Medical Packaging

A high-level overview of the requirements of medical packaging standards

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Learning Objectives

• What are the key medical packaging standards and what is their global impact?

• What are the basic functions of medical packaging?

• Why is it so difficult to test for sterility?

• What is the process to overcome these difficulties and to achieve a high level of patient protection?
Global Medical Packaging Standards


PART 1 FOCUS IS ON MATERIALS AND DESIGN


PART 2 FOCUS IS ON PACKAGING PROCESS VALIDATION
EN ISO 11607 Global Status

US
- Adopted as American National Standard without revision
- “Recognized” by the FDA Centers for Devices and Radiological Health (CDRH)

Europe
- Both documents approved as European Norms (EN)
- Harmonized Standard (published in the Official Journal)
EN ISO 11607 Global Status

Japan
- Japanese versions available from Japan Association for Medical Instrumentation (JAMI)
- Adopted as Japanese National Standard

China
- Previous version adopted as National Standard
- Current versions undergoing adoption as Chinese National Standard

Other Known Adoption Activities
- Taiwan, Singapore, Australia, Korea, Canada,
- Russia (previous version) …
Sterility!
Sterilisation of packaged devices

Sterilisation Processes

Radiation
- Gamma
- Electron beam

Gaseous
- Ethylene oxide

Low temperature oxidative

VHP
High temperature steam

Key Questions:
- Does the packaging material allow for sterilisation?
- Is the material compatible with the sterilisation process?
- After sterilisation, does the material and the package preserve sterility?
Historically: sterility viewed as absolute condition

Today: using sterility assurance level (SAL) to express probability of survivors (typically $10^{-6}$)

Before 1970: sterility test to assess sterilization efficiency

The problem: with sterility testing, there is no meaningful statement possible regarding the entire population
Let’s assume the SAL of a batch is $10^{-2}$ which is relatively high.

- With one sample, the probability to accept that batch is $1 - 10^{-2} = 99\%$
- With 2 samples $(1 - 10^{-2}) \times (1 - 10^{-2}) = 98\%$
- With $n$ samples $(1 - 10^{-2})^n$
- With 20 samples the batch is still accepted in 82% of the cases
- With 300 samples (with no false positives or negatives) the batch is accepted in 5% of the cases, which is still not really acceptable.
- With a SAL of $10^{-6} \rightarrow$ 3 million samples to achieve a similar confidence.
Conclusion

• Sterility cannot be verified

• What cannot be verified, needs to be validated

• For this reason sterilisation and medical packaging standards introduce
  - a number of requirements that have to be met and
  - validation steps that have to be followed successfully

• The overall objective is to achieve a high level of patient safety and protection
Sterile Barrier Systems

- Must prevent the ingress of microorganisms in order to maintain sterility

Films and non-porous materials
- Must be free of holes and cracks

Porous barrier materials
- Allow the sterilisation gasses to enter and exit the package
- Allow the package to adapt to changing pressures and temperatures as well as volume changes
- Adequate **Microbial Barrier Properties** are required!

**Integrity** of seals must be guaranteed
Protection through Transportation & Storage

Will your design survive and protect as required?

Performance & Stability Testing is required to qualify the design.
Handling & Aseptic Opening

Sterility!
Basic Functions of Medical Packaging

Allow for sterilization

Product protection
- Physical protection from damage and environment
- Maintain sterility and integrity until point of use
- Microbial barrier

Easy opening and aseptic presentation

Identify the product, clearly state information and cautions
What do EN ISO 11607 - Parts 1 & 2 Say?

International Standards, EN ISO 11607 – Parts 1 & 2 “Packaging for terminally sterilized medical devices”, simply state that

You must:

- Design to minimize the safety hazard while meeting the requirements
- Test your package (validate the design)
- Validate your packaging process

And maintain your packaging process under control
The miracles of science
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