



ISO 9001: 2008 CERTIFICATION

How A Medical Test/Device Manufacturer Can Be Assured of Obtaining Appropriate, Cost-Effective Packaging for Their Product

This article will address the basic information that you, as a packaging purchaser for medical tests and devices, should have readily available when interacting with potential packaging manufacturers.

Sourcing your packaging is arguably the most critical “out-of-laboratory” decision you’ll make. The knowledge and experience of your primary contact at the manufacturer who wants your business can dramatically affect the development, time-to-market, approval, distribution and acceptance of your product in addition to your bottom line.

It’s important to understand there is no “standard” construction of high barrier laminated packaging material for medical devices and tests. In order to achieve your objectives and be presented with the best information to make your decision, you need to think through the potential lifecycle of the package and be prepared to provide guidance to your packaging consultant. This is the critical step; sharing basic information in four general areas will elicit follow up questions that will ultimately result in achieving the structural and performance requirements best suited for your product.

1) What is your product ?

A simple but necessary question that will set the direction for all that follows. Be prepared to describe it in terms of size and shape, does it have sharp edges, was it previously packaged in a rigid container, does it have to be kept wet/dry, what’s the end use and who is the end user.

2) What can happen to your product during its lifecycle ?

Your responses to this will allow your packaging consultant to add the most value to the process. Three primary considerations, what can happen physically, environmentally and atmospherically, converge and will result in a short list of the most appropriate laminates.

It is equally important to protect the contents and protect the package from the contents so be prepared to think “from the inside out” as well as “outside in”. This

is the part of the discussion that will touch on many potential dangers to the integrity of your products. Examples include:

- environment(s) in which it will be shipped and stored
- O2 transmission
- water vapor transmission
- aroma
- light
- adhesive type
- package porosity
- pressure
- vacuum

3) How long is protection required ?

While the preceding addresses what you're protecting your product from, you also need to consider the length of time that protection needs to be at its optimal level. This is when the shelf life discussion occurs. Shelf life is a bit of a misnomer because the key consideration is to make your best conservative estimate of the sum of time the packaged product spends in various stages of its lifecycle. The shelf life clock starts ticking when the product is packaged in the manufacturing facility. You then need to add estimated time spent in inventory, time in transit, time at the distributors and time and turnover frequency with the end users. Note on the last item - don't think about averages, think about when the last package will be opened in its customary end user's location.

4) What other features may be required ?

While containment is the primary goal, there are numerous other features that may be desirable, required or used to distinguish your product from a marketing or regulatory perspective. Examples include:

- reclosability
- tamper resistance construction
- tamper evident design
- puncture resistance
- how and where will the package be opened
- shape
- information – color, graphics, print, legal requirements, marketing, information/instructions)
- utility – convenience, optimizes unit use/control, quality, choice of product forms, waste prevention

5) What are some important attributes I should look for in my manufacturer?

- Accreditation by an independent organization – a good first step is to look for a current designation by a well known certification entity that reviews

quality standards. Your packaging should be sourced from a company with the processes and controls in place that are recognized to be effective and to do what they're supposed to do.

- Vertical integration – the greatest degree of assurance that a finished product will be consistent and reliable occurs when the components are manufactured and the end product is produced within the same four walls.
- Type III DMF listed materials and constructions – a manufacturer with a robust portfolio of listed constructions can support your objectives of optimizing time-to-market and compliance.
- Knowledge and experience – While there certainly are some good manufacturers in this country, how do you avoid spending uncounted hours to vet your candidates and cut through the clutter of everyone saying they are knowledgeable and have experience producing medical packaging? A good proxy is to review a list of your prospective manufacturer's current customers. Think of it as "validation by association". Look for breadth and depth in a customer list and give extra credit to anyone with international pharmas on their customer roster. If a number of companies with packaging requirements similar to yours have chosen a particular manufacturer, it is with good reason.
- Sustainability – there is a growing interest and focus on how to do something beneficial for the environment to offset the fact that healthcare related recycling and recovery results are still limited at best. If you are on any part of the spectrum embracing sustainable design, consider how your packaging manufacturer can support your sustainability goals. Examples of packaging manufacturer attributes that do not compromise patient health or increase liability exposure and are environmentally friendly include use of renewable energy and incorporating energy saving processes at the packaging manufacturing site.

We hope this has helped you begin to appreciate all of the considerations that need to be taken into account to define the requirements of the best packaging for your product. With today's broad choice of materials, each with their own set of performance characteristics, the time spent on the front end of the process to thoroughly review your product's characteristics and lifecycle will be one of the better investments you can make.