



# Considerations for Healthcare Packaging Testing & Inspection

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## Important Considerations

The life sciences industry represents one of the most heavily regulated industries in every major market and territory in the world.

These regulations serve as important guardrails to protect patient and consumer safety and ensure healthcare products perform as expected. For packaging professionals in the healthcare space, ensuring regulatory compliance, product efficacy and end user safety means rigorous testing to confirm that packaging protects and preserves the product.

While the need for testing, inspection and safety practices may be easy to grasp, the processes for testing packaging can be more complex. The variety of regulations and industry standards can be challenging to navigate, and each product's packaging will have its own unique protection requirements. The need to document packaging specifications and testing procedures calls for careful, thorough record keeping. Once packaging has passed its testing procedures and protocols and meets regulatory approval, ongoing inspection is required to ensure quality and safety are maintained over time as product is manufactured and packaged.

This white paper outlines the important considerations healthcare packaging professionals should keep in mind throughout the process to ensure the efficacy and safety of their products.





# Variations by Country

The U.S. Food and Drug Administration (FDA) issues regulations that cover packaging for both medical devices and pharmaceuticals as well as labeling in the United States.

Title 21 of the Code of Federal Regulations (21 CFR) covers both food and drugs. 21 CFR Part 820 focuses on packaging for medical devices; 21 CFR Part 211 does the same for pharmaceuticals and 21 CFR Part 801 lays out the labeling requirements.

### **Other countries and regions have their own regulatory bodies and sets of regulations.**

Examples include the European Medicines Agency (EMA) for the European Union, the Medicines and Healthcare products Regulatory Agency (MHRA) for the U.K., the Department of Health Canada and many others. It is important to understand in which markets the product will be distributed and any unique regulations for those markets.

Specific to medical devices, the International Standards Organization (ISO) has issued the ISO-11607 standard, which specifies requirements for the design of sterile barrier systems and packaging systems for terminally sterilized medical devices, the basic attributes required of materials and preformed sterile barrier systems, and design validation requirements. The document contains more than 115 “shall” statements that define requirements packaging must meet to comply with the standard. Because of its thoroughness, documented proof that packaging complies with ISO 11607 is generally sufficient to pass regulatory review in the U.S. and other territories, though it is advisable to consult the regulatory bodies of the target markets to fully understand any unique requirements.





## Performance Requirements

A key part of the process is establishing well-thought-out performance requirements for packaging.

Performance requirements should account for the unique needs of the product, including storage and handling needs. Clearly defining any special needs for protection from factors such as light and moisture and any temperature requirements to maintain the product's safety and efficacy is crucial to planning performance requirements. For most life science products, the top priority is maintaining sterile barrier system throughout storage, shipping and handling as the product makes its way from the packaging line to the end user.

Regulations for each market in which the product will be sold as well as industry standards such as ISO-11607 should also factor into performance requirements, as packaging must comply with those regulations to be sold in the market.





# Important Testing Standards

Generally, brands in the healthcare space rely on ASTM testing standards to confirm packaging performance.

ASTM is a consensus testing standard for the FDA, as their standards typically require longer duration tests and more sophisticated equipment than comparable standards from other organizations such as ISTA.

### **USEFUL ASTM STANDARDS FOR TESTING PACKAGING OF HEALTHCARE PRODUCTS INCLUDE:**

**ASTM D4169**, “Standard Practice for Performance Testing of Shipping Containers and Systems” – It includes vibration, drop and compression testing as well as environmental conditioning to factors such as temperature and humidity.

**ASTM F1980**, “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices” – Accelerated aging tests provide helpful insight into how packaging performance will hold up over time. ASTM F1980-16a also provides guidance for conducting real-time aging studies, which should be initiated at the same time as accelerated aging studies to validate their results.

**ASTM F1886**, “Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection” – Its purpose is to provide standard methods for visually inspecting the integrity of seals in flexible packaging, especially as part of a sterile barrier system.

**ASTM F2096**, “Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)” – Its purpose is to provide standard methods for detecting gross leaks in nonporous flexible packaging such as sealed foil laminate pouches and porous flexible packaging such as Tyvek to film pouches.

**ASTM F88**, “Standard Test Method for Seal Strength of Flexible Barrier Materials” – This test method covers the measurement of strength of seals in flexible barrier materials to ensure the seals are acceptable in protecting and containing the packaged product.



# Determining Sample Size

Knowing the key standards packaging engineers can use to validate specifications is an important first step, but determining a sample size that can provide a high level of confidence that testing yields accurate results is a process of its own.

In most cases, determining an appropriate sample size for each test is relatively straightforward once a handful of parameters are determined.

A risk assessment is a key component, as it can help reveal potential hazards that may impact the product's efficacy and safety. A thorough risk assessment can help determine an expected failure rate, which is an important factor in determining sample size. Ultimately, sample size is dependent on the number of packages that will be produced during a run, the expected/acceptable failure rate and the desired confidence level in the accuracy of the test results.

A confidence level and reliability level of 95/95 percent is standard across many fields and typically works well for packaging testing. In many cases, a sample size of 60 packages should be sufficient to reach that confidence level, though the exact needs for testing on a given run of product may vary. For a more thorough breakdown of the process for determining sample size, [refer to our white paper on the topic.](#)





## Ongoing Monitoring and Documentation

The work of ensuring product efficacy and safety isn't over when a packaging system passes its shelf life and distribution performance tests.



### MONITORING

Ongoing monitoring and inspection are essential for ensuring quality and safety over time. Packaging equipment can experience wear and tear that affects quality, and inspections conducted daily or at the start of each run/lot can monitor for variations in quality and help catch potential issues before they impact large quantities of product, preventing costly recalls.



### DOCUMENTATION

Exact documentation procedures will vary from company to company, but consistency and uniformity across all documentation is key. Consistent, thorough documentation practices serve as proof of compliance when submitting new products for regulatory approval and can take much of the pain out of potential audits of testing practices.

Documentation extends beyond simple records of testing and includes items such as standard operating procedures (SOPs), packaging specifications and work instructions that ensure consistent packaging practices to maintain quality over time.

Maintaining accurate, detailed documentation can be an important tool for troubleshooting when issues arise. Proper documentation also ensures knowledge transfer as packaging teams experience turnover or team members transition between projects. Documentation also supports continuous improvement efforts by maintaining historical data that can be reviewed and compared over time to refine testing procedures and improve packaging design based on lessons learned from previous engineering and testing activities.





Lean on the Experts

## Contact Us

If you need guidance on testing and inspection practices for your packaging department, [get in touch](#) with Adept Group.

Testing and inspection are essential elements of an effective packaging program for healthcare products. By revealing potential problems and providing data from a statistically significant sample, they can help packaging teams address issues effectively before they create major problems for the department or the company overall.

We have experts in packaging testing, include members on the boards of the organizations that issue testing standards, and we can provide insight that will help your team ensure its packaging facilitates safe transportation and storage of the vital products it contains.

