2010 PLACE CONFERENCE
A PLACE to Soar
April 18-21, 2010
Albuquerque Marriott
Albuquerque, New Mexico USA
TAPPI
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Package Integrity—*How to get started?*

PRESENTER:
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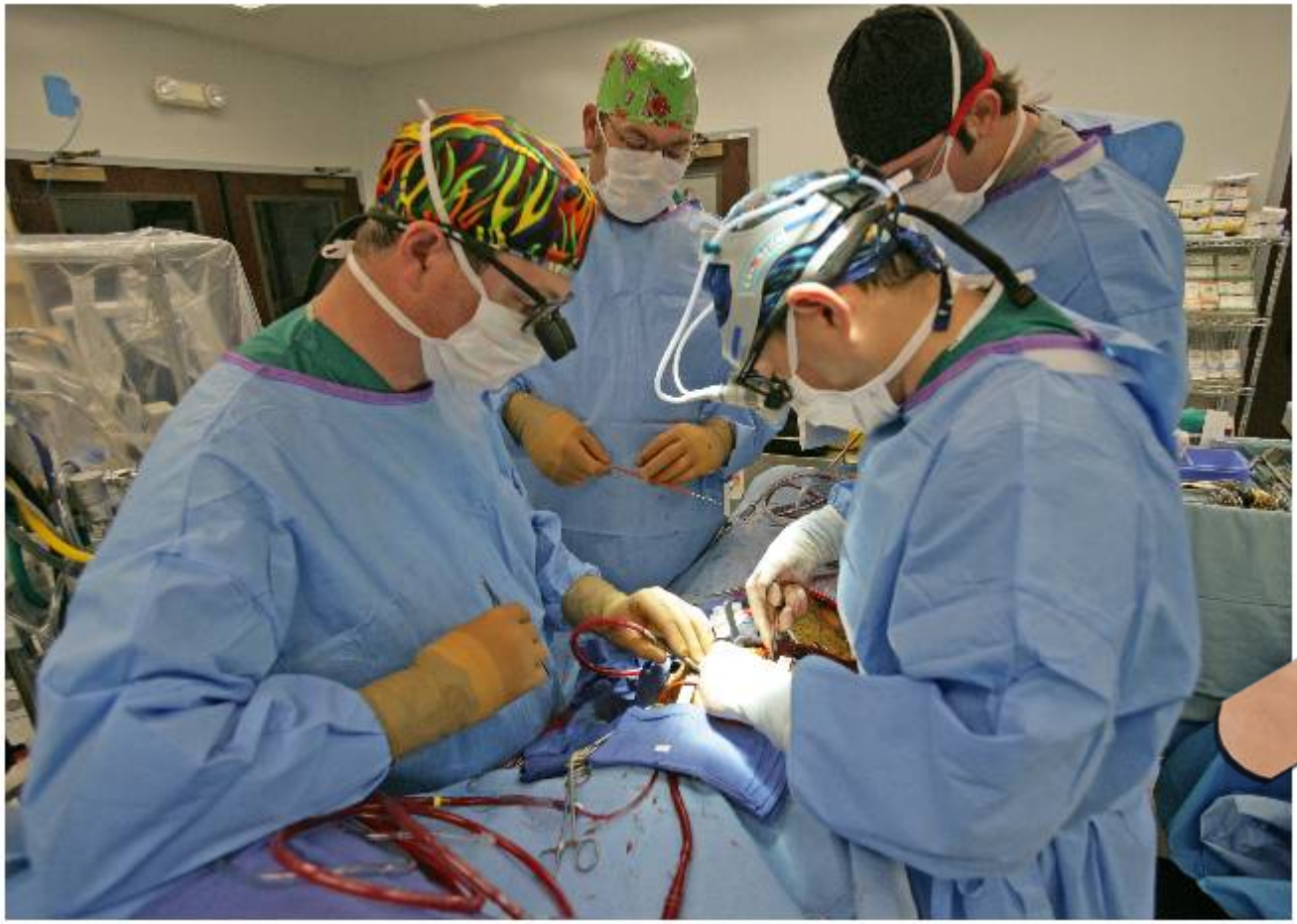
The life of a device



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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)

ASTM INTERNATIONAL
Standards Worldwide
www.astm.org

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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

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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

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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

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Development Phase: Tool #5

PROTOTYPE PACKAGE DESIGN

Considering tools 1-4

- Product sensitivities
- Regulatory requirements
- Packaging and processing
- Storage and distribution
- Risk assessment

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Development Phase: Tool #6

CHARACTERIZE PACKAGE INTEGRITY

Evaluate protection gaps

Laboratory methodologies

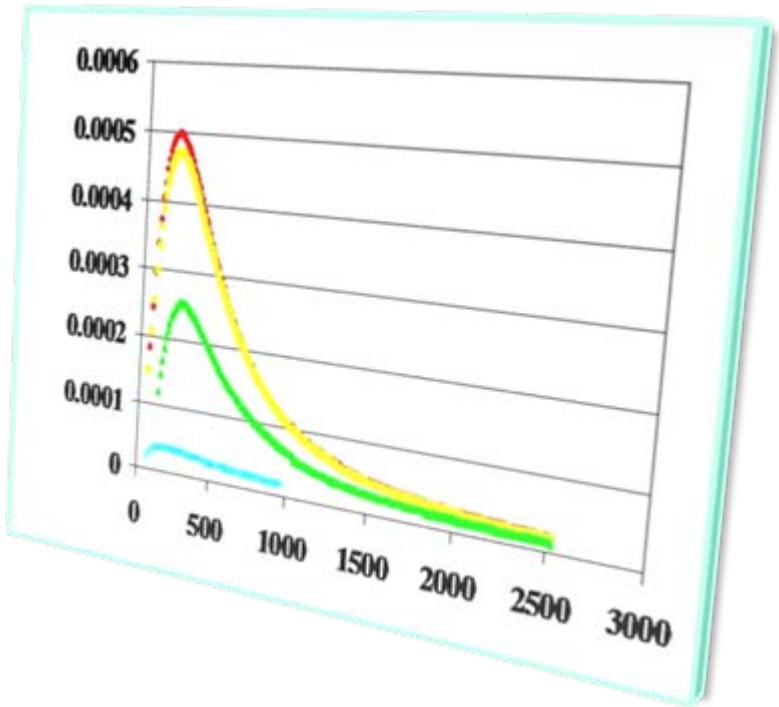
- Air Gases, Vacuum or Moisture
- Physical Seals or Leaks
  - Sterility
- Fragility

Development Phase: Tool #7

REFINE PACKAGE DESIGN

Based on:

- prototype integrity characterization
- risk assessment
- regulatory requirements



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Performance Phase: Tool #8

VERIFY PACKAGE INTEGRITY

Precise laboratory measurement

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

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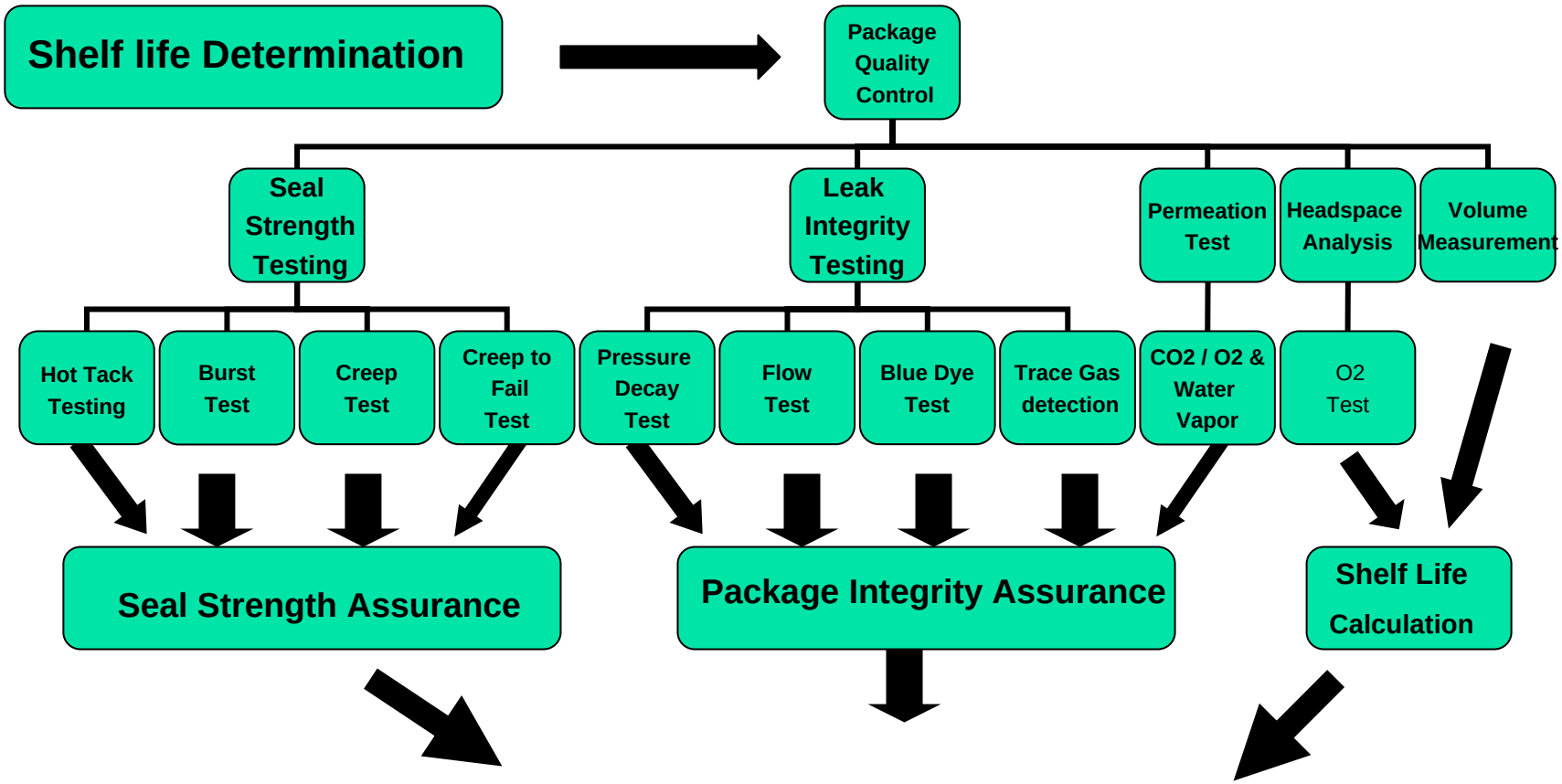
Packaging & Material Evaluations Technology Overview



Solutions

Assure Package Integrity, Minimize Risk

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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Appendix

Helpful Links:

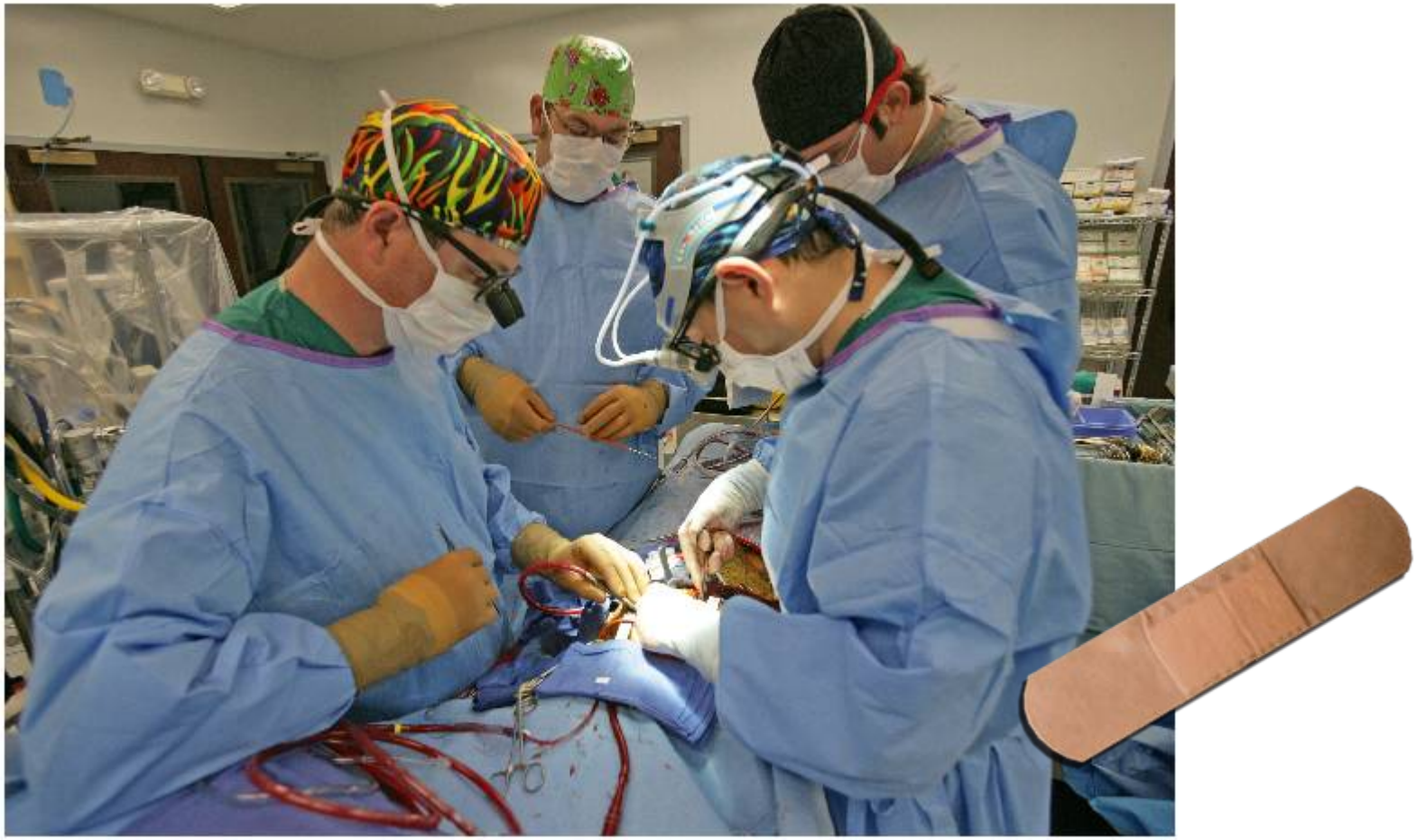
- Food and Cosmetic Compliance Program Manual http://tinyurl.com/ygf7973
- Current Good Manufacturing Practices for Food http://tinyurl.com/yh32fkw
- Hazard Analysis Critical Control Points http://tinyurl.com/n4m2dr
- Drugs, CDER http://tinyurl.com/yzhkxv3
- Biologics, CBER http://tinyurl.com/yfpdmew
- 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

Appendix

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.

The life of a device



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Thank you!

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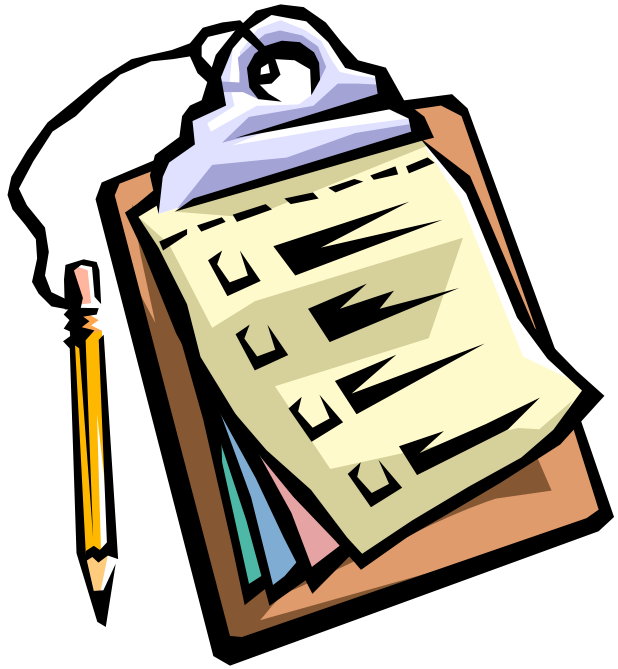

Please remember to turn in your evaluation sheet...