EO Packaging Design: Product Definition

DR. STEFAN REISBACHER
TECHNICAL ADVISOR, EO EMEAA

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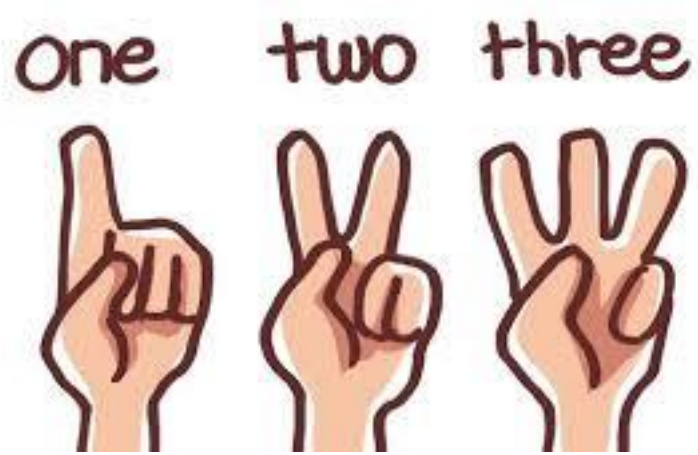
CONFIDENTIAL

Agenda

- Introduction to Packaging
- Levels Packaging
- EO vs Gamma
- Packaging Changes

Primary / Secondary / Tertiary

As easy as 1, 2, 3



Packaging Layers

Primary / Secondary / Tertiary

Primary packaging assures
product sterility
Direct product contact

Secondary and Tertiary packagings assure product preservation.
No direct contact with product

EO vs Gamma

EO Considerations

- Pressure (sealing)
- Temperature
- Humidity
- Density
- Material compatibility
- Aeration (residue + EO emission)

Gamma Considerations

- Material compatibility
- Some temperature
- Some density

Packaging design is linked to the selected sterilization method !

Typical Materials

Tyvek®

Plastic/Tyvek® (Bands or Patches)

Paper (can break down under certain conditions)

What doesn't work!

Mylar

Foil Pouches

Poly Bags (dust covers)

Possible Packaging Design Problems

- Placement of packaged devices in shipper box
- Tyvek surface area
- Vacuum Depth and Rates
- Label Placement
- IFU packets
- Very high density (difficult to heat and humidify)
- No humidity absorbing material (min 30%RH required)

Packaging Changes

Evaluate for impact to the sterilization process

- Will the packaging results in stable pallet configuration?
- Will the material be ok?
- Will the new packaging change the validated load configuration?
- Has the appropriate testing been performed on the new packaging (aging, transportation, etc.)?
- Will the packaging assure good product preservation (damages)

Possible Packaging Changes

- Manufacturing locations
- Pouch Sizes
- Tyvek portion size
- Type of corrugate carton used for shipper
- Pouch to tray configuration
- Chipboard holder / slip sheet added or removed
- Quantity of cartons/product per pallet
- Shrink wrap (type, number of turns)

Possible Impact of the new MDR on Sterilization Validation

- Additional requirements for Instrction for Use (IFU) by new MDR
- Product Density may increase significantly


Instructions For Use

1 - DESCRIPTION

2 - INTRODUCTION

Validation of packaging integrity

Validation Testing for Sterile Barrier Systems

- Validated sterile barrier packaging system is essential to ensure continued sterility of your products after the sterilization process
- Products can be claimed sterile only as long as packaging integrity is assured

Testing on 2X (two-time) processing is highly recommended

- Simulates reprocessing of a routine production run by the facility

Summary

- Packaging is very important
- There are different layers of packaging to consider
- Some materials work well and others don’t
  - Breathability is important
- Think about gas penetration (sterility) but also about residuals and EO emissions
- All changes should be evaluated for their impact

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Thank you