

Package Integrity—*How to get started?*



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Webinar Outline

- What is package integrity?
- Package integrity tool kit
- Question and Answer



What is Package Integrity?

How well a package protects the product over a defined period from physical, microbiological or chemical challenges

(ASTM F-17 standard terminology)



Package Integrity—How to get started?

Ultimately, package design determines a product's success for its intended use

- Maintains safety and efficacy
- Ensures positive consumer experience



Package Integrity Tool Kit

8 Tools for Success

- To help with these packaging stages:
 - Design
 - Development
 - Performance

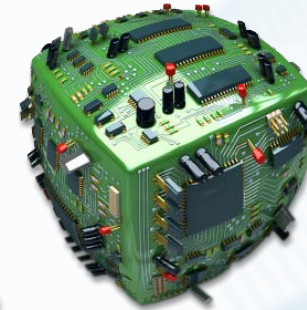


Design Phase: Tool #1

DEFINE PRODUCT PROTECTION REQUIREMENTS



- Identify product sensitivities and Regulatory requirements –Appendix
 - Foods
 - Cosmetics
 - Drugs, Devices, Biologics
 - Electronics
 - Consumer Products



Design Phase: Tool #1

DEFINE PRODUCT PROTECTION REQUIREMENTS



- Other Worldwide Guidance
Shipping Temperature Sensitive Goods



Design Phase: Tool #2

DEFINE PACKAGING AND PROCESSING



- What are our capabilities vs. requirements?



Design Phase: Tool #3

IDENTIFY DISTRIBUTION AND STORAGE



- Define all environmental hazards:
 - Global and Regional Distribution
 - Logistics Support
 - Cargo Modes (Truck, rail, sea, air)
 - Temperature Controlled (Refrigeration)
 - Shipping unit (Palletized, Gaylord, Single Parcel)



Design Phase: Tool #4

RISK ASSESSMENT



- Criticality of loss of integrity
 - Product sensitivities
 - Design inputs
 - Manufacturing and processing inputs
 - Distribution and storage
 - Tools 1 - 3



Development Phase: **Tool #5**

PROTOTYPE PACKAGE DESIGN



- Considering tools 1-4
 - Product sensitivities
 - Regulatory requirements
 - Packaging and processing
 - Storage and distribution
 - Risk assessment



Development Phase: **Tool #6**

CHARACTERIZE PACKAGE INTEGRITY



- Evaluate protection gaps

Laboratory methodologies

- Air Gases, Vacuum or Moisture
- Physical Seals or Leaks
 - Sterility
- Fragility

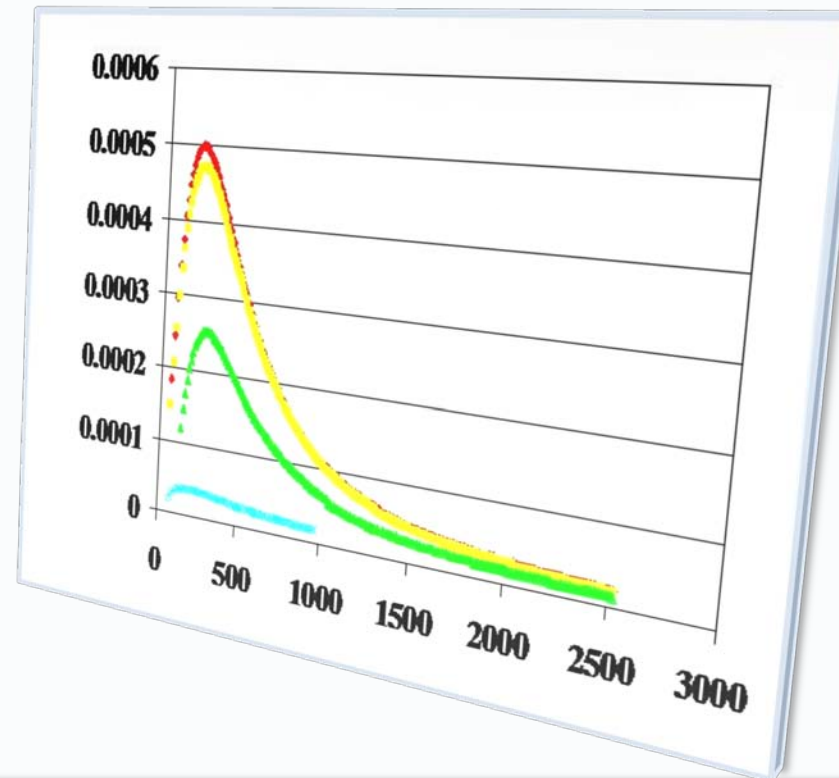


Development Phase: Tool #7

REFINE PACKAGE DESIGN



- Based on:
 - prototype integrity characterization
 - risk assessment
 - regulatory requirements



Performance Phase: Tool #8

VERIFY PACKAGE INTEGRITY



- Precise laboratory measurement
 - Package leak rate
 - Package transmission rate
 - Headspace analysis
 - Flavor and Odor detection
 - Fragility testing



Performance Phase: Tool #8

VERIFY PACKAGE PERFORMANCE



Package Performance

Integrity, Shelf-life & Sustainability Testing where MOCON Helps...

1. UV light

2. Temperature

3. Product Chemistry

4. GAS
(O₂, CO₂, CO)

5. Moisture

6. Bacteria/Contamination

7. Flavor and Aroma

8. Barrier → O₂, CO₂, water vapor

inline monitoring

M.A.P.
diffusion
leak
residual

cracking

pin hole

channel leaks

seam

heat seals

closure

headspace
absorption

Identification of off odors
and flavors

Summary

- Focus on understanding your product integrity requirements
- Consider and Manage
 - Design
 - Development
 - Performance
- 8 Tools:
 - #1 Identify Integrity requirements and regulations
 - #2 Define Processing inputs
 - #3 Define Distribution and storage factors
 - #4 Perform Risk assessment
 - #5 Prototype package design
 - #6 Characterize integrity
 - #7 Refine package design
 - #8 Verify integrity performance

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Questions??

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Next Month's Webinar...

FEBRUARY 10TH

*"High Temperature
Permeation Testing"*



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Thank You

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Appendix

Helpful Links:

- Food and Cosmetic Compliance Program Manual <http://tinyurl.com/ygf7973>
- Current Good Manufacturing Practices for Food <http://tinyurl.com/yh32fkw>
- Hazard Analysis Critical Control Points <http://tinyurl.com/n4m2dr>
- Drugs, CDER <http://tinyurl.com/yzhkxv3>
- Biologics, CBER <http://tinyurl.com/yfpdmew>
- Devices, CDRH <http://tinyurl.com/lptacx>
- Combination Products Office <http://tinyurl.com/ygnd9cg>
- Bureau Veritas, electronics safety <http://tinyurl.com/yan3tbv>
- Cosmetics labeling and security <http://tiny.cc/e74hx>
- U.S. Consumer Product Safety Commission <http://tiny.cc/dPMte>

Package Integrity—How to get started?

Appendix, Continued

Regulatory requirements—Global Shipping

- **World Health Organization (WHO)**—International packaging and shipping of vaccines
- **WHO**—Good Distribution Practices for Pharmaceutical Products
- **USP**—General Chapter 1079, Good Storage and Shipping Practices
- **Canada**— Guide 0069--Guidelines for Temperature Control of Drug Products during Storage and Transportation
- **EU**— 94/C63/03--Guidelines on Good Distribution Practice of Medicinal Products for Human Use
- **Irish Medicines Board**—Guide to Control and Monitoring of Storage and Transportation
- **Australia**--- Code of Good Wholesaling Practice for Therapeutic Goods for Human Use
- **US PDA**—Technical Report No. 39, Cold Chain Guidance for Medicinal Product: Maintaining the quality of temperature sensitive medicinal products through the transportation environment.
- **IATA (International Air Transportation Assoc)** trade body, represents airlines, cargo agents and passengers—July 2009--9th Edition-The Perishable Cargo Regulations Manual—Management of time & temp sensitive goods, chapter 17.