



# 3 PILLARS OF PACKAGING VALIDATION:

Your Guide to Understanding ISO 11607



# FOUNDATIONAL REQUIREMENTS

## INTRODUCTION

The goal of a sterile packaging system is to keep patients and end users safe. The three pillars of packaging validation are intended to demonstrate that. However, there are some other basic requirements that do not fit as neatly into a specific activity- let's consider these to be foundational requirements.

Activities comprising the 3 Pillars of Packaging Validation assume the following:

## 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

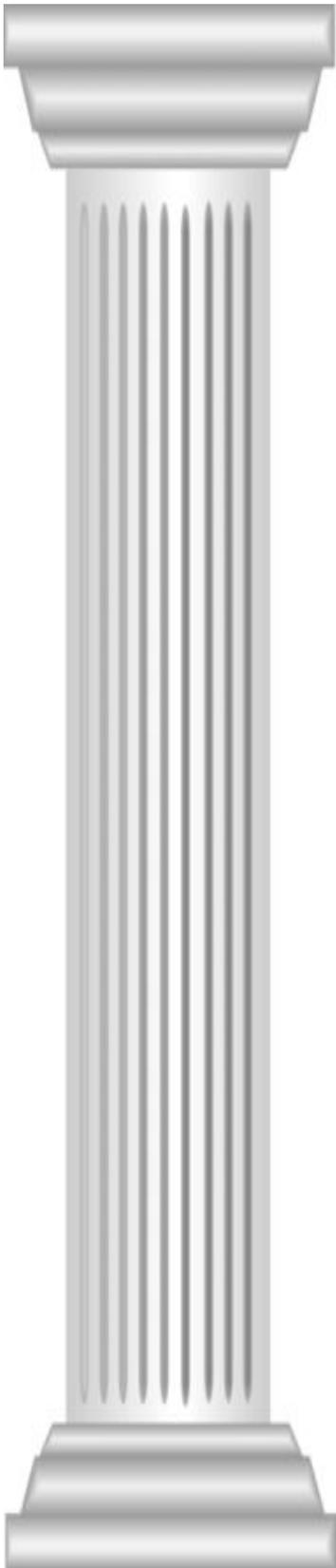
## MATERIAL REQUIREMENTS

- ▶ 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 throughout the supply chain, from factory to hospital.





## **MAKE**

### **PROCESS VALIDATION – IQ/OQ/PQ**

A process validation verifies that equipment operates as intended. This includes ensuring that the sealing and forming processes are repeatable and reliable.

#### **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:

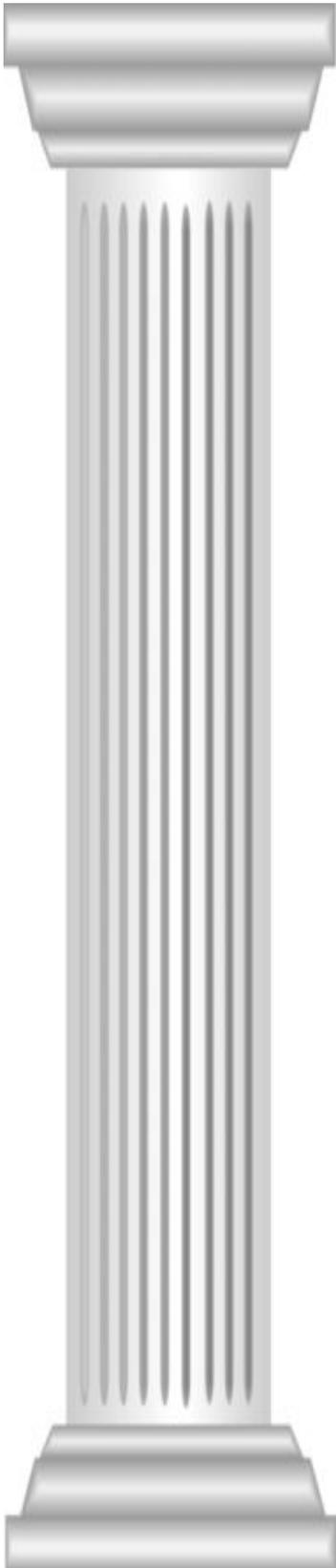
- ▶ Intact seal for specified seal width
- ▶ Channels or open seals
- ▶ Punctures or tears
- ▶ Aseptic opening

#### **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.



## **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.

#### **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:

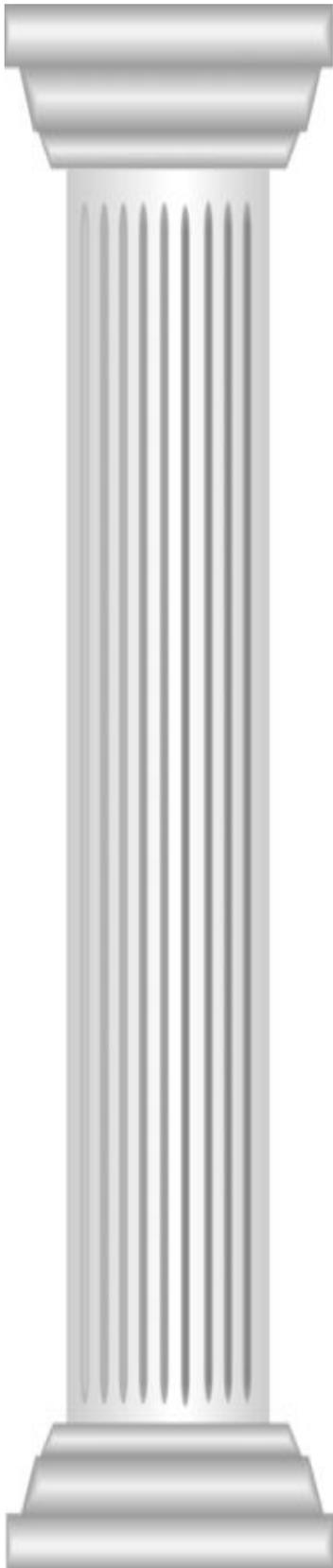
- ▶ Is the product sterilized?
- ▶ Does the product ship by truck, boat, air, or rail?
- ▶ Is it exposed to climate extremes?
- ▶ Does it ship as an individual box or on a pallet?

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



## STORE ACCELERATED & REAL-TIME AGING

Shelf life testing (aka “Stability” or “Aging”) testing demonstrates ability of the packaging system to maintain sterile integrity and other key performance properties over time. Note that ISO11607:2006 regards transit testing and aging to be two separate entities.

### 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
- ▶ Aseptic presentation and delivery
- ▶ Label legibility, Barcode scanning, Tamper evidence
- ▶ Physical and chemical characteristics
- ▶ Intact, functional device

## SUMMARY

With the help of this guide, you should have a general overview of ISO 11607:2006 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 11607:2006 and help your medical device speed to market with confidence. Contact us with any questions at [info@pkgcompliance.com](mailto: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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