MEDICAL DEVICE PACKAGING
PLAYBOOK

UDI & Serialization
Materials Selection
Package Design
At-Home Diagnostics
Kitting & Sensitive Devices
Validation, Verification & Testing
Regulation
Wearables

EXCLUSIVE SURVEY OF MEDICAL DEVICE PACKAGERS:
How does outsourcing affect innovation?
Playbook Sponsors

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EDITOR’S NOTE Protecting Devices Throughout the Supply Chain

With so much to think about in terms of testing, shipping, storage and use, the design of medical device packaging can be extremely complicated.

It can be tough to know where to start—there are so many stakeholders with differing priorities. Experts spoke to us about streamlining the approach by following a material selection matrix to narrow down the choices in a no-nonsense order, beginning with consideration of the desired sterilization method. In that vein, we also heard from technical experts who discussed articulating your needs to suppliers, and pitfalls to avoid in package design.

Beyond material selection, we looked at the ways that companies meeting certain criteria can expedite their device approval process with the Expedited Access Pathway (EAP) program, as well as the best practices for performing GUDID submissions with the FDA.

All the experts we spoke to were clear about one thing: you cannot overlook the importance of field research. Knowing what happens to your package once it leaves the dock, as well as its short and long term storage environment is integral to the preparation of the package for the journey, storage and clinical end use. For the new territory of at-home diagnostic kits, we look at logistics considerations for returns and consumer use of test kits outside of the healthcare environment.

The cost of producing and distributing this playbook has been underwritten by the companies who have sponsored it. We thank them for their support, and we thank you for reading.
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SECTION ONE

10 Can't-Miss Packaging Considerations
10 Can't-Miss Packaging Considerations

From realistic packaging volumes to lighting conditions in the warehouse, experts provide the following points to consider during your design phase.

1. **Packaged product dimensions and the sterilization process**
   Gamma irradiation and ETO (ethylene oxide gaseous sterilization) are the two most common terminal sterilization methods for medical devices. As an example, a 74” long catheter package, packaged flat on a 40” X 48” standard pallet, is not a viable sterilization configuration. The ETO sterilization provider will prefer the use of standard pallets for throughput efficiency. The use of packaging designs to organize the long packages vertically, may be a viable option.

   Sterilization processing equipment dimensions are different for each method (e.g. ETO and gamma) as well as for each individual sterilization provider. The packaging engineer must determine this important information as part of the design requirements/inputs for the packaging design. Another important sterile barrier system attribute relative to sterilization is sterile barrier system density. Sterile barrier system (package) density is integral to the validation of a gamma irradiation sterilization process and gamma irradiation dose range.

2. **Shipping cost considerations**
   If you are going to ship single parcel post, there is a Dimensional Weight or Volume Weight, called “DIM charge” by many carriers. The DIM charge is based on an estimated weight-to-size (length, width, and height) ratio of a package. You want to make sure you optimize the weight-to-size ratio, or you’ll wind up paying more for shipping than necessary. This can occur even if your package is only off by half an inch. Shippers started DIM charging
because the original gross weight basis did not work well for large lightweight items such as medical devices. This ratio consideration might not be necessary for a pallet load shipment where you want to maximize pallet efficiencies, but it is for individual shipping cases. You should perform an evaluation of your specific shipping options early in the process to optimize sizing.

3. Design size restrictions in the warehouse
One expert mentioned visiting a warehouse and finding out that they did not have racks that would hold their product. They came up with a customized way of storing the devices before they began receiving product. Being proactive helped their customer avoid a disappointing and frustrating end use experience. Packaging engineers must consider their customers’ clinical storage environment for optimized identification, access and ease of use.

4. Environmental storage conditions
Packaging and labeling materials and printing inks can be affected by lighting in their storage conditions. Also, temperature and
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10 Can't-Miss Packaging Considerations

humidity can be factors in packaging materials integrity as well. These are additional reasons to investigate your customers’ facilities to the greatest extent possible.

Experts have reported incidences of color change on packaging materials due to lighting conditions. As many of our readers know, color is often indicative of device attributes such as size and specifications so unintended color change is problematic.

5. Packaging case count and unit of sale
It is important to investigate your customers’ typical use patterns for your medical devices in order to create case counts and units of sale that are pragmatic in their clinical environments.

The packaging engineer has the responsibility to research their customers’ use patterns and balance that need with their companies manufacturing efficiencies and current packaging systems and pack out configurations.
6. **Shelf life of packaging and raw materials**
Purchasing cost efficiencies may be achieved by purchasing packaging materials in high volume, but that high volume needs to be matched against the product demand and/or sales forecast. Packaging materials and raw materials all have an effective shelf life (expiration) and expired materials should never be used in the construction of a sterile barrier system. As an example, rubber cap liners can become brittle over time, to the point of potentially damaging their mating glass container. The lesson here is to thoroughly understand all the components and raw materials included in your sterile barrier system and verify the shelf life period for each component and material as you integrate them into your packaging design.

Raw material and component quality are additional critical attributes to be considered as you design your sterile barrier system. Partner with your supplier quality assurance team to ensure appropriate quality standards are in place when developing purchasing contracts.

7. **Leveraging existing packaging validations vs. re-validation**
With limited budgets and pressure to meet production timelines, it is a reasonable approach to pursue leveraging existing packaging validations. However, if there are significant changes to the packaging system (e.g. cases, materials or head space, closure equipment) or testing procedures, it is wise to re-validate.

MDMs need to have a well-established risk assessment program in place and subject new devices to the “worst case” product family assessment. A recent white paper Dr. Michael Scholla and Thierry Wagner of DuPont published in the ITV network provides a step-by-step guide for determining when to conduct a revalidation.

8. **Printed components qualification**
ISO 11607, part 1 requires that the printing and labeling systems be compatible with the sterile barrier system processing, device and materials as well as remain intact and legible until point of use. It is imperative that the packaging engineer investigate and
evaluate all aspects of the printing process, materials, sterilization processes, shipping, storage and environmental conditions so that there are no "mislabling" occurrences for your medical devices.

Adhesive choices for labels (e.g. glues, pressure sensitive labels) depend on the label substrate. There are many considerations, so it is important to test and understand the substrates, the environment of use, and the shelf life or aging performance characteristics to ensure the label remains intact and legible.

Pressure sensitive labels are a popular option because the adhesive can normally be aggressive regardless of the substrate (though rubber based adhesives may dry out and lose adhesion faster than acrylic based adhesives). Glue labels require considerations about dyne surface levels (dyne level refers to the surface energy of a material) and plastic surface treatments that
may be affected by surface blooming of chemicals or changes in surface energy over time.

Beyond the adhesive, there are considerations for the printing stock (paper, plastic), web stock, release liner, to identify the major components. The total pressure sensitive label design should be evaluated as a system with specific consideration of how the pressure sensitive label will be applied in your manufacturing environment. Another important consideration is the printing of variable information, such as lot code dating and expiry information, directly on to the label.

All printed components or labeling must be qualified as part of the sterile barrier system validation. In compliance with ISO 11607, part 1, the printed components or labeling must be compatible with the entirety of the processing of your terminally sterilized medical device, from component storage to labeling and manufacturing process, sterilization processing, shipping, handling and storage for the stated shelf life of the medical device.

9. **Get it right the first time**
Optimizing packaging design from the outset is important from a design performance, design compliance and design excellence perspective as re-design efforts are inefficient from a long term cost perspective. Re-design efforts take resources away from new product launches, line extensions, and other value added activities.

10. **Anticipate the unexpected**
While difficult to diagnose, experts noted that there are atypical scenarios in which metals (like jewelry) in the production area, electrical brownouts or overloaded electrical systems can cause machinery to malfunction such as measurement or weighing devices and sealers. Implement CAPA (corrective and preventive action) procedures as critical elements of your packaging quality plan.
SECTION TWO

Articulating Your Material Needs to Suppliers
Articulating Your Material Needs to Suppliers

Establishing material requirements is a critically important activity and the best opportunity for success is to begin early in the packaging development process. A vital task is to understand the medical device/product sensitivities in order to select optimally performing materials. For those pursuing materials providing barrier properties, the following are common inputs and design outputs for provision of light, moisture and oxygen barriers.

- light barrier, where a clear film is made opaque by adding white color or using foil to completely block out light, or

- for oxygen and water vapor barriers, it is critical to measure the oxygen and or water vapor transmission rate through the selected films. Film suppliers typically supply the oxygen and water vapor transmission rate of their flat films or this transmission rate measurement can be produced by third party test labs. The transmission rate (permeation) data can be used to estimate the permeation of oxygen and moisture into or out of the package, depending on the package internal environment and external environmental conditions.

Regarding flexible packaging design, packaging film converters offer stock film combinations to provide common film requirements such as barrier properties, puncture resistance, peelable seals, non-peelable seals, flow wrapping functionality or thermoformability. Additionally, film converters can offer custom film combination options to meet unique customer requirements, including cost effectiveness.

Occasionally, the converted package design request is attribute based, like "easy to open" and this design effort will require close collaboration with your supplier. This type of attribute based design requirement may be a candidate for human factors or usability assessment by a representative end user group.

Effective packaging design for flexible, semi-rigid or rigid configurations should include a plan to evaluate the package or material performance characteristics in order to select the optimal material(s) or package design. This activity will likely include packaging prototyping and laboratory testing for those material or packaging design attributes that must be characterized and defined in order to select an optimal packaging design. Having a defined test plan strategy helps to prevent incomplete design requirements and last minute design requirement requests for the materials or packaging suppliers. Incorporating a testing plan into your design process also mitigates the potential for packaging design failure.
SECTION THREE Logistics Considerations for At-Home Diagnostic Kits
In an effort to deliver patient-centric care, companies are marketing prescription-based test kits for home use to minimize trips to the lab or healthcare site. Patients receive the test kit by mail, provide a sample, and return the kit by mail, typically to a lab for testing.

- Sample collection kits must be labeled, with one label for delivery to the patient and a second for return the lab/R&D facility. One company opted to use thermal-transfer paper for the label materials, which are printed flexographically.

- Return logistics should be made as user-friendly as possible. Will the patient call the delivery company or lab to schedule a pickup? Will they be able to drop the sample off at a forwarder location?

- Depending on the sample type and storage conditions, overnight mail to the lab may be necessary.

- Packaging is an important part of the kit in making the test patient- and physician-friendly.

- Consider packaging of all components. In one case, a kit contains a shipping box filled with a plastic sample container, plastic bracket, patient instruction guide, sample labels, a bottle of preservative liquid and a tube containing a buffered detergent solution with an antimicrobial agent.

- Companies seeking to market a test kit as a medical device in the in-vitro diagnostics therapeutic category should perform research on the user experience, including issues and limitations the user may have in their ability to open and close the container, as well as extensive human factors testing. There may be packaging considerations specific to the patient demographic.

- Storage and shipping conditions, such as temperature and whether the kit can be exposed to sunlight, must be clearly communicated.

- Forwarders must be part of the conversation in developing a logistics strategy tailored to transporting the test in a simple and efficient manner.
SECTION FOUR

By The Numbers: Expedited Access Pathway Program
The Center for Devices and Radiological Health’s (CDRH) new review process, the Expedited Access Pathway (EAP) is a program that allows device sponsors to work with the FDA in an attempt to reduce the time and cost from development to marketing decision for potentially life-saving medical devices, while still meeting FDA’s approval standards.

Key qualifications for acceptance into the EAP program include:

- The device should treat or diagnose a life threatening or irreversibly debilitating disease or condition;

- The device meets at least one of the following criteria:
  * No appropriate alternative treatment or means of diagnosis exists.
  * The device represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology.
  * The device offers significant, clinically meaningful advantages over existing legally marketed alternatives.
  * The availability of the device is in the best interest of patients.

- The company should have a Data Development Plan outlining what will be included in future submissions to FDA.
By The Numbers: Expedited Access Pathway Program | continued

**APRIL 15, 2015**
The date the EAP program began.

**30 DAYS**
Amount of days from receipt that the FDA intends to notify the sponsor of its determination whether or not to grant EAP designation based on the Pre-Sub.

(If there is insufficient information for FDA to make a decision about EAP designation, FDA may request the sponsor submit additional information.)

**29**
Decisions made by CDRH on requests for designation into the EAP Program in its first year. Requests included devices to help treat brain, heart and kidney diseases and conditions.

**60%**
Percent of requests for EAP designation approved in first year of the program (17 approved/12 denied)

**3**
Number of Sections in a Data Development Plan

According to final guidance, the Data Development Plan should include the following sections:

- An explanation and justification for the proposed balance of premarket and postmarket data collection, if a premarket-postmarket data shift is proposed and applicable;
- A description and summary of the data collection plan, including study synopses and study design; and,
- A timeline for the development and marketing of the device as well as for the postmarket data collection.

*In October 2016, the U.S. Food and Drug Administration updated the EAP Program website with two Data Development Plan examples that serve as a resource for sponsors.*

**SEPT 30, 2017**
The date by which CDRH plans to increase the number of Expedited Access Pathway data development plans or regulatory submissions that consider patient perspectives (compared to FY 2015 baseline.) This is part of the CDRH goal to increase use and transparency of patient input as evidence in decision-making.
By The Numbers: Expedited Access Pathway Program | continued

Other pathways
The EAP program features benefits such as priority review, more interactive review, senior management involvement, and assignment of a case manager (depending on the availability of FDA resources). However, this pathway is not the only way to reach approval in an expedited manner. Device sponsors can complete an optional pre-submission package, which includes a data development plan and early interaction with the FDA. Sponsors do not need to qualify (as they do for EAP) to undergo the pre-submission process.

Additionally, the Expanded Access (or “compassionate use”) program allows patients with life threatening or serious conditions access to investigational devices outside of clinical trials for certain circumstances in which there are no generally acceptable alternatives for treatment of the condition.

In August 2016, the FDA issued updated recommendations (in draft form) applicable to medical devices cleared through premarket notification. The guidance is intended to help manufacturers determine when they are required to notify the FDA about modifications made to certain medical devices already on the market through submission of a new 510(k).

Manufacturers are required to submit a new 510(k) when changes or modifications made to an existing device could significantly affect its safety or effectiveness or the manufacturer makes a major change or modification in the intended use of the device. This could include changes to instructions or indications.

The update includes a separate guidance applicable to software devices, with a flowchart to help manufacturers decide when to file a new 510(k).
SECTION FIVE

Complex Requirements: Pitfalls in Kitting, Wearables and Sensitive Devices
Complex Requirements: Pitfalls in Kitting, Wearables and Sensitive Devices

Whether you package in-house or use a 3PL, there are added challenges in kitting or packaging sensitive devices that cannot be ignored.

**Kitting**
When kitting, the kit components and positioning of items must be clearly communicated, with proper sealing and labeling methods in place. With a number of subcomponents, misassembly is a risk. Some device companies use RFID technology to tag components and improve efficiency in kitting.

Kit recalls related to packaging integrity in recent years have included:
- Diagnostic kits - poor lamination between sample reaction wells, which could have lead to leakage and cross-contamination between samples. This defect had the potential for false positive, false negative, or invalid test results.
- Sterile convenience surgical packs – individual packs adhering to one another inside the shipping case. (In some cases, plastic from one bag adhered to the end seal on an adjacent pack.) Separating the bag could tear the film, which could have lead to a loss of product sterility and potential for contamination and infection.

In the event of a medical device recall, lot and serial number traceability are critical. Device manufacturers should have the ability to identify which devices used a given component, in case a component defect is found. Traceability requirements for devices, device components and packaging, are addressed in 21 CFR 820 and ISO 13485. When the need for traceability arises, effective Quality Systems are invaluable for identifying products down to the individual component level. This can be difficult when procedure kits are created that contain more than one medical device SKU. They must also keep record of serial numbers of devices that are implanted, in case of a recall. Reverse logistics must also be considered for cases where an unused device in a procedure kit is sent back to a manufacturer for use in another procedure.

**Wearables and precise devices**
It is also important to take precautions with the packaging and
shipping of electronic devices like wearables or precise measurement tools. Some measurement tools have extremely small tolerance requirements, where movement of several microns can cause the device to be out of tolerance.

Packaging for these precise tools should be commensurate with the amount of protection needed from shock and vibration. Test shipments with sample parts to measure stresses during transportation may shed light on package robustness.

**Future growth**
If you use a third party logistics provider for kitting, packaging or shipment, you’ve already determined that they have the resources to handle your product volume. But you should not overlook that your volumes may grow. Ensure that they are capable of handling projected volumes to avoid looking for (and qualifying) a new, specialized service provider just as you begin to scale up.
SECTION SIX

Material Selection Matrix
Material Selection Matrix

One way to approach material selection is to think of it as a matrix of “must-have” versus “nice-to-have” features in each of four categories: product, customer, material performance and company objectives.

**Start with sterilization**

In the journey from starting a project to the final package design, many companies have a checklist, which works well under normal scenarios. The minute they are not under a normal scenario, it can be difficult to know what questions to ask because you don’t know what you don’t know.

Before getting into the matrix of questions, the most critical question for the packaging engineer is “What is the method of sterilization?”

This is question number one, because the chosen sterilization method will immediately eliminate some packaging materials from consideration and potentially limit the packaging sizes possible. Until that question can be answered, it is difficult to move forward since the sterilization method will set boundaries for material selection. If the product design engineer knows the product will be sterilized via ETO, then the packaging engineer should know a breathable substrate is needed for the package.

Based on the sterilization method and the device material composition, the packaging engineer can start to whittle down packaging material choices to compatible materials.

It is important to consider material interactions as well as sterilization compatibilities of materials. AAMI TIR 17 is a useful guide for plastic materials sterilization compatibilities.

In consideration of materials compatibilities, this is another excellent application for evaluation through production and sterilization processes as well as environmental simulation testing and subsequent evaluation.
Defining the product fragility for products, though often only considered for some electronics, is important. The products' fragility can be compensated for or occasionally amplified within the packaging design.

Drug-coated products like stents or other combination products could be sensitive to light, moisture or oxygen.

In orthopedics, some products are fairly bulky and are actually designed with porous, rough surfaces to allow a patient’s bone to grow into the implant. The implants need to be secured well within the package to prevent movement that could scratch the inside of package and create debris. When the product can scratch the inside of a package, the end user, during surgery, may open the orthopedic hip stem product packaging and discover debris on the device, making it unsuitable for implantation. Particulate generation can occur with all types of devices and packaging configurations and evaluation of this attribute should be included in sterile barrier system test plans.

The following is a brief identification of design requirements developed through stakeholder collaboration:

- **Customer:**
  
  * Is there something the customer (user) needs that this product must have?
  
  * Does the product have multiple components that require assembly or flushing during a surgical procedure?
  
  * Do all those components need to be laid out in a tray? If so, the product cannot simply be placed in a pouch.
  
  * Consider the component organization, orientation and securing of the components within the package as it relates to the process flow of their clinical procedural use.

- **Material performance:**
  
  * What does this packaging material require, in order to perform?
WHAT IF YOU COULD TRACK MEDICAL DEVICES FROM THE MANUFACTURING PLANT UP TO THE PATIENT?

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BENEFITS

- **Maximize your ROI**
- **Minimize your risk**
- **Decrease downtime**
- **Reduce recalls**
- **Improve quality control**

Material Selection Matrix | continued

- Devices for military use may be shipped out to the Afghanistan desert or in other harsh conditions.

- Consider the environmental shipping, handling and storage conditions for the required distribution of your medical devices and build these requirements into the required performance requirements.

- Manufacturing, processing and logistics constraints:
  - An organization’s operational and packaging equipment constraints are important considerations as capital investments in packaging machinery may not be feasible at any certain time.

- Corporate initiatives such as sustainability objectives and/or cost reductions are important packaging requirements and the packaging engineer must collaborate with the appropriate stakeholders to achieve these type of objectives.

BENEFITS

- **Maximize your ROI**
- **Minimize your risk**
- **Decrease downtime**
- **Reduce recalls**
- **Improve quality control**

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WHAT IF YOU COULD TRACK MEDICAL DEVICES FROM THE MANUFACTURING PLANT UP TO THE PATIENT?
Once all four of these categories have been discussed, the packaging engineer can get serious about choosing actual materials.

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<thead>
<tr>
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<th>MUST HAVE</th>
<th>NICE TO HAVE</th>
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<td>Product</td>
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<tr>
<td>Customer</td>
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<td>Material Performance</td>
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<tr>
<td>Company Objectives</td>
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Note
An effective and thorough design requirements process mitigates future packaging redesign activities and/or disappointed or aggrieved customers.
Business Objectives vs. Compliance Requirements, balancing for the best outcomes

Marketing: With limited space, device shipping cases are typically discarded on a hospital's back dock. Experts are starting to see a trend where even the shelf carton is discarded upon delivery. In these cases, users do not see the fancy three-color print carton and everything that went into the marketing side of the shelf carton.

When this happens, the sterile barrier system does not have the protective sales carton within the hospital walls, which is not how a packaging engineer typically tests a product (normally testing is conducted in the shelf carton). This is considered the last mile of the product's life cycle as it makes its way to the surgical suite and is used on a patient.

When the nurse uses the product, the pouch or tray becomes the important marketing piece because it becomes the company image. It is a part of material selection that can be overlooked during technical development.

The importance of this depends on the company objectives and whether an impeccably designed sterile barrier system is a must-have or nice-to-have in the matrix. Some companies are content when the sterile barrier system passes distribution testing, while some feel strongly that the system helps to give a high quality impression when a nurse holds it. Most medical device packages must allow for aseptic presentation to provide a clean transfer of the device into the sterile field or an operating room or sterile setting.

Sizing: Good fundamental design skills and the right materials must be balanced with company needs. For example, a company might decide they only want to stock five pouch sizes. When a new product comes along, they want the packaging engineer to try to fit it into one of those five pouches. There may be a device that does not need a four by six pouch, but that is the smallest pouch they stock, and the company does not want to add a new smaller pouch to the packaging stores, particularly at lower volumes. The larger-than-necessary pouch may not have the ideal appearance but the company is willing to make that compromise. Every product may not receive a custom fit, designed perfectly for the device.

Most companies work with product families, similar in function, material size, etc. When a new product is developed, the packaging engineer has to decide if fits into the current product family bracketing or if it is a new worst-case. If the new product does fit, they determine the choices for materials based on what they currently use for this product family.

A company may start out as a small medical device company, using certain trays and coated lids. Over the years, they grow and acquire other med device companies, each time acquiring all of their
packaging combinations. This may mean they will have many different trays with a variety of lid formulations or pouch material combinations and sizes. This can be quite the headache from a supply chain and material management standpoint. The company may choose the best few combinations and standardize based on their objectives. There have been huge projects over the years to try to consolidate and standardize materials; a company will define why they prefer certain materials and suppliers to make more streamlined decisions in the future—strategic sourcing is often given as the name for this effort.

**Timing:** Timing is also a big factor in material selection. If a company has a major product launch in six months, that does not leave time for new material or supplier development, so the packaging engineer must select from commercially available materials. With a longer timeline, film development may be possible but not normally in a short time period. Some companies have a list of validated materials or combinations of materials and choose from the list. Adding a new material or supplier to the list of options usually requires significant additional effort for a packaging engineer and company.

**Global Sourcing:** Ideally, material choice is based on a long-term strategy more than a knee-jerk quick reaction. The next key question becomes whether a company can source a material all over the world. If a coated material from a manufacturer that only produces in the U.S. is selected, then the company may become in the business of transporting the material to allow their product to be packaged at facilities in other countries.

For many multinational companies, global sourcing is a must-have for the company to maintain consistency. They may choose materials that can be sourced in at least two regions where they manufacture, such as in the US and in Europe.

Some companies are willing to transport materials as long as it meets the company’s strategy for materials selection. It might be more important for some products versus others.

For example, a European company may be extremely happy with a film manufactured in France. They begin operations in the U.S., but decide that the film is so perfect for their needs (and the customers’ needs) that they continue to use it. This means they spend extra resources on shipping the film from Europe, but they also avoid the costly revalidation of a new film. Companies must weigh the cost of revalidation and the potential submissions required with the choice of materials to use for their product(s) and making it work. There is no “one-size-fits-all” solution. You have to consider the supply chain and potential costs associated with sourcing specialized materials that require international shipping.
SECTION SEVEN

Tales from the Basement: Five Reasons for Retail Research
Tales from the Basement: 5 Reasons for Field Research

With so much to consider in terms of keeping the medical device sterile and maintaining all the required branding and labeling, people can lose sight of the device’s actual journey from warehouse to the end user, whether that’s the nurse, EMT or military medic. In the field, the sterile barrier system does not necessarily remain in the manufacturer’s secondary packaging.

1. **Central supply storage**
   Central Supply is one main function in hospital basements, where medical devices are often stored. Central Supply is not always a spacious place. Whether this is referred to as “human factors” or “storage configuration,” experts see some pretty creative ways that hospitals squeeze a volume of products into a small area within drawers, bins or rack systems.

   Generally speaking, most medical devices have a carton. A lot of times, Central Supply may remove a device from the carton—especially if it is a multi-pack. The part could go from a very stackable, neat storage orientation to a bin where items are piled together. In some cases, there may be ten pouches in one folding carton, which are removed and divvied up across different parts of the hospital floor. This depends on the way the device manufacturer labels the product and how creative or cramped hospital inventory locations may be. Manufacturers may include warnings such as “Keep as unit” or “Void if separated” to help reduce the divvying of components.

   It’s also a good idea to find out the customer’s storage measurements whenever possible, i.e. what space they are putting the device in once inside the hospital. A 74-inch catheter may be a valuable device, but if the hospital cannot store it, the device will not be available to help people. Of course, it is not possible to research every customer’s inventory closet, but having an idea of typical storage limits will help in designing the package system.

2. **Manual handling**
   Hospital procedures are similar to other defined procedures—personnel start with a bill of materials, or list of items needed to conduct a specific procedure. Items needed for a procedure are collected from inventory and placed in a tub or cart to transport to the operating room (OR). The items that are not used may be brought back down to Central Supply and re-inventoried. Items
may go through this cycle several times before the product is used in a procedure.

Packaging engineers are typically not testing for this type of manual handling inside the hospital walls. How do we know that the packaging is still providing a sterile barrier when wrinkled during inventory stocking or restocking? There are no standardized test procedures for this manual handling, partly because it is difficult to know what hospitals are doing once they obtain the product. More literature and photography are emerging on the hospitals’ manual handling and storage of packages within the hospital walls.

Information or details that a company can gather on how their product is used and handled within a hospital, before opening and use on a patient, can be beneficial to the material selection process and testing to conduct.

3. **Product removal from SBS packaging**

There is a lot of information available about sterile presentation: how a nurse or clinician opens the package and presents the device to a scrub nurse or doctor in the sterile field. Many people think of the doctor as the end user of the packaging, but in most cases, for a terminally sterilized medical device that is implanted, the package end user is actually a nurse or clinician opening

<table>
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<tr>
<th>Note: OR vs. ER</th>
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<tr>
<td>The basic needs and desires of the nurses or emergency personal opening sterile barrier system packaging in an emergency room (ER) are different than those in an OR surgical suite. In the ER, staff is focused primarily on keeping a patient alive, and infections, while avoided as much as possible, can be dealt with later. Know the device use environment for packaging.</td>
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</table>

In the OR, the procedures are typically high-cost (or elective) so personnel are very focused on keeping infections low or non-existent. A good recovery record is a part of a surgeon’s reputation and infections can diminish that reputation. Doctors do not want to make the patient sicker than they would be. It is important to keep in mind that while sterility is always important, there are different thresholds for different clinical situations.
the package for doctor access to the device. The Association of periOperative Registered Nurses (AORN) is one resource for information on sterile presentation.

The sterile barrier system (SBS) package must protect the device (and make the nurse feel confident that the package is robust). However, it must also be easy to open to allow the doctor or sterile operating nurse to pull the device out and use it properly. If the outer sterile barrier package is hard to open and the device inside is loose, a prep nurse may struggle and cause a (potentially expensive) sterile implant to sail across the room or roll underneath the OR sterile field.

4. **Changing hospital protocols**
Hospitals, or third party distributors, may adopt new cleaning and sterilization techniques that are not likely to be communicated to the device manufacturers. Experts note that some hospital sites have recently installed ultraviolet (UV) light cabinets for device exterior sterile barrier system packaging or spraying surgical areas with hydrogen peroxide for additional sterilization measures; this subjects packaging to conditions that are not tested for during packaging development. These measures need to be evaluated for potential new test requirements on medical devices and the packaging.

5. **Emergency and military use**
Some devices may be used in field emergency situations or emergency room. Ambulance or field storage space is normally more limited than a hospital’s Central Supply. Packages used in the military may need a higher level of material strength based on the harsh use conditions (e.g. extreme temperature or humidity). Material selection and package structure for these environments may require additional field research or information gathering to ensure the packaging design is robust enough for the environment.

It is important to remember that in the emergency situations, cartons and instructions for use may not be available, leaving only the device product in the sterile barrier system. Package opening and device use must be very obvious or intuitive for products used in true emergency situations.
SECTION EIGHT

Medical Device UDI: Do’s and Don’ts of GUDID Submission
Medical Device UDI: Do's and Don'ts of GUDID Submission

In September 2016, the FDA released an industry letter extending the Unique Device Identification (UDI) label and Global UDI Database (GUDID) submission deadline for certain class II devices. The extension will allow the agency to publish guidance on “convenience kits” and “repackaged single-use devices.” The previous deadline of Sep. 24, 2016 for these particular class II devices is extended to coincide with the Class I device compliance date of Sept. 24, 2018. These device groups are part of a much broader FDA UDI mandate for all devices with some exceptions to implement UDI over a phased plan starting in 2014 and ending in 2020.

As defined by the FDA, a UDI has two components that a Labeler must create and present according to standards of an FDA-approved Issuing Agency (GS1, HIBCC, or ICCBBA):

- Device Identifier (DI), which is a fixed, ISO-based code “that identifies the Labeler and the specific version or model of a device…”
- Production Identifier (PI), which is the variable portion of UDI that contains specific information, such as the lot/batch number, serial number, manufacturing date and expiration date of the device.

Though some class II device Labelers may be breathing a sigh of relief in light of the extension, it’s best to register early with the FDA’s Global UDI Database (GUDID) and adhere to the following good practices for GUDID submissions:

**Do: Verify your data values.**
This should be of particular concern if you collect/enter data manually, as there can be typos, transposed or omitted characters. Ensure the proper quality checks are in place—these errors can be difficult to identify. Confirm all values meet the specified format and if the data value is from an FDA List of Values (LOV), make sure the entry is an exact match.

**Don’t: Include the PI in the GUDID submission.**
There is often confusion about how to address production identifiers in the GUDID submission. The FDA does not collect production
information such as lot/batch number, serial number, manufacturing date and expiration date—the actual values of these identifiers are not reported to the FDA. The GUDID submission record does include Yes/No data fields to simply indicate if the device is controlled by these identifiers, i.e., do they appear on the device label.

**Do:** Verify that you use the correct device identifiers for each package level.

If one device is placed in one package, you will use the same device identifier. This first package level, with one product, does not need to be reported to the GUDID.

But when the number of devices in a package is greater than one, you must assign a new device identifier to that package level and report this package level to the FDA up to, but not including, the shipping container. If 5 items go into a box and 10 boxes go into a carton, then the box (second level of packaging) and carton (third level) need unique identifiers that are associated with the base product being packaged.
Bell-Mark has a full line of Ink Jet printers capable of printing UDI, Serialized Codes, Logos, Barcodes, Variable Data, Product Info and much more on a wide range of materials.

**Medical Device UDI: Do's and Don'ts of GUDID Submission | continued**

**Don’t:** Include extra letters or descriptors in the Model/Version field.
The FDA prefers that text, like “Model,” “V,” or “Version,” in front of the model or version number be omitted from the Model/Version field.

**Do:** Include values if data is available.
While multiple fields, e.g., device description, catalog number, storage and handling, size, can be omitted from the GUDID record and it will pass FDA validation, the FDA prefers these “optional” fields be completed if the data is available thus providing a more comprehensive data set for GUDID downstream users. For example, the device description field can include a short description or the product’s approved/cleared indication for use. A good rule of thumb is to include the value if it appears on the label. The FDA also prefers data be placed in dedicated structured fields, e.g. size type, value, and unit, rather than combined in one free text description field.
Don’t: Assume your submission was received.
There may be cases in which you submit data but don’t receive FDA acknowledgement. This may be because, for example, the system is undergoing an upgrade at the time or is overloaded. Follow up with the FDA and confirm that the submission was received.

Do: Review your data before submission and/or before the end of the grace period.
One expert notes that a Labeler had data quality issues and did not review their submissions before the grace period ended. Once the data is published, only a portion of the fields can be edited. If incorrect data is published in a “fixed” field, you can reach out to the FDA, but the most likely scenario is that you will have to retire the record and generate a new DI, which is a major headache.

Don’t: Wait until the last minute.
Be aware that many Labelers submit their data close to the compliance date. This can be a challenge for the system, and there may be delays. If you can avoid the rush that occurs in the final two weeks, do so.

Do: Ensure you use the correct listing number and GMDN code.
There has been some confusion among Labelers about listing numbers. Your listing number is assigned by the FDA at the time of device listing. This means you may have to look through previous FDA documentation to find it.

Some Labelers have received rejections based on invalid Global Medical Device Nomenclature (GMDN) codes. A previously selected GMDN code may have been replaced by several more granular codes, so you should check to ensure you have a current code.

It’s also important to be aware of potential issues if you have to create a new GMDN code for your product. Because the GMDN Agency updates the FDA twice per month, it may take a couple of weeks for the FDA to have the new code in their system and recognize it as valid.
SECTION NINE

Tips for Successful Verification, Validation and Testing
Package integrity testing is a subset of package quality. Fundamentally, it is the focus on the physiochemical barrier of the package—whether or not a package holds together. There are a number of tests under ISO 11607 “Packaging for terminally sterilized medical devices,” a guidance document that lists all the methods that you might use for validating a package, such as a peel test or burst test. ASTM methods are generally reviewed and accepted by ISO and eventually ratified in the ISO 11607 document and recognized by the FDA.

**Packaging validation steps**

After packaging materials are selected, equipment is qualified and test samples are produced, companies will commonly:

1. Perform tests on package integrity and seal strength.
2. Perform accelerated aging tests.
3. Perform physical testing on the device and packaging.
4. Perform shipping simulations tests, including shock and vibration testing and thermal conditioning.

What you’re determining is whether the package protects the product from contaminations; such as microbes, moisture, dust, or any other environmental contaminant that can impact or reduce the safety and efficacy of the device. The testing is based on the risk associated with the package failure—Class III devices that are implantable will typically be subjected to more stringent testing than Class I devices based on a product risk assessment.

**Stepping away from manual inspection**

A very common test method is manual visual inspection, in which operators inspect the package or seal visually. The primary pitfalls here are:

1. It is widely acknowledged that the probability of defect detection is 60 to 100 percent (refer to ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection for quote on 60-100% reliability, and to review the precision and bias statement of the test method).

2. The method may not challenge all the defect modes a package will experience. A company may focus on a wire pull or some other type of defect, but it may not be the most common
defect mode or critical defect that would naturally occur in a production plant. F1886 is also only applicable to transparent and semi-transparent package formats.

3. The FDA does not recognize visual inspection, ASTM F1886, as a stand-alone method during validation.

One expert notes that if you do not have a reliable test method, you do not have any test method, because ultimately a test method is there to provide a definitive result that you can trust and make decisions with. An accuracy of 60 to 100 percent could be quite dangerous for life-saving Class III medical devices.

Another issue with manual inspection is that studies have shown that operator effectiveness decreases over time at the packaging line. With every ten minutes that they are performing a task, their detection probability decreases dramatically. An operator performing a task for 20 or 30 minutes on a normal day may already fall below the percent effective rate at detecting certain criteria. Add in potential factors such as lack of focus on off shifts, busy days or post-holiday periods, and it can be scary to use visual inspection on a med device line. (Most research in operation manual visual inspection performed in field of aviation inspection, with significant studies published by Drury & Watson).

The key here is that having more quantitative test methods provides you with more accurate results or better tools to address quality. The ultimate test method is a quantitative, non-subjective, non-destructive test method because this will allow you to produce much more reliable and discrete data and test far more samples.

**Other test methods**

There are two primary tests for medical devices that are commonly deployed to inspect seal quality:

- Vacuum decay is used on non-porous packages, or porous packages with Tyvek® lidded trays.

- Airborne ultrasound is a preferred technology for porous pouches, as it is difficult to leak test porous packages with vacuum decay. It may be deployed for all flexible package seals.

For most integrity testing methods available, results are fairly instantaneous. Vacuum decay is a very quick test (under five
Visual vs. Physical Defects

People often relate physical defects to visual defects. Though physical and visual defects can overlap, each can certainly exist without the other present.

Companies care about visual defects because they do not want a surgeon, nurse or patient to look at the package and presume that something is wrong with it. But more importantly, companies do not want physical defects as they could potentially put the patient’s health at risk because of a breach in package integrity.

The physical defects are the most critical to detect. The visual defects are important, but people may not be at risk because of them.

For example, experts noted that it is possible to perform a hot bar seal on a pouch where the seal imprint looks like you expect (knurling pattern on seal), but the inner layers have not properly bonded or cured. Improper seals that appear perfect can lead to scenarios where a device is being removed from packaging in the emergency room it suddenly falls from the bottom of the pouch through a completely open or weak seal.

Recalls often stem from a heavy reliance on detection of visual circumstances when the physical is, in fact, most critical.

The best way that companies can avoid this is by selecting methods other than:
• Manual inspection
• Methods that are emotionally based
• Methods that rely solely on the visual appearance or visual circumstances of a product rather than the physical circumstances of a product

Manual visual inspection may work when you are dealing with transparent or semi-transparent pouch seals, but experts note that the method is still being deployed for foil seals, foil pouch seals, and other non-transparent package materials.
seconds), while airborne ultrasound can provide results in less than one second. A destructive test typically used during validation, the blue dye test involves inserting dye into the package, which requires that the operator prepare the sample, insert the dye, rotate the package, and observe migration of dye. The dye test also presents issues associated with cleanliness and practicality.

The trade-off for quick sensory technologies is, of course, cost. Blue dye costs very little and manual visual inspection only costs the operator’s inspection time. The manual and destructive methods have a low upfront cost on paper, but gray costs reside in eventual deployment. Airborne ultrasound and vacuum decay typically start at around $40,000, but it can vary widely. The cost of a more reliable or rapid test method has a significant upfront cost, but may assist in reducing labor costs or cost associated with quality deviations down the road.

**Start early**
Experts advise reaching out to validation resources early, during the development process. They can help avoid major time investments and rework by pointing out that a certain packaging configuration would be very difficult to handle or inspect. One expert said they have received critical medical devices—where a leak detection or inspection is absolutely crucial—and they determined it was impossible to assure the package integrity. That is a very dangerous circumstance so it’s important for companies to address testing methods early on.

Some companies do not challenge the packaging system robustly enough. If you have a packaging material and design that your company has a lot of history with, then you are likely already aware of the ins and outs, and how the package will perform in the real world. But if the chosen materials are new to your company, you may be at risk of not thoroughly evaluating the packaging system for environmental hazards or for product-package interaction. With a thorough understanding of test methods, publically available industry information and ISO 11607 as a guide, packaging engineers should be able to determine the best validation and testing required for their product.
SECTION TEN

Q&A: Packaging for the Wearable and mHealth Device Markets
Wearable and mHealth technology developers ultimately aim to lower the cost of healthcare by enabling preventive and decentralized care, which combine to reduce the cost of care and increase patients’ quality of life.

Adoption of the technology has correlated with the rise of the smartphone starting in the mid-2000s, as these devices often use mobile phones as processing and communication hubs.

Additionally, many new players have entered the market as device start-ups, and may not have in-depth packaging and supply chain experience. Where established healthcare products have undergone years of trial and error in packaging and distribution, packaging for the wearables and mHealth markets is still a relatively new field.

Q: Do wearable/mHealth devices need to be kept within specific temperature ranges?
A: These devices are usually used in the same temperature ranges that a human experiences, since the device typically directly interfaces with human skin, blood, etc. However, if a device is reusable and used by multiple patients, it could be exposed to high-temperature sterilization methods that can reach up to 132°C.

Q: Beyond temperature considerations, how might manufacturing and distribution challenges differ for wearable/mHealth devices as opposed to consumer mobile electronic devices?
A: These devices face similar manufacturing and distribution challenges as typical consumer mobile products. However, particularly for in vitro diagnostics (IVDs), there is significant concern around any contaminants affecting the reliability of reagents and immunoassays. These tests often need to be aseptically sealed to ensure the accuracy of the test, much like over-the-counter pregnancy tests.
Centralized laboratories conduct most IVD tests today, but it can take days for a patient and their doctor to learn the results of a simple test. Although this delay is acceptable for some tests, a rapid time-to-result is beneficial in most cases. mHealth IVD devices can leverage consumer electronics’ processing and communications abilities to remotely run tests at home and in the field when a quick answer is most valuable. Another major reason why IVDs will be important for the device market is the need for increased access to healthcare around the world. Public health workers and local physicians can use mHealth IVD devices to perform screening and diagnostics tests in remote areas with little-to-no access to traditional healthcare facilities, as in rural India or sub-Saharan Africa.

Q: What is a “typical” distribution route for such products?
A: This depends on whether the end user is in a clinical or consumer setting. Consumer devices are distributed much like any other consumer electronics device. Clinical mHealth devices would typically be distributed through a healthcare provider, be it a hospital, primary care physician, or pharmacy.

Q: What are the shelf-life ranges for such products?
A: Depending on the device type, shelf life can range from a few months for some IVD tests to multiple years for electrophysiological electrodes.

Q: How do consumer and clinical packaging selections differ?
A: Packaging is extremely important for both consumer and clinical wearable and mHealth devices. Consumer and clinical mHealth markets have significantly different packaging needs.

On the consumer side, packaging needs to attract customers and show off the device, much like any other mobile consumer electronics device packaging.

For clinical mHealth devices, packaging must help ensure the device is sterile and safe to use. These devices must have much more robust packaging, including sterile compartments and easy-to-understand instructions to properly address the needs of the patient.
2016 MEDICAL DEVICE PACKAGING SURVEY
In February 2016, Healthcare Packaging magazine conducted a survey to hold up a mirror to the medical device community to identify trends beyond demographics. The following results represent a snapshot of the industry, and indicates differences in opinion, outlook, etc., can be seen as a function of company size, sophistication, amount of outsourcing, innovation, etc. Perhaps predictably, differing opinions are demonstrated between those respondents with more of an engineering focus, and those with more of a sales and management focus.

**Methodology**
This survey was sent to both Healthcare Packaging (magazine) email recipients and HealthPack (industry conference) email recipients, finishing in February 2016. Of the 193 total responses that were collected, 146 were deemed qualified, after filtering for suppliers to the industry, etc. Those answers are the ones reflected in the following survey results.
Demographics

The following demographics represent a snapshot of those surveyed, and you should see yourself represented among your peers. Sentiments from some of the subgroups represented here, such as job duty (engineering vs. management positions) and company size (small, medium and large) will later be compared and contrasted.
**DEMOGRAPHICS**

What best describes your company?

- **46%** Primarily a medical device manufacturer
- **13%** Primarily a pharmaceutical manufacturer
- **11%** Consultant/Integration
- **11%** Contract packager
- **9%** Manufactures combination of medical devices, biologics, and pharmaceuticals
- **2%** Contract Testing
- **7%** Other
- **1%** Primarily a biologics manufacturer

Medical Device Survey
What best describes your job duties?

- Packaging Engineer: 28%
- Senior Management: 16%
- Other: 3%
- Other Engineer: 5%
- Consultant: 6%
- Medical Device Survey: 6%
- Sales & Marketing: 10%
- Product Manager: 4%
- Packaging Designer: 3%
- Packaging Manager: 8%
- Quality Engineer: 9%
- Purchasing Agent: 2%
DEMOGRAPHICS Which range best describes your company size?

- **26%** Large (more than 10,000 employees)
- **53%** Small (fewer than 1,000 employees)
- **21%** Mid-Market (1,000 - 10,000 employees)
DEMOGRAPHICS  How innovative are your packaging business processes, compared to competitors and peers?

- **17%** Ahead of the curve, more innovative than peers and competitors
- **53%** Competitive, on par with peers and competitors
- **30%** Lagging, playing catch up to peers and competitors
DEMOGRAPHICS  Pain points among respondents

Most reported

- Compliance with governing bodies: 47%
- Validation: 43%
- Packaging/device compatibility testing: 38%
- Resource constraints: 31%

Least reported

- Remediation activities: 10%
- Lack of standard performance testing for shipping containers/systems: 14%
DEMOGRAPHICS  How much of the respondents’ testing is outsourced?

- 41% Very little
- 37% Most
- 22% About half
DEMGRAPHICS  Identify your most commonly outsourced tests

- Performance testing ship containers: 45%
- Accelerated aging tests: 36%
- Packaging integrity evaluation: 36%
Pain Points - Engineers vs. Management

We asked all respondents about where they feel their primary medical device packaging pain points exists, and compared responses of engineers to responses of sales and management job types.
Pain Points - Engineers vs. Management

Engineers pain points
- Validation, standard language, corrective and preventative action activities are top cited pain points.
- All things involved with execution. Engineers feel the pain on the facility floor.

Managers pain points
- Anti-counterfeiting has a 10% gap, management is more worried about this.
- More regulatory, back office concerns. Anti-counterfeiting is a planning topic, validation is an executable, practical thing.

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<tr>
<th>Pain Points</th>
<th>Engineers</th>
<th>Managers</th>
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<tbody>
<tr>
<td>Validation</td>
<td>50%</td>
<td>38%</td>
</tr>
<tr>
<td>Lack of standard terminology</td>
<td>27%</td>
<td>17%</td>
</tr>
<tr>
<td>Corrective and preventative action activities</td>
<td>22%</td>
<td>12%</td>
</tr>
<tr>
<td>Anti-counterfeiting</td>
<td>14%</td>
<td>24%</td>
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<tr>
<td>Packaging/device compatibility testing</td>
<td>34%</td>
<td>43%</td>
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Outsourcing — Based on Company Size

We asked all respondents about their outsourcing of different testing and validations, and compared responses of small, medium and large companies.
Counter intuitively, small companies are far LESS likely to outsource than their medium and large company counterparts. The more validation and testing is done in-house, the more streamlined these companies can be in pushing innovation, and the more control these smaller companies may have over their processes.
We asked all respondents about where they feel their primary medical device packaging pain points exists, and compared responses of small, medium and large companies.
PAIN POINTS – BASED ON COMPANY SIZE

- Smaller companies, who keep validation in house, report validation as a pain point because they’re doing it, they’re executing validation tests. They’re experimenting with new tests and so on, so they’re on the bleeding edge, not shipping it out somewhere else.
- Larger companies, who outsource, don’t have the in-house resources, so resource constraints are the major pain point.
- Correlation bears out what HealthPack experts would have expected to see.

Major pain points among different company sizes.
Smaller companies struggle with the testing itself.

![Bar chart showing validation pain points by company size]

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<tr>
<th>Company Size</th>
<th>Validation</th>
<th>Packaging/device compatibility testing</th>
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</thead>
<tbody>
<tr>
<td>SMALL</td>
<td>50%</td>
<td>51%</td>
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<tr>
<td>MEDIUM</td>
<td>40%</td>
<td>20%</td>
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<tr>
<td>LARGE</td>
<td>37%</td>
<td>24%</td>
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Major pain points among different company sizes.
Larger companies struggle more with resource constraints.

![Bar chart showing resource constraints by company size]

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<tr>
<th>Company Size</th>
<th>Resource Constraints</th>
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<tr>
<td>SMALL</td>
<td>24%</td>
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</tbody>
</table>
We asked all respondents whether they considered their company to be a trend-setter, an average performer, or a laggard when it comes to Innovation. Then, we compared responses of these three groups with likeliness to outsource.
LIKELIHOOD TO OUTSOURCE – BASED ON SELF-REPORTED INNOVATION LEVELS

Outsourcing comparison for Trendsetters vs. Laggards

- Trendsetters outsource the least
- Laggards outsource the most

Trendsetters: 34% Outsource Very Little (less than 33%), 44% Outsource Most (More than 67%) 24% Outsource About Half

Average Performers: 36% Outsource Very Little (less than 33%), 42% Outsource Most (More than 67%) 22% Outsource About Half

Laggards: 44% Outsource Very Little (less than 33%), 37% Outsource Most (More than 67%) 21% Outsource About Half
Pain Points — Based on Self-Reported Innovation Levels

We asked all respondents whether they considered their company to be a trendsetter, an average performer, or a laggard when it comes to Innovation. Then, we compared responses of these three groups with regards to their major pain points.
• Trendsetters pain points Validation and Packaging/device compatibility
• Anti-counterfeiting, big picture planning item, is something that trendsetters are worrying about TWICE as much as laggards. Trendsetters are on the leading edge for a reason.
• Laggards biggest issue is resources, which corresponds to larger companies.

Pain points among the more and less innovative companies.
Trendsetters have more trouble with testing, anti-counterfeiting

- Trendsetters: Validation 44%, Packaging/device compatibility testing 48%
- Average Performers: Validation 36%, Packaging/device compatibility testing 36%
- Laggards: Validation 35%, Packaging/device compatibility testing 42%

Pain points among the more and less innovative companies.
Laggards have more trouble with resources

- Trendsetters: Anti-counterfeiting 24%
- Average Performers: Anti-counterfeiting 19%
- Laggards: Anti-counterfeiting 12%

- Trendsetters: Resources 24%
- Average Performers: Resources 28%
- Laggards: Resources 40%
Considering Correlations — Outsourcing & Innovation

Taken together, the previous two charts, plus this one specific to innovators’ vs. laggards’ performance testing of ship containers, seem to suggest some strong correlations.
Trendsetters keep even expensive tests, like performance testing ship containers, in-house.

- Trendsetters, who aren’t outsourcing testing, report practical execution of validation and the subset of validation, pkg./device compatibility testing

- Laggards, who outsource their IP, report lack of resources as a pain point nearly twice as much as trendsetters

- This is most evident in the performance testing of ship containers. Performance ship testing is an expensive, labor intensive project that takes up a lot of space, machinery, and maintenance. Trendsetters are TWICE as likely to keep this in house as Laggards, with average performers falling somewhere in the middle.
We asked survey respondents the following questions directly, instead of to multiple-choice questions, and the following sentiments were most commonly heard.
RESPONDENT SENTIMENT
Describe how you strike a balance between flexibility and innovation, while complying with new and changing regulations...

It’s Hard...We Don’t...
“Hard to be flexible with all the regulations.”
“Innovation and change is slow, because of new and burdensome regulations.”

Regulations First!
“I don’t strike a balance; new and changing regulations come first.”
“...we’ve done well by viewing regulations as just another of our many ‘customers’ to satisfy our innovation, instead of viewing them as the ‘enemy’...”

Partnerships and Education
“Attend package seminars, conventions and shows to keep a breast to new ideas.”
“Collaboration between innovative packaging manufacturers and ourselves.”

Focus On the Project Needs
“The customer needs, and market needs for the product, determine if it requires innovative designs.”
“Whether or not to use new innovations usually depends on the time available, how far along the innovation is (is it ready to go or still experimental?) and the stomach the customer has for trying something that potentially no one else has yet.”

Stick With What Works
“Don’t be afraid to change and take risks, the worst thing is it doesn’t work and you go back to the baseline and try again, that’s why small incremental changes work well.”

Innovation First
“Regulations do not need to restrict innovation.”
“Be ahead of the pack!”

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“Regulations do not need to restrict innovation.”
“Be ahead of the pack!”
How do you reduce time to market?

Use Lean-style Philosophies, Continuous Improvement, QRM, Fil Fast, etc.
“Eliminate waste, reduce WIP [work in progress], streamline resources and suppliers paths.”
“Optimize and streamline all processes in the lifecycle.”

Get Out Ahead of The Project
“Bench testing early on in development; Get Packaging Engineering to be a part of New Product Development team from start.”
“From packaging perspective, early marketing involvement with design, branding, and labeling/IFUs.”

Schedule Adeptly and Manage Lead Times
“More efficient project management, firm deadlines, and constant communication with customers.”
“Proper scheduling and priorities management.”

Outsource
“...outsourcing, and most recently, contract employees.”
“Personnel capacity management.”

Leverage Existing, Pre-validated Designs
“Modular designs, leverage the existing validations for identical materials or seal surfaces.”
What difficulties are you having with UDI requirements and demands for serialization?

**Implementing Across Many Different Product Lines**
“We need to change the labeling on over 300 SKU’s to meet upcoming UDI requirements.”
“Enormity of product line scope.”

**Getting a New Program Up and Running**
“Just getting it set up and running according to the standard.”
“Starting the serialization process.”

**Lack of Serialization Standards**
“Working with FDA website has been interesting. Implementing UDI label changes for other products not requiring it for consistency in labels has been challenging along with multiple site integration and rollout.”

**Label Size and Legibility Difficulties**
“Label size requirements, may not fit on current packaging materials. Meeting the required implementation dates.”
“Print legibility on media with current equipment.”
“Using a risk-based approach to performance validation and identifying/considering the most critical aspects of package performance (to maintain the sterile barrier system throughout the distribution and handling of a product).”

“We believe in “overkill”—using packaging that exceeds the requirements for our product. Although more expensive than is probably necessary, it has reduced the number of issues and concerns.”
“We use time-tested packaging materials in order to avoid problems rather than trying to be cutting-edge.”

“I am constantly looking for my packaging suppliers to help solve problems with material innovation.”
SECTION TWELVE  Vendor Resource Guide

OPTEL is a well-established supplier of choice, providing customized inspection automation solutions that comply with device identification regulatory requirements. Leveraging the renowned expertise and 27+ years of successful Track & Trace implementations in the pharmaceutical industry, OPTEL now brings all the advantages of proven inspection technologies and applies them to medical devices and their packaging.

Our Core Expertise:
A True Understanding of Device Identification Complexities

Perfected over nearly three decades, our core expertise resides in the development and integration of innovative vision, inspection, verification and traceability technologies. We have in-depth knowledge of the complex technologies, regulations, and processes involved in the successful implementation of such systems. These key points, along with our deep understanding of the challenges you are facing to ensure regulation compliance, make us the ultimate partner for your UDI implementation project.

CONTACT US
For any information about our company, solutions, or events, please contact us:

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OPTEL provides you with extensive inspection and/or verification vision solutions based on your own specific needs, whether your products require identification through codes marked directly on the parts or only at the packaging level. In addition, our solutions allow you to verify the quality of your products, ensuring that they meet expected standards. Plus, we can customize your solution based on your level of IT integration and degree of automation of your product packaging workflow. Our vision technology solutions can ensure the integrity and accuracy of data being applied to your products. For example, your data can be compared with multiple sources, confirming that the right data always goes on the right packaging level and that it meets industry requirements per the UDI regulation.

TRACEABILITY SOLUTIONS
Whatever your requirements are—from serialization to internal process optimization or warehouse management—OPTEL will support your teams in order to develop and implement the most efficient and cost-effective solutions for your current and future needs.

Our traceability solutions enable increased quality and efficiency for your production and packaging lines.

CUSTOM SOLUTIONS
OPTEL develops fully customized solutions based on your objectives and constraints for your current and future needs.

Our solutions lead you towards the future and empower you for industry 4.0.

VISION INSPECTION SOLUTIONS
At OPTEL, we provide world-class vision solutions based on your specific requirements, whether they are basic or highly complex. Our solutions support manual, semi-automated and fully automated packaging flows, which can be stand-alone or fully integrated with your IT infrastructure.

OPTEL designs inspection solutions based on your inspected component, manufacturing workflow—from manual to fully automated—and your degree of IT integration (ERP/MES).

Device Marking Inspection
UDI-compliant solutions providing efficient inspection, verification and grading of marks etched or printed directly on medical parts.

Printing Inspection
Solutions used to inspect and verify the print quality on medical devices’ packaging material, including flexible web, label pouches, blisters and any other type of packaging.

Seal Packaging Integrity and Inspection
Solution for the inspection and verification of packaging integrity as well as content confirmation.

Physical Specifications, Color and Placement Inspection
Solution for the inspection and verification of the medical devices’ physical specifications, their presence and position in the packages.