

EO Packaging Design: Product Definition

DR. STEFAN REISBACHER TECHNICAL ADVISOR, EO EMEAA



21 MARCH 2019

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



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





- 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 !



EO Packaging

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)



EO Packaging

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)



Packaging Changes

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

Bearing The Robustowith Maximum Section with the south Robustowick Maximum Section 201

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2 - INTRODUCTION

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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





Thank you

