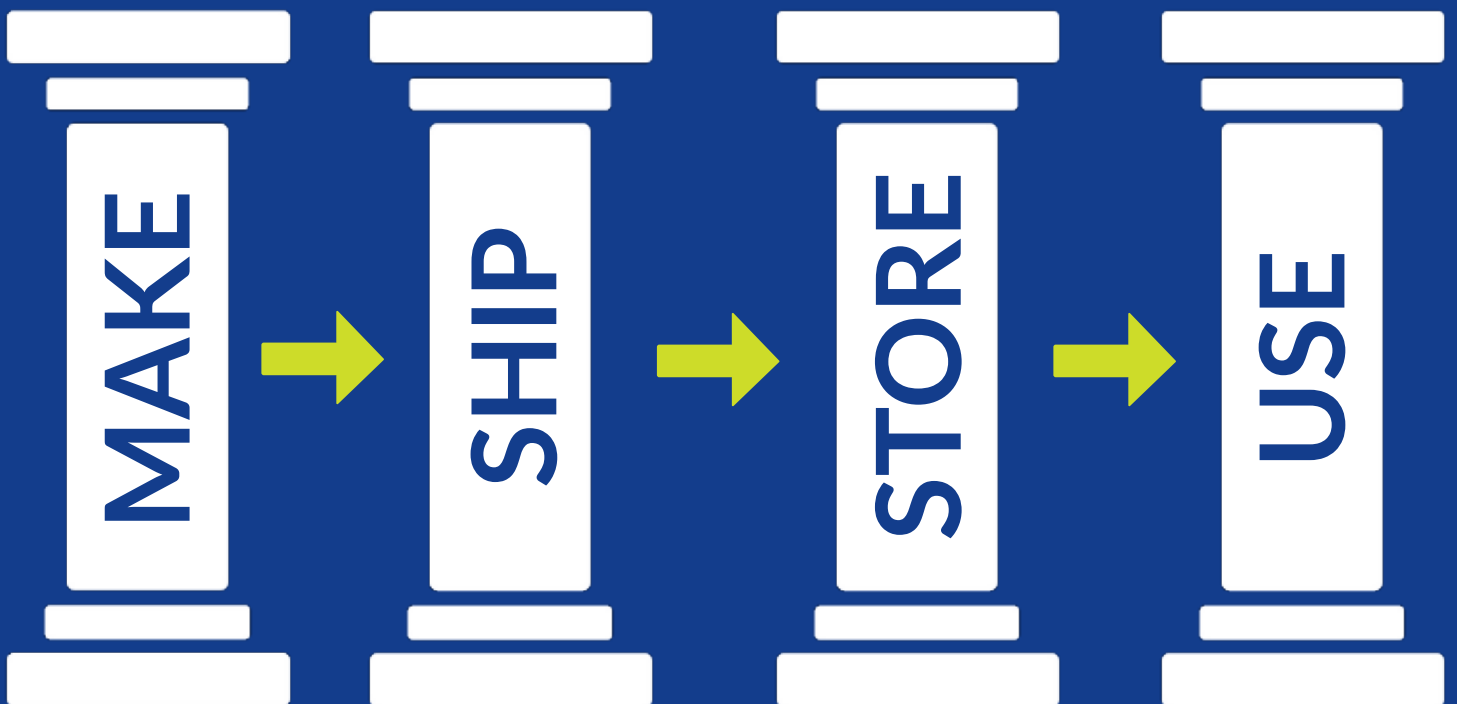




4 PILLARS OF PACKAGING VALIDATION

Your Guide to Understanding ISO 11607



FOUNDATIONAL REQUIREMENTS

Introduction

The goal of a sterile barrier packaging system is to protect patient safety by maintaining sterility until the point of use or expiration date. The FDA recognized consensus standard ANSI/AAMI/ISO11607:2019 Packaging for Terminally Sterilized Medical Devices provides the requirements and expectations for demonstrating that your medical device packaging system is safely and effectively validated. PCL has put together this document – what we call The Four Pillars of Packaging Validation – to be an educational tool to help explain the basics. We hope you find this a helpful resource as you plan your next medical packaging project.

Foundational Requirements

Activities comprising the 4 Pillars of Packaging Validation assume the following (refer to Part 1 of ISO11607):

Supplier Requirements

- Source, history, and traceability of materials are known and controlled
- The manufacturing process for materials used to construct the sterile barrier must be controlled, repeatable and reliable
- Key material properties, both physical and chemical, must be specified and maintained
- Transportation, handling, and storage of materials must not contaminate or adversely affect material quality

Material Requirements

- Materials comprising the sterile barrier system must be compatible with the intended sterilization process
- Materials used to construct the sterile barrier system must provide a microbial barrier, before and after the sterilization process and through the shelf life of the product
- Materials must be safe for human contact

Design & Performance Requirements

- Packaging system design must allow aseptic delivery of product to the sterile field
- Use of the packaging system must minimize hazard to end user
- Design inputs must be established early in the project, considering user needs through out the supply chain, from factory to hospital.

1 MAKE PROCESS VALIDATION - IQ / OQ / PQ

A process validation verifies that equipment operates as intended and that good parts can be produced consistently. This includes ensuring that the sealing and forming processes are repeatable and reliable. For more information, refer to Part 2 of ISO 11607.

IQ - Installation Qualification

Demonstration that equipment has been installed correctly and operates as intended. Some considerations during an IQ are:

- Equipment connections & hookups
- Design and operational features
- Critical process parameters
- Safety features
- Software validation
- Work instruction and training

OQ - Operational Qualification

Demonstration that the packaging process produces acceptable results at the limits of the process window.

Some considerations for forming processes:

- Sterile barrier system completely formed / assembled
- Product fits into the sterile barrier system
- Essential dimensions are met

Some considerations for sealing processes:

- Intact seal for specified seal width
- Channels or open seals
- Punctures or tears
- Aseptic opening

PQ - Performance Qualification

Demonstration that the packaging process is stable and capable when run under normal manufacturing conditions. Some considerations include:

- Use of product or simulated product
- Shift changes, Maintenance Activities, Changeovers
- Power outages

If a piece of equipment is repaired or relocated, the process validation should be reviewed to see if changes are significant enough to warrant re-execution of the IQ, OQ or PQ.

2 SHIP DISTRIBUTION / TRANSIT TESTING

Transit testing challenges the packaging system's ability to withstand the forces of sterilization, handling and distribution while maintaining a sterile barrier and other important characteristics. For more information, refer to Part 1 of ISO 11607.

What To Test?

Products that are packaged similarly may form part of a "packaging family". Identify the worst- case product-package combination from the family to test. Some considerations include:

- Largest / heaviest product
- Fragile or high risk product
- Product that poses risk to sterile barrier (slicing, puncture, tearing)
- Worst case sealing or forming processes
- Shipping systems with excess headspace

It may be necessary to test multiple products if each presents its own unique challenges.

How To Test?

First create a map of the real-world distribution channel. Some considerations include:

- Is the product sterilized?
- Does the product ship by truck, boat, air, or rail?
- Is it exposed to climate extremes?
- Does it ship as an individual box or on a pallet?

Then, select a consensus standard that best aligns, or create your own. The key is to make sure that you are challenging the shipping method to a worst case extreme. Make sure to include sterilization as part of the study design, where applicable.

What To Inspect For?

Go back to your DFMEA / PFMEA documents for ideas. Ask yourself what is important about the condition of the product-packaging system when it arrives to a hospital? Some considerations include:

- Sterile barrier integrity
- Label legibility, barcode scanning
- Tamper evidence
- Intact, functional device
- Aseptic presentation and delivery

3 STORE ACCELERATED & REAL-TIME AGING

Shelf life testing (aka “Stability” or “Aging”) demonstrates the ability of the packaging system to maintain sterile integrity and other key performance properties over time. Note that ISO11607:2019 regards transit testing and aging to be two separate entities. For more information, refer to Part 1 of ISO 11607.

What To Test?

Again, identify products which are similarly packaged in order to create a “packaging family”. From an aging standpoint, identify the worst case to test. Some considerations include:

- Largest / heaviest packaging system
- Fragile or high risk product
- Product that poses risk to sterile barrier (slicing, puncture, tearing)
- Worst case sealing or forming processes

It may be necessary to test multiple packaging configurations if each presents a unique challenge to packaging stability over time.

How To Test?

First identify how long is the target expiration date. Then, a study can be designed to meet that timing. Keep in mind that real-time aging is a requirement: The use of accelerated aging protocols are acceptable for initial market launch only if they are backed up by real-time aging data when it becomes available. Some considerations include:

- Use of product—always a good idea to include product or simulated product unless there is historical evidence to suggest that product does not impact package stability over time
- Project timeline—use accelerated aging to improve launch schedules, but be careful not to go too hot or there could be false positives

What To Inspect For?

Always refer to your DFMEA / PFMEA documents. Ask yourself what is important about the condition of the product-packaging system over time? Some considerations include:

- Sterile barrier integrity
- Label legibility, Barcode scanning, Tamper evidence
- Physical and chemical characteristics
- Intact, functional device
- Aseptic presentation and delivery

4 USE USABILITY EVALUATION

The recent 2019 revision of ISO11607 introduced a new requirement – usability evaluation (see Part 1 of the standard). Medical device manufacturers are now required to conduct usability assessments while considering input from actual clinical end users.

What To Test?

The usability evaluation is primarily intended to assess the ability of the end users to aseptically open the package and dispense the product. At minimum, the following is considered:

- The ability to identify where to begin opening
- The ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents, and
- The ability to subsequently present the contents aseptically

How To Test?

PCL has invested in the construction and build-out of a mock operating room as a venue for conducting usability studies. We have also developed two turnkey programs that you can take advantage of:

Usability Panel Evaluation

This program is best suited for early-stage design & development work. The format is a roundtable panel exam hosted by PCL. We invite one clinical consultant and at least three of PCL's medical packaging engineers to review preliminary design concepts and give input that can be used to modify or enhance packaging system designs.

Usability Clinical Evaluation

This program is best suited for late-stage validation work. PCL invites real clinical end users to visit our mock operating room and evaluate your product-packaging system. A PCL engineer serves as a moderator and will direct a panel of clinical users through a cognitive walkthrough. Users experience gowning, surgical suite setup, aseptic opening, and presentation of contents to the sterile field. We author the protocol, moderate the study, take video and audio recordings, and issue a report of findings and observations.

When Can I Apply Usability to my projects?

Usability evaluation can occur before or after packaging design freeze or after launch. Our recommendation is to at least perform usability evaluation prior to project launch. See our packaging validation roadmap below for the magnifying glass that represents when usability evaluation can occur.

SUMMARY

With the help of this guide, you should have a general overview of ISO 11607:2019 and be on track to begin your medical device packaging validation. As you begin to formulate what your validation process looks like, it is important to start with the strong foundation. This involves ensuring you have met supplier, material, and design/development requirements to set your sterile packaging system up for success as it progresses through validation.

Once that solid foundation is built, you are ready to move to process validation, where you ensure that your equipment is working as intended and is reliable. After this is confirmed, your packaging can then go into transit testing where it will be subjected to the worst-case shipping simulations. Following transit testing the package system should be inspected for how it held up and maintain its integrity. Finally, your packaging should go through shelf life testing to demonstrate the packages ability to maintain a sterile barrier over time. This includes accelerated aging and real time aging testing to make shelf life claims.

After completing all the above your medical device packaging should be well on its way to market with confidence! Packaging Compliance Labs is an expert in this topic and is a reliable and readily available resource for you as you embark on packaging validation.

Need help?

Packaging Compliance Labs is an ISO 17025 accredited test lab that has a full team of medical focused engineers ready to help you on your packaging project! Let us be your experts on ISO 11607:2019 and help your medical device speed to market with confidence. Contact us with any questions at info@pkgcompliance.com

About Us?

Packaging Compliance Labs is an independent packaging engineering partner. We provide design, development, and validation services for sterile packaging systems on behalf of medical device and pharmaceutical manufactures. Our focus is always on sound engineering discipline and regulatory compliance.

Your packaging engineering partner:

- We are an extension of your product development team
- We bring the people, systems, and capabilities to create innovation, cost effective packaging solutions for your healthcare products
- We offer precision expertise to address breaking developments in the healthcare industry
- We have extensive experience across a variety of industries to service additional sectors such as food, consumer products, and technology packaging

Get Started

Packaging Compliance Labs fuses design, development, and validation into one streamlined experience to get your products to market on time and on budget. What can PCL do for you? Let's sit down together and discuss your needs. We look forward to working with you!



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