

Challenges Ahead For Medical Device Packaging Materials

Hal Miller
PACE Solutions, LLC

ABSTRACT

Newer materials for medical device packaging have improved the processing and cost of sterile barrier systems; however, there still is a need for tougher films with greater resistance to abrasion, puncture and flex cracking; clear foil alternatives with high barrier sealants; and uncoated lids for rigid trays. Resources are the barriers to implementation of new materials. Prequalification and characterization of materials to medical device industry standards will reduce the resource requirement. Machine qualification time is precious; therefore, characterizing the material's ability to form, seal and accept print will enhance the probability of success. Risk reduction within the medical device industry is now moving to the supplier in the form of validation for critical processes and products. Finally, drug-device combination products now entering the marketplace have different requirements than their predecessors.

INTRODUCTION

The medical device industry has used peel pouches, bags, and rigid and flexible blisters for decades. For the past several years medical device packaging has seen newly engineered materials enter into the market place. Coextrusions are replacing heat seal coatings with wide sealing windows and consistent seal strengths, metallocenes and new blends of resins are offering better and cheaper alternatives, but are they enough? The challenge to the medical packaging supply community is to truly understand what is needed. With all these new and improved materials available to packagers, how many have been implemented? The medical device industry is a highly regulated environment and, therefore, moves at a much slower pace than one would like. Regulation is moving up the supply chain. This paper will attempt to address some of those still unmet needs and how the supplier base can help quicken the pace and make implementation easier.

Materials

For decades, the stalwart of medical device packaging has been the peel pouch. Whether the pouch is a film/film combination or a paper or Tyvek/film composition doesn't matter. New coextrusions and laminates have eliminated the need for adhesive coating one component and provide clean peel separation. These new materials provide a very wide sealing window with a flat seal strength curve. These new products have provided the medical device manufacturers with capable and robust sealing processes. You saw a need and rose to the challenge. However, there still exist more challenges. For years now, one of the greatest causes of material related medical device recalls or near misses is pinholes and cracks in pouches. Medical device manufacturers will try to put everything in a pouch if they could, and some do. Polyester and nylon films are not the answer. Product abrades or punctures the film through normal handling and distribution. Film cracks when folded over on itself. Yes, I know the folding of pouches is not a good package design, but let's face it, it is reality. If not folded, then the pouch can crack upon impact with the corners or edges of the secondary box. We need tougher films for flexible peel pouches.

The concept of clear "foil" has been around and a desire for some time now. The moisture and gas barriers of the better materials are probably acceptable for most products. However, the limiting factor for most barrier packages is the moisture and gas penetration through the seal. There is the challenge. We still have to seal these two barrier materials together to form a package.

Rigid thermoformed trays with adhesive coated lids are another long standing medical device package. Just like the elimination of the adhesive on a coated pouch can reduce the overall pouch cost, the elimination of the adhesive coating process for die-cut or rollstock lidding should also reduce this blister package cost. But what seals to PETG? For years PETG has been the material of choice for rigid blisters. Has its time run the course as well? If one eliminates the heat seal coating from the lid, what will form, provide impact resistance, have water clear clarity, and easily seal to the lid? That is the challenge.

Qualification

Think of the packaging material sales representative in front of a device packaging engineer trying to persuade the engineer to just try this new or alternative material. The packager sits on the other side of the table thinking my current material is just fine, and there are limited resources to qualify this material; therefore, mister supplier, what's in it for me? Your answer should be, "I have characterized and pre-qualified this product and performed aging studies to your industry's standards, and demonstrated and documented the material's ability to form, seal and accept print for the type of equipment that you use. Your qualification resource needs and time to market have just been reduced by 50-70%."

The most time consuming and resource intense part of new package or material introductions is the qualification process. This process typically includes physical, chemical and biological testing for the most appropriate properties, real time and accelerated aging studies after sterilization, machine trials or proof of principle to determine if the package can be produced on production equipment, and process parameter development. The more documented evidence the material supplier can provide to this qualification process the less time and resources the device packager will need. This is true added value and competitive advantage.

Material aging studies and proof of principle are the most challenging to suppliers. Aging studies, both real time and accelerated, do not have to be in final package form. What you are attempting to demonstrate is that your material properties do not degrade over time. If physical properties and seal strength do not degrade over time, then performance testing of the final package with product can be performed by the device packager at time zero. The basic assumption for material aging here is that there is no device and package interaction that may adulterate the device. What about sterilization? There are so many different processes and cycle configurations that make it difficult to determine what is needed. Depending on the sterilization process compatible with the material, expose the material to the most difficult or anticipated cycle. For irradiation that may be up to 45 kGy. This is the range for most contract sterilization processes. With ethylene oxide consider the highest concentrations of gas, temperature and vacuum that could be expected. Lastly, most manufacturers want the ability to pass their packages through the sterilization process at least twice and some times three times.

The concept of proof of principle is to provide material profile information from off-site machine trial evaluations. Some of the profile information should include pre-heat forming window, forming parameters to a depth of 1-2 inches, in-line stretch, visual attribute and seal strength curves, demonstrated printability, and clean cut capability. Obviously the amount and extent of the proof of principle will depend on how the material is intended to be used. Statistical sampling and run time considerations are critical to demonstrating successful machine trial evaluations. The overall goal is to provide the packager with enough documented evidence so that a machine trial run on production equipment is reduced to a minimum.

Validation

The medical device industry has long been a highly regulated industry. A significant part of this is process validation for sterile device packaging. The key issue at stake is the ability of the package to be sterilized and maintain that sterile state until the time of use; more specifically, the validation of the heat sealing process. In the past several years, regulatory guidance and standards organizations have attempted to make this process easier for compliance. This concept is now moving up the supply chain to include heat sealing process validation of preformed pouches and bags. Currently, ISO 11607, *Packaging for terminally sterilized medical devices*, is in the final revision process and will be split into two parts. Part 1 will deal with the requirements of the materials and package, while Part 2 addresses process validation. The proposed scope of ISO 11607-2, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes* states that processes include the sealing and assembly of preformed sterile barrier systems. For years, the medical device industry has had to validate the final end seal of a pouch or bag. However, this purchased, preformed package has other seals that have not been validated. This new international standard, expected to be recognized as a consensus standard by the FDA, will require the pouch or bag producer to validate their sealing and forming processes.

While on the topic of sealing validation, one of the most difficult processes to validate is the impulse sealing of films in packages such as bags. This equipment and process simply is not suitable for process validation. With that in mind, consider a different approach. Heat sealing is a well documented and easily validated process. Why not

produce header bags, for instance, with the header end open so that the device manufacturer can more easily validate their process using heat seals instead of impulse seals.

Drug-device combinations

Recent industry trends are to combine a drug with a medical device for better therapeutic effect. Take the drug coated coronary stent as an example. These products while still considered a medical device have additional packaging qualification requirements found with drug products. Additional testing for light protection, solvent loss or leakage, moisture and gas permeation, chemical composition, extractables, and heavy metal content are required. Also, different stability testing and conditions may be applicable. Material suppliers should now consider preparing a Drug Master File, DMF, for submission to the FDA. A DMF is a confidential file held by the FDA that includes material composition and processing for referencing by new device applicants.

CONCLUSION

While the medical device industry has seen new packaging materials developed to reduce cost and increase performance, there still are gaps to fill. Of particular interest to the industry is a more robust film for flexible peel pouches. The medical package material supplier can significantly reduce the implementation time and increase the probability of success of a new or alternate material by performing prequalification testing for the device packager. Process validation has come to the supplier base. Demands by device manufacturers and new international standards will require the supplier to validate their sealing and forming process of preformed sterile barrier systems. Drug-device combination products will require additional testing and qualification of packaging materials in addition to requesting Drug Master Files. These challenges are real and need to be addressed to meet the needs of the sterile medical device packaging industry.