2nd Annual
MEDICAL DEVICE PACKAGING:
INNOVATIONS IN DESIGN AND TESTING
APRIL 30 - MAY 1, 2015 | BETHESDA, MD

Optimizing Medical Device Package Design through Incorporating End User Feedback, Leveraging Legacy Testing Studies & Identifying Innovative Materials, while Maintaining Validation & Verification Standards through Examining Test Methods to Satisfy Global Regulatory Expectations

DISTINGUISHED PRESENTERS INCLUDE:

Abhishek Gautam
Manager, Packaging Engineering
CONMED CORPORATION

Catherine Olson, MSN, RN
Director, Institute for Quality, Safety and Injury Prevention
EMERGENCY NURSES ASSOCIATION

Philip Desjardins
Counsel
ARNOLD & PORTER LLC

Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standard
DUPONT PACKAGING

Art Castronovo
Dir. of Labeling and Packaging Engineering
SMITHS MEDICAL

Rients Van Werven
Execution Excellence Manager
Packaging and Product Labeling
ETHICON ENDO-SURGERY

Dawn Hamblett
OR Clinical Product Coordinator
GEORGE WASHINGTON UNIVERSITY HOSPITAL

Katie Tran
Lab Supervisor
WESTPAK

Dr. Javier de la Fuente
Assistant Professor
CALIFORNIA POLYTECHNIC STATE UNIVERSITY

Daniel Burgess
Principal Packaging Engineer
BOSTON SCIENTIFIC

Charlie Rivera
Corporate Packaging Operations Manager
CONMED CORPORATION

Nora Crivello
Vice President
WESTPAK INC.

Shirley Gibson
Associate Vice President of Nursing
VCU HEALTH SYSTEM

Paul Marshall
Manager, Global Packaging Technologies
SMITH & NEPHEW

Santosh Madival
Sr. Packaging Engineer
EDWARDS LIFESCIENCES

Ron Valerio
Sr. Manager Medical
UFP TECHNOLOGIES

Maimunatu Mansaray
Operating Room Nurse
HOWARD UNIVERSITY HOSPITAL

Ewald Heersema
Technical Business Manager
ZOTEOFOMS INC

Changchun Liu, PHD
Research Assistant Professor
UNIVERSITY OF PENNSYLVANIA

Dhuanne Dodrill
Chairman
ASTM INTERNATIONAL COMMITTEE F02

A.J. Gruber
Executive Vice President
ISTA

Dawn Fowler
Senior Manager, Labeling & Documentation
ENDOLOGIX

Tomas Pla
Sr. Development Packaging Engineer
EXACTECH

Jonathan Bull
Director Gas and Heat Sterilization
JOHNSON & JOHNSON

Rod Patch
Senior Director, GSG Package Development COE
JOHNSON & JOHNSON

Darian Flewellen
Development Engineer, Packaging
EXACTECH

Alison Tyler
Director of Technology
BEACON CONVERTERS, INC.

Chetan Patadiya
Sr. Packaging Engineer
EDWARDS LIFESCIENCES

Dan Penny
Director of Packaging Engineering
CARDINAL HEALTH

CONFERENCE SPONSORS:
PREMIER SPONSORS:
**PROGRAM OVERVIEW:**
Reducing costs while maintaining innovation in packaging continues to be of top priority throughout the medical device industry as the healthcare landscape moves towards a customer-centric business model engaging the end-user throughout the product lifecycle. Engineers are tasked with the responsibility of creating innovative packaging that will protect lifesaving medical devices throughout the supply chain and lifecycle of the product while also reducing cost and remaining compliant with regulatory guidelines. This year’s conference will build upon the concerns of last year’s event by addressing the current concerns of packaging engineers through case studies, panel discussions and end user small group feedback.

Attendees of this year’s program will be provided with the unparalleled opportunity to discuss testing validation and verification challenges through case studies surrounding good manufacturing practices including identifying where legacy studies can be leveraged or testing is needed. Testing presentations will also address sterilization, shelf life, sample size and unique testing methods available. End user concerns including sterility and ease-of-use will be addressed through small group discussions where nurses will examining and providing feedback on packages provided by attendees.

**KEY CONFERENCE SPEAKERS INCLUDE:**

**Dr. Javier de la Fuente**
Assistant Professor
**CALIFORNIA POLYTECHNIC STATE UNIVERSITY**

Dr. de la Fuente serves as Assistant Professor of Industrial and Packaging Technology in the Orfalea College of Business at the California Polytechnic State University. He teaches courses in design thinking, product design and development, computer aided design, and packaging. Dr. de la Fuente’s background includes industrial and graphic design, packaging, and scientific research. His research interest lies in the area of user-centered design, universal/inclusive design, communication of functionality (affordances), and healthcare packaging. He has more than 30 publications including books chapters, peer-reviewed articles, refereed conferences, and trade-press articles. He has co-authored the “Packaging Design and Development” and the “Medical Device Packaging” chapters in the last edition of the Wiley Encyclopedia of Packaging Technology. One of his papers won the prestigious Best Paper Award at the Cambridge Workshop on Universal Access and Assistive Technology organized by the Engineering Department at University of Cambridge.

**A.J. Gruber**
**Executive Vice President**
**ISTA**

A.J. Gruber is the Executive Vice President for the International Safe Transit Association. He is responsible for both internal and external relationships which include interacting and communicating with staff across functional areas, motivating a team commitment to the ISTA’s vision and mission, and representing the Association through public speaking and communications with members and other industry partners. Also responsible for overseeing the processes through which ISTA maintains contact with members or other stakeholders ensuring that the relationships remain conducive to the success of the Association. Before joining ISTA, A.J. held roles within UPS as an Engineering Solutions Specialist and Supervisor of Dangerous Goods. A.J. currently also resides as the chair of IoPP Transport Packaging Committee and is on the board of the Michigan State University Packaging Alumni Association.

**PREVIOUS ATTENDEES INCLUDE:**

- Director, Engineering, ACUMED
- Product Manager, ACUMED
- Sr. Engineer to Project Engineer, ALLERGAN
- Senior Packaging Engineer, AMERICAN MEDICAL SYSTEMS
- Senior Quality Engineer, APOLLO ENDOSURGERY
- Manager, Packaging Engineering, ARTHROCare CORP
- TEN-E Packaging Services (O10 Chair), ASTM COMMITTEE
- Chairperson, ASTM COMMITTEE
- Director EHS and Sustainability, BAXTER
- R&D Manager/ HPREC committee Member, BD
- Packaging Engineer, Packaging, BD MEDICAL
- Team Leader - Graphics and Packaging, BD MEDICAL
- Senior Manager, BECKMAN COULTER
- Manager, Packaging Engineering, BOSTON SCIENTIFIC
- Principal Packaging Engineer, BOSTON SCIENTIFIC
- Corporate Packaging Operations Manager, CONMED
- Manager of Packaging Engineering, CONMED-LINVATEC
- Packaging Engineering Manager, COVIDIEN
- Sr. Design Engineer- Packaging, COVIDIEN
- Sr. Sterile Packaging Engineer, DEPUI SYNTES
- Manufacturing Eng, Packaging Manager, DSM BIOMEDICAL
- Senior Packaging Manager, DSM BIOMEDICAL
- Packaging Engineer, EDWARDS LIFESCIENCES
- Manufacturing Engineer Manager, ENDO THERAPEUTICS
- Sr. Manager, Document Control and Labeling, ENDOLOGIX
- Director of Filling & Finishing, FUJIREBIO DIAGNOSTICS
- Supervisor, Operating Room, GEORGE WASHINGTON HOSPITAL
- Corporate Packaging Manager, GEORGE WASHINGTON HOSPITAL
- Packaging Engineering Manager, HEARTWARE, INC.
- Packaging Manager, HOLLISTER
- Manager, Packaging, INTEGRA LIFESCIENCES
- Manager of Packaging, INTEGRA LIFESCIENCES
- Sr. Packaging Engineer, INTUTIVE SURGICAL
- VP Sterile Process Technology, JOHNSON & JOHNSON
- Project Engineer, K2M
- Packaging Engineer 1, KIMBERLY CLARK HEALTHCARE
- Vice President of Technology, LANSMONT
- Senior Packaging Engineer, LIFECELL CORP
- Packaging Engineer, LIFECELL CORP
- Principal Quality Engineer lead statistician, MEDTRONIC
- Associate Packaging Engineer, MEDTRONIC
- Associate Professor, HUMAN MEDICINE
- VP of sterilization Operations, NOVOSCI
- Principal Packaging Engineer, PACKWISE CONSULTING
- Marketing Manager, PETOSKEY PLASTICS
- Contract Sterilization Manager, REVOX STERILIZATION
- Eastern Regional Manager, REVOX STERILIZATION
- Product Manager, REVOX STERILIZATION
- Packaging Engineer, RTI SURGICAL
- Project Manager, Marketing, SHL GROUP
- Packaging Development Engineer, SMITH & NEPHEW
- Dir., Global Packaging Development, SMITH & NEPHEW
- Sr. Packaging Engineer, SMITH & NEPHEW ORTHOPEDICS
- Lifecycle Packaging Engineer, STRYKER
- Associate Project Engineer, STRYKER
- Packaging Engineering Manager, STRYKER
- Packaging Engineer, STRYKER
- Principal Packaging Engineer, STRYKER
- Senior Packaging Engineer, STRYKER
- Senior Packaging Engineer, STRYKER
- Director, Packaging Design, STRYKER

**RAPS CERTIFICATION:**
This conference has been pre-approved by the Regulatory Affairs Professionals Society (RAPS) as eligible for up to 12 credits towards a participant’s RAC recertification upon full completion.
**Medical Device Packaging: Innovations in Design & Testing**

**Day One / Thursday, April 30**

### 7:00 - 7:50

**Registration & Morning Coffee**

### 8:00 - 8:50

**Balancing Regulatory Compliance and Innovative Packaging Design**

To remain competitive within the medical device industry, engineers focus greatly on developing innovative designs for product packaging to ensure sterilization and safeguard a medical device, augment the value of a product through dual-use packaging and minimize carbon footprint while maximizing cost savings and increased material efficiency. While innovation is at the center of all packaging endeavors, packaging teams must also remain compliant with regulatory guidelines set forth by the FDA and international regulatory bodies. Without hindering progress within the medical device industry, packaging executives must find a happy medium in identifying and creating innovative packaging while also adhering to strict regulations.

- Challenges of developing innovative packaging designs
- Understanding regulatory expectations US/DUS
- Design implications for regulatory submissions

**Paul Marshall, Mgr., Global Packaging Technologies, Smith & Nephew**

### 8:45 - 9:15

**How Will UDI Impact You in 2015?**

This UDI session will take look back on the September 2014 deadline for class III medical devices, looking to understand how effective implementation has been and will provide lessons learned for the future deadlines.

- How class II companies can ensure successful UDI implementation
- Lessons learned from implementation – where are the gaps?
- The US implementation was just the beginning - international UDI guidance, where do we go next?
- Discussion around UDI implementation - real case studies

**Dawn Fowler, Senior Manager, Labeling & Documentation, Endologix**

### 9:15 - 9:45

**Coffee & Networking Break**

### 9:45 - 10:30

**Panel Discussion: Best Practices for Implementing UDI Requirements**

With phases of the UDI program in place, medical device companies are either already implementing UDI requirements for class III device and or preparing for the next round of implantable, life-supporting and life-sustaining devices labeling and packaging requirements. How this new requirement is affecting packaging professionals as well as how the FDA is dealing with noncompliance is of high concern within the industry. Through this panel discussion industry experts will share firsthand experiences on the challenges specifically facing packaging professionals in regards to UDI implementation as well as examining how the FDA is handling noncompliance.

**Dawn Fowler, Senior Manager, Labeling & Documentation, Endologix**
**Art Castronovo, Dir., Labeling & Packaging Engineering, Smiths Medical**
**Phil Desjardins, Counsel, Arnold & Porter LLC**

### 10:30 - 11:30

**Small Group Discussions: Answering to the Healthcare Provider Concerns**

As the healthcare landscape navigates towards a patient-centric driven industry, it’s more important than ever that medical device manufacturers produce products that fit seamlessly into this model. Oftentimes the deciding factor for devices selected ends with the nurse or clinician choosing the most appropriate product for the patient. Ease-of-use, sterilization abilities and historical success rates are just a few examples of the elements customers evaluate in choosing a medical device. By inviting nurses and other clinicians to lead small groups and analyze packaging from medical devices provided by conference attendees, engineers will have the unique and valuable opportunity to receive first-hand feedback from healthcare providers.

**Dawn Hamblett, Gr Clinical Product Coordinator, George Washington University Hospital**
**Maimunat Mansaray, Operating Room Nurse, Howard University Hospital**
**Shirley Gibson, Associate VP of Nursing, VCU Health System**
**Catherine Olson, MSN, RN, Director, Institute for Quality, Safety and Injury Prevention, Emergency Nurses Association**

### 11:30 - 12:15

**Lunch for All Attendees, Speakers & Sponsors**

### 12:15 - 1:30

**Panel Discussion: Choosing Cost Effective and Innovative Packaging Material**

Medical device manufacturers need to develop packaging that not only protects and sterilizes a product but also satisfies end-user desires to maintain competitiveness within a market. Packaging engineers must carefully analyze the cost savings and benefits of various materials and technologies to select the best material combinations for a product. Several factors including budget, a medical device’s components, shape and size along with expected handling and use are crucial factors when determining appropriate packaging materials.

The panel discussion will examine various packaging materials that have been validated and approved to highlight new material options and combinations available for engineers.

- Examining name brand vs. generic packaging materials
- Identifying innovative packaging material suppliers
- Lessons learned through combination trial and error

**Ewald Heersema, Technical Business Manager, Zotefoams Inc**
**Ron Valero, Senior Manager Medical, UFP Technologies**
**Dan Penny, Director of Packaging Engineering, Cardinal Health**
**Rod Patch, Sr. Dir., GSG Package Development COE, Johnson & Johnson**

### 1:30 - 2:15

**Overcoming Challenges in Designing and Updating a Packaging Prototype**

Evaluating the performance of various packaging prototype designs allows engineers the ability to identify flaws or potential risks within designs prior to production. Outlining the packaging design inputs like device classification, shelf-life expectations, packaging materials and manufacturing processes will streamline design decisions ultimately leading to successful validation of a package. Examining best practices for developing an accurate prototype while also addressing changes after a prototype has been designed ensures successful packaging development is achieved.

- Working with prototyping, design and material manufacturers
- Managing effects of device design changes in packaging prototype
- Collaborating with marketing on prototype design input
- Reviewing input and modifying packaging designs

**Abhishek Gautam, Mgr., Packaging Engineering, ConMed Corporation**

### 2:15 - 3:00

**Coffee & Networking Break**

### 3:00 - 3:45

**Drafting a Robust Packaging Validation Plan**

Validation of the packaging process is an important step to ensure that the package and device are交付 sterilization and assembly a sterile barrier system is in fact qualified. The first step in aligning an organization with ISO 11607-2 is drafting an effective validation plan which will outline the packaging process, qualifications steps, sterilization processes and intended materials and equipment to be used. Utilizing this plan throughout the organization will reduce risk and variations used throughout the packaging process.

- Best practices for effectively developing a validation plan
- Harmonizing validation processes throughout an organization
- Identifying non-conformities to mitigate risk

**Charlie Rivera, Corporate Packaging Operations Manager, Conmed Corporation**

### 3:45 - 4:30

**Strategically Executing a Validation Plan Across an Organization**

Drafting a validation plan early in the design process will set the stage for downstream success allowing for collaboration between packaging engineers and teams members to set clear parameters for potential design issues. Identifying implementation strategies for IQ, OQ, PQ, peeling test and documenting quality properties will produce a robust validation report resulting in validation approval. Attendees will leave this session with tools and techniques to improve and harmonize their packaging process validation plans.

- Obtaining accurate IQ, OQ and PQ documentation
- Best practices for conducting the peeling test
- Inspecting quality properties including: seal, tear and separation

**Toni Pia, Sr. Development Packaging Engineer, Exactech**
**Darian Flewellen, Development Engineer, Packaging, Exactech**

### 4:45 - 5:00

**Coffee & Networking Break**

### 5:00 - 5:45

**Sterilization Process and Materials: Making the Right Choice**

With an abundance of various sterilization options including steam, ETO, radiation and E-Beam, it can be difficult for packaging engineers to correctly identify the best method for testing a particular package. Crucial factors that must be taken into account include the composition of materials used within a package and identifying when changes should result in retesting. Attendees will delve below the surface in this presentation that examines proven testing combinations of sterilization and material selections.

- Combining materials with sterilization methods for success
- Understanding what types of changes require retesting
- Sterilization methods of the future reviewed
- Strategies for stability testing

**Jonathan Bull, Director Gas and Heat Sterilization, Johnson & Johnson**

### 5:45 - End of Day One Conference
Medical Device Packaging: Innovations in Design & Testing
Day Two | Friday, May 1

7:30 Registration and Morning Coffee
7:50 Chairperson’s Opening Remarks

8:00 HCP Feedback: A Review of Small Group Discussions
The conference chairperson will guide attendees through key insights shared by healthcare professionals during the small group discussions on the first day of the program. This 30-minute review will provide attendees with valuable feedback provided by HCPs regarding preferences for materials and components of medical device packaging.

8:30 Status Update of the Tyvek® Medical Packaging Transition Project
Michael H. Scholla, Ph.D., Global Director, Regulatory and Standards
Dupont Medical and Pharmaceutical Packaging

9:15 Identifying Process Changes and When Revalidation is Necessary
Requirements for validation of ISO 11607-2 is fairly common knowledge but one area sometimes lacking clarity is the process of understanding what types of changes require revalidation. The process of revalidation can be a timely and costly event, and therefore it is critical that packaging engineers can differentiate between self-evident changes that require revalidation efforts versus events that can leverage existing regulations for partial revalidations or avoid revalidation entirely. Developing rationale to support revalidation plans and understanding packaging regulatory requirements in the US and abroad will ensure resources are streamlined throughout revalidation.

- Examining various change scenarios for revalidation
- Building a revalidation process before change
- Understanding regulatory requirements for retesting in US and abroad

Chetan Patadiya, Sr. Packaging Engineer, Edwards Lifesciences
Santosh Madival, Sr. Packaging Engineer, Edwards Lifesciences
Allison Tyler, Director of Technology, Beacon Converters, Inc.

10:00 Coffee & Networking Break

10:30 Designing Test Method Packaging Validation Systems
A recent increase in scrutiny by the FDA regarding methods used to evaluate medical device packaging during the development process is due in part to the fact that 47% of all sterility-related recalls were attributed to packaging defects according to the medical device packaging handbook. Therefore putting a robust packaging test plan in place is essential as it ensures that the end user receives a sterile device and mitigates the risks of discovering design failures late in the development process. By understanding the components that make up such a test plan, attendees can begin designing their own effective product development packaging test methodologies.

Daniel Burgess, Principal Packaging Engineer, Boston Scientific

11:15 ASTM Testing Expectations and Updates to Dye Penetrating Testing
Evaluating the ability of packaging to withstand stressors such as climate, vibration, shock, humidity, temperature extremes, and altitude changes is arguably necessary to ensure medical devices remain safe and effective for use. Understanding ASTM testing standards and anticipating expectations prior to testing will ensure that packages are validated and comply with regulatory guidelines. In addition, recent enhancements to the standard dye penetrant testing of nonporous [ASTM F3039-13] packaging will be reviewed and will allow for user flexibility when performing packaging seal integrity testing.

- ASTM testing preparation and onsite expectations
- Dye penetrant testing enhancements reviewed
- Testing standards pipeline: future methods examined

Dhuane Dodrill, Chairman, ASTM International Committee F02

12:00 Best Practices for Mitigating Potential Packaging Pitfalls
Medical device packaging engineers face many challenges throughout the packaging process from designing innovative packaging configurations with limited resources to diagnosing that the material and components can maintain sterility throughout the supply chain. Discussing these challenges and solutions to other common roadblocks, packaging engineers will have the unique ability to incorporate risk management strategies and tactics into the validation process. In previous sessions, Westpak will share some of the challenges observed to help avoid common packaging failures others have encountered. Confidentiality will be maintained while learning how to successfully streamline validation processes.

Katie Tran, Lab Supervisor, Westpak
Nora Crivello, Vice President, Westpak

12:45 Luncheon for All Attendees, Speakers & Sponsors

1:45 Optimizing Packaging & Labeling Configurations for the International Supply Chain
Shipping medical devices internationally requires specific knowledge of labeling requirements in order to obtain regulatory approval and market access. Utilizing this regulatory knowledge will give packaging engineers the ability to properly calibrate and configure medical device packaging in a cost-effective manner. This session will highlight specific international primary and secondary packaging labeling expectations and examine best practices for reducing the risk of regulatory scrutiny.

Rients Van Werven, Executive Excellence Manager Packaging and Product labeling, Ethicon Endo-Surgery

2:15 Panel Discussion: Voices of the Supply Chain on Packaging
Maintaining complete control of the sterility of a product is achievable within the confines of a manufacturing facility; however, once a product is shipped, it can be exposed to circumstances or conditions which may compromise the integrity of a medical device or its packaging. It is imperative that packaging engineers understand the complexities within the supply chain in order to prepare packaging to withstand those elements. Collaborating with supply chain professionals to establish risk-based design features will ensure packaging maintains the sterility of the device throughout transit.

Rients Van Werven, Executive Excellence Manager Packaging and Product labeling, Ethicon Endo-Surgery
Katie Tran, Lab Manager, Westpak

3:00 Coffee & Networking Break

3:15 Case Study: Understanding the Importance of Distribution Testing
Medical device packages undergo rigorous sterility, agenizing, integrity, design and qualification testing to ensure safety and efficacy of the product. While much attention is placed upon the other aspects of package testing, distribution standards ASTM D4169, ISTA 2 Series and ISTA 3 Series are crucial to ensure defects are avoided and sterility is maintained. Examining potential challenges a package will face throughout the supply chain will ensure that distribution testing is a successful event.

- Reviewing ASTM D4169, ISTA 2 Series and ISTA 3 Series
- Adapting testing criteria to shipping patterns
- Accounting for environmental factors throughout transportation
- Evaluating the outsourcing of distribution testing

A.J. Gruber, Executive Vice President, ISTA

4:00 Design, Fabrication and Assembling of Microfluidic, Point of Care Medical Devices
Lab-on-a-chip (or microfluidic chip), which hosts a miniaturized fluidic network with pre-stored (lyophilized) reagents for processing and analysis of clinical specimens (blood, saliva, urine), is an emerging, point-of-care (POC) diagnostic, medical devices. These devices are often used in resource-limited settings which place stringent demands on device design and assembling to minimize contamination during operation in the field. Manufacturing methods must be compatible with pre-loading dry-stored reagents (enzymes, dyes) during their assembly and packaging.

- Microfluidic, POC device design, fabrication & formats including packaging
- Novel methods and packages of POC device for blood fractionation (plasma separation)
- Lyophilization, encapsulation and sealing of enzymes and reagents for POC molecular diagnostics devices.

Changchun Liu, PhD, Research Asst Prof., Dept. Mechanical Engineering & Applied Mechanics, University of Pennsylvania

4:45 End of Day 2 & Conference Conclusion

WHO SHOULD ATTEND:
Executives that will find this program of greatest relevance are those currently working to design and develop innovative and efficient packaging for medical device manufacturers as well as those of those executives that will find this program to be most applicable to their job functions include:

- Packaging
- Global Packaging
- Packaging Engineer
- Strategic Packaging
- Packaging Development
- Packaging Services
- Packaging R&D
- Product Assembly & Packaging
- Packaging Sterilization

MEDIA PARTNERS: