Integrate Medical Device Labeling Processes while Fulfilling Global Standards

Cultivating Versatile Labeling Strategies to Accommodate a Dynamic International Regulatory Environment

August 10-11, 2016
Minneapolis, MN

More Registration Details, Click Here!

Pre-Conference Workshop: August 9, 2016
Workshop A: Discussing Actionable Strategies for Efficient Labeling Translations with Fresenius Kabi, USA, LLC
Workshop B: Underscoring the Role of Advertising, Marketing, and Promotional Materials in Labeling to Address Associated Challenges on the Labeling Lifecycle with Medtronic

Attending This Premier marcus evans Conference Will Enable You to:

- Design flexible labeling systems to manage global regulatory requirements
- Adopt precise language that is easily translatable and culturally transferable
- Enhance labeling processes and protocols to achieve compliance with impending global UDI requirements
- Centralize data storage to create control within labeling strategies
- Analyze cost-saving opportunities to determine practicality per product, resource allocation, and market of operation
- Implement a content management system to ensure consistency and reliability throughout the labeling lifecycle
- Assess processes utilized to define appropriate Country of Origin to achieve local regulatory compliance
- Benchmark best Merger & Acquisition practices to effectively consolidate labeling efforts
- Explore functionality of e-Labeling as a cost-saving initiative
- Leverage UDI submission protocols to optimize supply chain capabilities

Who Should Attend:
marcus evans invites VPs, Directors, Senior In-House Counsel, and Managers from:
- Global Labeling
- Global Packaging & Labeling
- Global Regulatory Affairs-Labeling
- Global Regulatory Affairs
- Labeling & Technical Publications

Featuring Sessions from Leading Medical Device Labeling Professionals Including:

Jackie Rae Elk in
Global Process Owner – Standard Product Identification, Global Regulatory Affairs
Medtronic

Mercedes Bayani
Global Director, Regulatory Affairs
Bioness, Inc.

Kurtis Montegna
Global Director, Quality Assurance and Regulatory Affairs
Oriicare, Inc.

Ardi Batmanghelidj
Chairman, AIM North America-Healthcare Committee (UDI & SNII)
President & CEO
Innovatum, Inc.

Christie Larson, PMP
Senior Manager
R&D Labeling & Packaging
Fresenius Kabi, USA, LLC

Laura Johnson
Senior Account Executive-Medical Devices
Lifetexts

Angie Kilgore
Quality Assurance Manager
One Lambda, Inc.

Kent Allen
Senior Manager
Lifecycle Labeling
Johnson & Johnson

Colleen O’Keeffe
International Regulatory Affairs Manager
CareFusion/BD

Kevin Grygiel
Vice President of US Sales
Prism ID

Margaret Mucha, MJ, FRAPS, RAC, CQA
Director of Global Regulatory Affairs
Mortara Instrument, Inc.

Ken Legault
Vice President, Sales, Marketing, & Business Development
enLabel Global Servies, Inc.

Jennifer Perkins
Manager, Technical Writing
St. Jude Medical

Andrea Schneiderman
Project Leader, Operator’s Manuals and Labeling
Fresenius Kabi, USA, LLC

Pierre-Yves Brevet
Product Manager
Diagenode Diagnostics

Robert Lane
Program Manager
Global Labeling Systems
Boston Scientific

Sandy Dobs
Manager, Document Control and Labeling
Teleflex Medical

Gary Saner
Senior Manager, Information Solutions-Life Sciences
Reed Tech

Erin Salbilla
Manager – Respiratory Solutions Labeling
CareFusion

Laura Torok
Program Manager
Smiths Medical

Shital Bhammar
Supervisor, Product Labeling
Hologic, Inc.

LeeAnne Swiridow
Senior Regulatory Affairs Specialist | Interventional Lung Solutions
Medtronic

Dirk Stynen
President, Principle Consultant
Qarad BVBA

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Booking Info:
Faraz Tafti | T: 416 304 7990
E: FarazT@marcusevansto.com
**Day One | Wednesday, August 10, 2016**

7:15  Registration and Morning Coffee

8:00  Chairperson’s Opening Address

### CONSOLIDATING GLOBAL LABELING EFFORTS TO SHORTEN PRODUCTION TIMELINES WHILE MAINTAINING GLOBAL REGULATORY COMPLIANCE

**8:15  Case Study**

Managing Product Labeling Through Mergers and Acquisitions to Efficiently Bring Products to Market

- Approaching labeling from a broader perspective to identify necessary resources, departments, and data to deliver quality and compliant labeling
- Opening channels of communication to allow for cross-functional visibility
- Recognizing priorities to align various departments responsible for labeling
- Extracting best practices to ease harmonization and develop best in class procedures

**Sandy Dobs,** Manager, Document Control and Labeling

**Teleflex Medical**

### DEVELOPING A COMPREHENSIVE e-LABELING STRATEGY IN A GLOBAL CONTEXT AND EVER-CHANGING REGULATORY LANDSCAPE

**9:00  Case Study**

Evolving a global regulatory strategy to accommodate new e-Labeling requirements

**Kent Allen,** Senior Manager, Lifecycle Labeling

**Johnson & Johnson**

### ESTABLISHING STANDARDIZED LABELING PROTOCOLS WHILE MANAGING DISRUPTIONS TO THE LABELING LIFECYCLE

**9:45  Case Study**

Considering Localization when Attempting to Streamline Global Labeling Initiatives

- Acknowledging all factors at play when addressing localization
- Managing constantly changing country-specific regulations to update impacted departments
- Designing labeling templates that accommodate country-specific regulations
- Understanding variances in symbol requirements to maintain compliance

**Margaret Mucha, MJ, FRAPS, RAC, CQA,** Director of Global Regulatory Affairs

**Mortara Instrument, Inc.**

### INTEGRATING CONTENT THAT IS TRANSLATABLE TO A MULTITUDE OF LANGUAGE, COUNTRY AND REGIONAL SPECIFICATIONS

**11:00  Interactive Panel Discussion**

Incorporating Content that is Translatable to a Multitude of Language, Country and Regional Specifications

- Utilizing simple and precise source terminology to expedite translation
- Examining the benefits of destination labeling to expand access to an entire region rather than a single country or customer
- Identifying culturally transferable language to mitigate risks associated with device misuse
- Determining available packaging real-estate when confronting localization challenges

**Panelists:**

- **Margaret Mucha, MJ, FRAPS, RAC, CQA,** Director of Global Regulatory Affairs
- **Mortara Instrument, Inc.**

**LeeAnne Swiridow,** Senior Regulatory Affairs Specialist | Interventional Lung Solutions

**Medtronic**

**SPONSORSHIP INFO:**

Does your company have solutions or technologies that the conference delegates would benefit from knowing? If so, you can find out more about the exhibiting, networking, and branding opportunities available by contacting Faraz Tafti at 416 304 7990 or faraz@marcusevans.to.com.

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Day One

11:45 Case Study


- Cataloguing Country of Origin regulatory nuances to ensure compliance across markets
- Recording the various factors considered when computing Country of Origin
- Solidifying internal processes for formulating Country of Origin
- Delegating Country of Origin compliance responsibility to create awareness across the supply chain

Mercedes Bayani, Global Director, Regulatory Affairs
Bioness, Inc.

12:30 Case Study

Implementing Flexible Systems to Accommodate Future Industry Shifts and Keep Pace with Business Needs

- Designating ownership to drive the labeling strategy and manage change
- Standardizing labeling and labeling processes to become more agile in the marketplace
- Paring down labeling templates to allow for easy adjustments
- Incorporating IFUs and marketing materials when developing a consistent labeling strategy

1:15 Networking Luncheon

Day Two

8:00 Chairperson's Opening Address

NAVIGATING THE CONSTANTLY CHANGING INTERNATIONAL REGULATORY ENVIRONMENT TO PRESERVE ACCEPTANCE AND EXPAND MARKET OPPORTUNITIES

8:15 Case Study

Forecasting Forthcoming Changes in International UDI Requirements to Best Prepare for Industry Impacts

- Cataloguing what countries are introducing UDI drafts to leverage previously used strategies
- Breaking down the EU UDI Guidelines to ascertain future labeling requirements
- Examining the effect emerging markets will have on future standardization
- Deducing upcoming barcode requirements as outlined by changing international UDI standards
- Examining the effect emerging markets will have on future standardization

Jackie Rae Elkin, Global Process Owner - Standard Product Identification | Global Regulatory Affairs
Medtronic

10:30 Networking Break

PRODUCER INFO:
I would like to thank everyone who has assisted with the research and organization of the event, particularly the speakers for their support and commitment. Morgan Frohling, morganf@marcusevansch.com.
Day Two | Thursday, August 11, 2016

11:00 Interactive Panel Discussion
Examining Efficiencies in the UDI Submission Process for the Upcoming September Deadline
• Comprehending technical requirements to avoid submission errors
• Addressing final concerns and questions to relieve any confusion
• Benchmarking best practices in logistical planning to meet deadlines
• Negotiating with the FDA to circumvent superfluous requirements
• Exploring direct part marking methodologies

Panelists:
Shital Bhammar, Business Development Consultant
LeeAnne Swiridow, Senior Regulatory Affairs Specialist
Interventional Lung Solutions
Kurtis Montegna, Global Director, Quality Assurance and Regulatory Affairs
Oricare, Inc.
Pierre-Yves Brevet, Business Development Consultant
Diagenode Diagnostics
Laura Johnson, Senior Account Executive-Medical Devices
Loftware

11:45 Case Study
Lessons Learned: Adapting FDA UDI Strategies to Meet Global Regulatory Requirements and Garner a Competitive Edge
• Building adaptable internal checklists to use as a point of reference
• Developing systems that are open-ended to be applied in numerous arenas
• Leveraging GUIDID submission to increase supply chain agility
• Looking beyond disruption: Understanding UDI healthcare implications

Kurtis Montegna, Global Director, Quality Assurance and Regulatory Affairs
Oricare, Inc.
Laura Torok, Program Manager
Smiths Medical

12:30 Case Study
Addressing the Challenges of UDI with Enterprise Labeling
• Standardizing label data to one Source of Truth to ensure accuracy throughout the supply chain
• Fulfilling regulatory requirements while scaling to meet high-volume customer demands
• Leveraging dynamic, data-driven labeling to develop a change-agile strategy
• Streamlining labeling templates to reduce labeling times and costs by 50%

Laura Johnson, Senior Account Executive-Medical Devices
Loftware

1:15 Networking Luncheon

2:15 Panel Discussion
Benchmarking Best Practices to Implement an Outsource e-Labeling Solution
• Monitoring e-Labeling implementation to maximize ROI on outsourced solutions
• Developing a strategy to achieve regulatory compliance through e-Labeling
• Undertaking the cost-saving benefits of e-Labeling to build the case for solution adoption
• Resolving internal issues at the front-end to efficiently integrate e-Labeling

Pierre-Yves Brevet, Product Manager
Diagenode Diagnostics
Dirk Styten, President, Principle Consultant
Qarad BVBA

3:00 Interactive Roundtable
Exploring e-Labeling as a Method to Decrease Labeling Costs and Increase Usability
• Replacing packaging inserts with online documentation to reduce print costs
• Going green: Serving European markets by eliminating waste
• Recognizing user preferences to meet market needs
• Devoting resources to the process development and validation used to support e-Labeling
• Safeguarding against information misuse by filtering access to online documentation

Facilitated By:
Shital Bhammar, Supervisor, Product Labeling
Hologic, Inc.

3:45 Networking Break

4:15 Case Study
Establishing Factors & Criteria to Develop a Robust Labeling Postponement Strategy in a Global Supply Chain
• Deconstructing the MANY-to-MANY-to-MANY relationship of the global supply chain to pinpoint all internal and external drivers, inputs, and downstream consequences
• Evaluating the costs and benefits of global distribution and labeling postponement models
• Building the business case to manage the complexities of the global supply chain
• Integrating Program Management and Agile Software Development Methodologies to optimize labeling postponement strategies

Robert Lane, Program Manager, Global Labeling Systems
Boston Scientific

5:00 Case Study
Optimizing Outsourcing Opportunities while Preserving Quality
• Rigorously researching possible vendors to determine best fit
• Wrangling outsourcing costs while not forsaking quality integrity
• Giving clear directives to adequately lead provider
• Fostering the manufacturer-vendor relationship to effectively strategize labeling efforts

Shital Bhammar, Supervisor, Product Labeling
Hologic, Inc.

5:45 Chairperson’s Closing Remarks

6:00 Close of Conference

WHY YOU SHOULD ATTEND:

Medical Device Labeling is a highly regulated industry as labeling represents all that is a medical device. However, as more regions, countries, emerging markets, and customers introduce specified standards keeping track of constant changes and adjusting practices as needed can be analogous to walking through a minefield. This conference aims to clarify forthcoming regulatory requirements, as well as benchmark best practices in the consolidation of global labeling efforts.

By attending this 4th Annual Medical Device Global Labeling Strategies event, delegates will receive practical knowledge and advice from leading global labeling, regulatory affairs, and technical writing and communications professionals on how to implement open-ended global labeling systems, optimize e-Labeling initiatives, as well as glean the latest insights surrounding international regulatory standards. Event participants will have the opportunity to share key practices in a highly interactive environment.

TESTIMONIALS:

“This was a perfectly balanced agenda. The topics were all relevant to aspects concerning medical devices. The speakers were excellent. The smaller group dynamic made the discussions more meaningful.”
Abbott Vascular

“Great content & speakers, wonderful networking opportunities, enjoyed discussion sessions.”
DePuy Spine

“Information pitched at the right level-great real life examples applied.”
Stryker
QuickLabel Systems innovates solutions for printing color labels on-demand, in-house for the use of manufacturers in FDA-regulated industries. QuickLabel’s Kiaro! inkjet label printer and Innovatum’s ROBAR software create a complete, on-site solution for printing and controlling medical device labels as part of a lean process of on-site control and risk-reduction.

Software is the global market leader in Enterprise Labeling Solutions with more than 5,000 customers in over 100 countries. Offering the industry’s most comprehensive labeling solution, Software’s enterprise software integrates with SAP®, Oracle® and other leading enterprise applications to produce mission-critical barcode labels, documents, and RFID Smart tags across the supply chain. With over 25 years of industry leadership, our design, native print and built-in business rules functionality drives top-line revenue, increases customer satisfaction, and maximizes supply chain efficiency for our customers.

Reed Tech offers a data management and submission solution for the FDA’s Global UDI Database. We apply a decade of SPL expertise to help manufacturers fulfill the FDA’s submission requirements. Our solution builds and submits SPL messages in a secure and compliant environment. www.ReedTech.com

PRISM ID designs and delivers label management software for organizations that need complete product auto-identification and lifecycle traceability. With the continual tightening of labeling regulations and audits, PRISM ID empowers its clients to safeguard their reputation by ensuring compliance, removing risk and significantly reduce costs by eliminating recalls resulting in labeling errors.

Founded in 2005, enLabel Global Services has completely changed the pace of the global enterprise packaging industry, by providing the world’s only end-to-end Integrated Packaging Management (IPM) Software Platform. Headquartered in the historic North End of Boston, MA, enLabel Global Services is a Technology and Consulting Services Company that works diligently with manufacturers and distributors in the Medical Device, Biotech, Pharmaceutical, Aerospace and Petro / Chemical industries. With a state-of-the-art streamlined approach to the global packaging process, enLabel is an industry leader in achieving zero-defect packaging, worldwide. For more information on the enLabel IPM Software Platform, as well as global compliance and additional services, please visit enLabel.com.

Qarad is a consulting company specialized in Regulatory Affairs and Quality Assurance. It assists IVD and Medical Device manufacturers with CE marking and quality system implementation. It also acts as Authorized Representative. Moreover, Qarad offers E-Labeling Services for online distribution of Instructions for Use in full compliance with European and FDA regulations.

Other Labeling services include translations and advice on REACH and CLP requirements. Qarad supports IVD and MD manufacturers through training, gap analysis, risk assessments and more.

NiceLabel is the leading developer of barcode and RFID labeling software. With NiceLabel, companies are able to comply with FDA device identification labeling requirements, eliminate errors, and quickly respond to label change requests; all without costly development cycles. NiceLabel software is used by the majority of Fortune 500 companies.


The Journal of Medical Device Regulation is intended to educate, provide professional guidance, develop core competence of regulatory professionals, and promote debate on fundamental and topical matters within the medical device industry. In addition to publishing review and discussion articles by opinion leaders from the device community, it summarizes the international news headlines and provides useful reference information. www.globalregulatorypress.com

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PharmaVOICE magazine provides commentary about the challenges and trends impacting the life-sciences industry, covering a range of issues from molecule through market. PharmaVOICE’s more than 27,000 BPA-qualified subscribers are also kept abreast of the latest trends through additional media resources, including WebSeminars, Podcasts, Videocasts, and White Papers.

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MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical technologies that enhance patient care and advance patient outcomes. The medical technology industry in Canada employs over 35,000 Canadians in close to 1,500 corporate facilities, and has sales of nearly $7 billion per annum. We are committed to ensuring that Canada has a strong and vibrant medical technology industry.

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