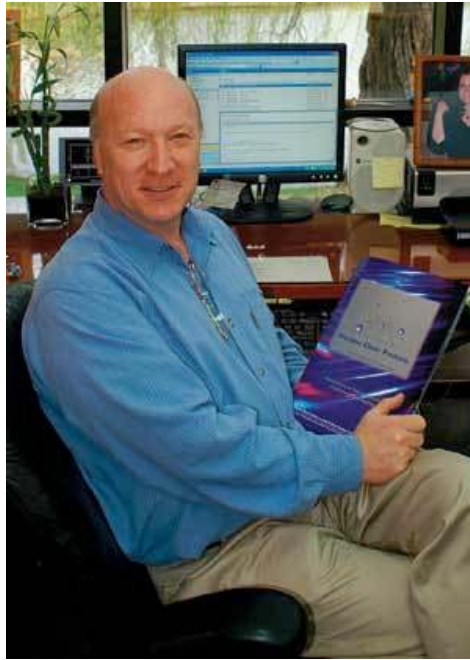


Without the right package, your cleanroom product isn't going anywhere

Cleanroom packaging decisions should never be an afterthought



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Michael Fisher, president of Fisher Container Corp. (Buffalo Grove, IL), says it's very easy for him to describe the market of his company's "Precision Clean Products" division. "Wherever there's a product manufactured in a cleanroom or some other contamination-controlled environment, and that product has to be shipped somewhere, even if it's just across a hallway, we have a potential customer." And that pretty much also explains the size and critical importance of the cleanroom packaging industry.



Figure 1. Precision Clean manufactures cleanroom bags, pouches, and materials used to package a wide array of cleanroom products.

Precision Clean manufactures cleanroom bags, pouches and materials used to package a wide array of cleanroom products ranging from wipers and swabs to cleanroom garments, as well as products produced by a host of other contamination-sensitive industries including microelectronics and aerospace, medical devices, food and bio/pharmaceuticals (see Fig. 1). The total size of this worldwide market would be nearly impossible to estimate, but just looking at the world market for cleanroom consumable products, which is estimated around \$5.7 billion, and culling out a conservative 3 percent for packaging, results in \$175 million for just this segment.

Fisher observes the cleanroom packaging industry has come a long way since he first got into this segment of the business some 23 years ago. "In general, customers have become much more serious and concerned about doing things the right way relative to their cleanroom packaging. They've also become much better educated to their particular industry's cleanliness requirements."

The reasons behind this evolution have more to do with the amount of information available to customers than changes in the products being packaged, says Fisher. "Today, specifications are well defined and technical data is easier to obtain. Unlike the situation years ago, when users had to rely on a lot of vague and unsubstantiated claims, today they can really evaluate and compare products (be it a swab, wiper, garment, etc.) and know that what they're getting is a true example of what a provider is consistently producing."

This change has clearly had a parallel impact on the cleanroom packaging industry as well. "Packaging manufacturers can't just send out product anymore with false claims and sketchy descriptions that don't really meet the specifications required by the user industry," says Fisher. To make his point, he points out that today Precision Clean manufactures its cleanroom bags and packaging materials in an ISO Class 4 (Fed. Std. 209E Class 10) cleanroom and certifies its products to specific surface cleanliness levels (see Fig. 2). Precision Clean was also the first cleanroom packaging company to be ISO-certified (ISO-9001-2000).

Prescribing the right package

Another significant change in the cleanroom packaging industry is the number of different packaging options that are now available, and with them more choices and decisions for the user. Choices include multiple packaging types and film materials, various thicknesses (gauges) of films, different types of seals or closures, printed or unprinted, testing parameters and protocols, and of course, price points.

Making the best choices for a particular product can be a daunting task, particularly for those new to the technology. To help them through the process, Fisher says they basically assume the role of a no-fee industry consultant. "We do a full evaluation of each customer's specific requirements and desires starting with basic questions like, 'What's it used for and where's it going? Is it fragile and does it have sharp edges?' Then, we look at specific requirements such as cleanliness level, package clarity, printed or plain, desired seal type, sterilization method, etc. From this information, our policy is to prescribe exactly what is needed-not less, but also not more."

As a routine part of any new package-development process, customers are asked to provide samples of the product to be packaged. "Usually, as a minimum we request two sets of the items that will go into the package," says Fisher. "Using these, we go ahead and mock up a package to demonstrate and discuss with them."

This is not always possible, however, as it's not uncommon for customers who are just ramping up a new product to be unable, or unwilling, to submit a finished piece. In these cases, the package design and specification job becomes much more difficult. "Working only with drawings, it's difficult to confidently prescribe material and gauge, and also cleanliness levels. We can guess, and will do the best we can with the information provided, but always with the caveat that it is an educated guess until we see the actual product."

Although Precision Clean tests and verifies that its materials and products meet accepted industry specifications, ultimately, customers must take ownership of the agreed-to packaging solution and perform the necessary testing to ensure the materials and specifications fully meet their needs for the intended use, and that their usage procedures are also appropriate and adequate. For example, as Fisher points out, "A package is only as good as its shipping container. If the final packaging doesn't complement ours, you take out all the beneficial engineering that we put into the package design." Customers are asked to perform a stress shipping test to ensure this compatibility.

New packaging, new equipment

Cleanroom packaging requirements continue to evolve and, as Fisher points out, many of his company's new development products have come from customer inquiries and requests for special capabilities or features. Making many of the new packaging options possible is the company's new lamination and pouch machine equipment (see Fig. 3). "This new equipment allows us to address a wider range of requirements with more products for a greater variety of applications." In particular, Fisher notes that outside the realm of conventional cleanroom products, cleanroom packaging requirements often demand not only cleanliness and/or sterility, but also protection from other external factors such as oxygen, moisture or UV light.

For example, Precision Clean now offers a line of autoclavable bags for cleanroom-suitable products that also require sterilization, such as stoppers, vials, ampules and other products. The line is composed of 100 percent breathable Tyvek® on two sides, offering significantly faster sterilization cycle times.

In contrast, the company's "Barrier" bags are manufactured with a foil lamination specially designed to protect products from moisture and oxygen, or to retain moisture in the packaged product. The bags have a typical moisture vapor transition rate (MVTR) of 0.006 g/24 hr/100 in². Also available are ESD, UV-inhibitor, and flame-retardant anti-stat films.

The new machinery gives Precision Clean the ability to combine different material types (nylon/poly, saran, foil/polypropylene, Tyvek/polyethelene, etc.) into an array of unique pouch types, as well as to offer different seal or construction options. "For example," says Fisher, "if, instead of tearing open or cutting open a product, I want it to peel open as a sterile presentation, I can use different materials with different sealing temperature points. Instead of adhering like a weld, these pouches peel apart smoothly without generating large amounts of particulate matter."



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Figure 2. Precision Clean manufactures its cleanroom bags and packaging materials in an ISO Class 4 cleanroom.

Looking ahead, Precision Clean plans to soon roll out the industry's first zip-lock bag certified for ISO Class 5 (Fed. Std. 209E Class 100) applications. The company has already produced its first samples and is compiling test data to support the product launch. Fisher says the bags will be targeted at laboratory scale and other relatively small applications. "There are a number of applications where people want to be able to go into a package, take some product out, and securely seal it up again. Using our 'Precision Zip Clean' bags, people will be able to do this."

Clean printing

Not so long ago, the notion of bringing the potential contamination problems associated with printed products into a cleanroom environment, let alone part of an actual printing process, seemed foolhardy. Today, however, it is commonplace to see print-branded products, from multiple vendors, in all levels of cleanrooms.

Fisher says Precision Clean was one of the first companies to print cleanroom packaging. "From our background in retail packaging, we recognized and pointed out to our cleanroom customers the value of being able to market their products not only on the basis of their cleanliness levels, packaging advantages, support, etc., but also the brand recognition benefit that would result from users being able to readily identify whose products were actually being used in cleanroom environments. The challenge was overcoming their fear of adding particle burden to the outside of the package."

At Precision Clean, the solution involves printing the outside of clean materials in a non-clean-certified area, then running the finished product through a special cleaning process to clean it to a level acceptable to the cleanroom industry. As explained by Fisher, "You can always print a bag in a clean manufacturing environment, but it's virtually impossible to do it with cleanroom results. You have to ensure that the inside of the package is, and remains, clean, and that the outside doesn't carry any additional foreign particulate matter into the cleanroom."

The cost factor

Cost, of course, is nearly always an important factor for customers. But this has to be carefully weighed against the risk of possible compromise to a product's cleanliness requirements and other factors. As noted by Fisher, there is a cost associated with certified cleanliness levels, and "we can't really make our cleanroom packaging line operate in a less clean mode so that someone's particular product can be less expensive. It doesn't work that way." The parent company, Fisher Container Corp., however, does address lesser requirement levels with a range of other products. "We've developed product solutions for those industries or applications that don't have such rigid requirements, but that still consistently meet the cleanliness requirements they do have at a satisfactory cost point."



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Figure 3. New lamination and pouch machine equipment enable Precision Clean to offer more packaging options.

Even change itself can be problematic in an industry (or industries) where a simple change in package appearance, whether neutral or even beneficial, can raise questions and red flags among users. Fisher notes this is particularly true for highly regulated industries such as pharmaceuticals. "Something as simple as changing gauge will require everything to be re-evaluated and field-tested from beginning to end. You have to carefully weigh the cost of taking something out of spec against the cost of recertifying."

As a final word of advice, Fisher notes that a common pitfall many customers fall victim to is waiting until the last minute to begin investigating their packaging needs, adding that this is ironic since "without the packaging, the product isn't going anywhere." To avoid a last-minute scramble, he recommends people budget enough time to learn about, evaluate and test packaging materials and options and still allow themselves enough leeway to meet their customers' delivery schedules.