time it doesn't. Analyzing the requirements of the product and user environment will get the job done right the first time, which is much faster than doing it over several times (see Pitfall #3).

## **Pitfall #3; More is better**

The thinking goes something like this: "The last package failed, so lets beef it up." This leads to additional costs and frequently fails to solve the problem. Often, the real solution is much simpler (and faster) and can be determined by root-cause analysis. That means old-fashioned investigative work and thinking about the issues involved.

## **Pitfall #4; Over-engineering is fail-safe engineering**

A common misconception is that there are "standards" that a medical package must meet. This often leads to over-engineering, such as specifying one foot-pound of force resistance when ½ pound gets the job done, or ultra-high tolerance when low tolerance is sufficient. The desire for speed to market drives the idea that over-engineering will make the package fail-safe. Typically, it only makes the package more expensive and introduces unnecessary complications into the process.

## **Pitfall # 5; Prototype process is the same as the production process**

A common misconception is thinking the requirements of the prototype development process are the same as the production process. This gaffe has brought many packaging projects to a screeching halt. The prototype phase demonstrates that a single object can be made at any cost. The production phase is about making thousands of identical objects at a fixed cost. Plan accordingly.

## **Pitfall #6; Choosing the wrong packaging partner**

There are many good packaging companies out there, but they are not all the same. They offer different expertise, equipment, and capabilities. There are six key items to look for when evaluating a packaging company for a project.

- Experience with similar products and materials
- What are their equipment capabilities? How is the equipment validated? How is the validation defined?
- What is the capacity of the production environment. How much capacity of the shop is currently being used?

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- Is the level of staffing sufficient? Will they have to staff up? If so, will your project get the rookie crew? How is the staff trained?
- What kind of quality system is in place? How robust is it? Is it a one-man operation? Is it challenged by audits?
- Does the company provide a review process during which engineering will look for ways to make improvements to the original specifications?

### **Bonus #7&#151;Put it in writing**

Finally, one last piece of advice to help ensure a successful packaging development project is to put the packaging specifications in writing (in detail). This single step will put the company miles ahead of the many competitors who stumble and fall for lack of organization and good communication.

### **Online**

For additional information on the technologies and products discussed in this article, see *MDT* online at [www.mdtmag.com](http://www.mdtmag.com) or Innovative Surgical Products at [www.innovativesurgical.com](http://www.innovativesurgical.com).

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