Guidance for ISO 11607 Compliance

In order to be compliant to ISO 13485 for sterilized medical device packaging, companies must achieve compliance to ISO 11607 for terminally sterilized packaging. The following stage gates mark major milestones that must be achieved in order to take medical device packaging from conception to commercialization. This cheat sheet outlines some of the main steps companies need to take to accelerate the process toward compliance.

DESIGN

- Identify packaging material and design
- Evaluate product and packaging interaction
- Evaluate human interaction for packaging presentation
- Evaluate the supply chain and distribution environments

VERIFY

- Verification and validation testing - ensuring the validity of the packaging system process
- Installation Qualification - demonstration that equipment has been installed correctly and operates as intended
- Operational Qualification - demonstration that the packaging process produces acceptable results at the limits of the process window
- Performance Qualification - demonstration that the packaging system process is stable and capable when run under normal manufacturing conditions

QUALIFY

Accelerated and Real Time Aging - test material stability over time.

Integrity Check - Cross reference your risk assessment, user, shelf life, and integrity requirements, which may include:

- Sterile barrier integrity
- Label legibility/integrity
- UDI verification
- Aseptic presentation

Distribution and Transit Testing - shipping a package through the supply chain environments: how does the product perform when shipped through the rigorous channel?

Integrity Check - Cross reference your risk assessment, user, shelf life, and integrity requirements, which may include:

- Sterile barrier integrity
- Label legibility/integrity
- UDI verification
- Aseptic presentation
- Device functionality

COMMERCIALIZE

- Ensure successful testing, cGMP and GxP compliance
- Documentation Artwork final verification
- Design transfer - ensuring ongoing compliance through commercial manufacturing
- Periodic review - maintaining compliance throughout product life cycle

ABOUT ADEPT GROUP

Adept Group believes that packaging is more than a container - it's a powerful vehicle, connecting iconic brands to consumers, safely transporting life-saving medicines and devices and protecting the food and drinks we consume every day.

Adept is the leading expert for packaging engineering, providing teams with flexible, scalable service through staffing, engineering services, business processes and technology. Our portfolio of accelerators and products capture and create value from packaging.

adeptpackaging.com
inquiry@adeptpackaging.com
+1.484.373.2504

AdeptGroup
ENGINEERING EXCELLENCE