4th Annual

Medical Device Global Labeling Strategies

Cultivating Versatile Labeling Strategies to Accommodate a Dynamic International Regulatory Environment

August 10-11, 2016
Minneapolis, MN

More Registration Details, Click Here!

Integrate Medical Device Labeling Processes while **Fulfilling Global Standards**

Streamlining global labeling efforts through the implementation of various content management and cost-saving initiatives to meet business demands and achieve international regulatory compliance.

marcusevans

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
- Technical Communications
- Labeling & Documentation
- Technical Writing
- R&D Packaging / Labeling
- Package Engineering

Featuring Sessions from Leading Medical Device Labeling Professionals Including:

Jackie Rae Elkin
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
Oricare, Inc.

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

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

Laura Johnson
Senior Account Executive-Medical Devices
Loftware

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
Prisym 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:
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Pre-Conference Workshop | August 9, 2016

12:00 Registration

12:30 Workshop A

Discussing Actionable Strategies for Efficient Labeling Translations

Development of a globally compliant label is challenging especially when taking into consideration localization and language requirements. Implementation of a streamlined label process from developing source content that can be authored for localization to ensuring compliance with core regulatory requirements is essential to maintain safety, quality and global access for a single product.

This interactive workshop will provide you with the tools and strategies to:

- Generate sound and concise content on the front end that is translatable in a multitude of languages
- Adapt processes to balance regulatory and suitable language requirements
- Align with a language provider who not only has the capacity to handle translation needs but also achieves same standard of quality objectives
- Devise design controls to manage changes in label content

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

2:30 Workshop B

Underscoring the Role of Advertising, Marketing, and Promotional Materials in Labeling to Address Associated Challenges on the Labeling Lifecycle

Advertising and promotional materials are increasingly becoming a source for customers to learn about the functions and usability of medical devices. As a result, labeling professionals must address the need to create dual-functionality within labeling while also ensuring compliance with regulatory requirements and meeting product development timelines.

This interactive workshop will provide you with the tools and strategies to:

- Examine the role of advertising and marketing materials within labeling to demonstrate dual-functionality
- Understand international regulatory standards addressing promotional requirements
- Incorporate the development of promotional materials into the labeling lifecycle to effectively execute all components of labeling while meeting deadlines
- Develop standardized templates for promotional materials that allow for easy adjustments in the occurrence of industry and organizational changes

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

4:30 End of Pre-Conference Workshops

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

9:00 Case Study

Developing a Comprehensive e-Labeling Strategy in a Global Context and Ever-Changing Regulatory Landscape

- Exploring new technologies to integrate e-Labeling strategies
- Redesigning organizational frameworks to best address emerging trends within e-Labeling
- Staying abreast of regulatory changes to ensure e-Labeling compliance
- 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.

10:30 Networking Break

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

Jennifer Perkins, Manager, Technical Writing
St. Jude Medical

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

11:45 Case Study

Clearing the Dust Cloud of Uncertainty: Formalizing Algorithms Necessary for Assigning Country of Origin

- 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

INCORPORATING DATA MANAGEMENT SYSTEMS TO CENTRALIZE NECESSARY RESOURCES

2:15 Interactive Roundtable

Identifying the Most Befitting Content Management System (CMS) to Create Control within Labeling

- Mapping current data strategy to identify most appropriate system
- Analyzing pros and cons of a centralized data system
- Balancing standardization and flexibility to maximize usability of a CMS
- Opting for a grassroots approach: Exploring capability of existing resources to meet the same objective while decreasing costs
- Evaluating cost-benefits achieved through CMS and end to end label management

Facilitated By:
Colleen O'Keeffe, International Regulatory Affairs Manager
CareFusion/BD

3:00 Case Study

Streamlining UDI Data Management to Synchronize Internal Systems with FDA GUDID"

- Optimizing master UDI data to avoid duplicates and inaccuracies
- Updating UDI data in real time to maintain alignment with FDA GUDID
- Circulating master UDI data values internally to ensure awareness
- Examining organizational impacts of global UDI requirements to engage internal stakeholders

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

3:45 Networking Break

4:15 Interactive Panel Discussion

Effectively Managing Data Changes within Automated Systems

- Designating ownership of automated systems to enable real-time data updates
- Allocating data authorities strategically to ensure data accuracy
- Establishing protocols to verify data validity
- Expediting data changes throughout automated systems to preserve cycle timelines

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

Angie Kilgore, Quality Assurance Manager
One Lambda, Inc.

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.

5:00 Case Study

Instituting Data Entry Practices that are Consistent and Reliable Across Departments to Achieve ROI

- Engaging individuals on the front end to overcome natural aversion to change
- Monitoring the implementation process daily to see consistent development and avoid overextending resources
- Sifting through copious amounts of information to collect data necessary for regulatory compliance
- Anticipating growth and industry changes to design accommodating systems

Jennifer Perkins, Manager, Technical Writing
St. Jude Medical

5:45 Chairperson's Closing Remarks

6:00 End of Day One

Day Two | Thursday, August 11, 2016

7:15 Registration

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
- Enhancing awareness of submission for messaging standards and labeling structure as outlined by HL7
- 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

9:00 Case Study

Participating in Regulatory Formation to Best Prepare for Regulatory Changes and Provide Industry Perspective

- Predicting what standards will serve as the foundation for forthcoming UDI drafts
- Joining advocacy trade associations to ensure inclusion of industry perspective in regulatory formation
- Guaranteeing harmonization across core UDI requirements
- Assisting in UDI implementation to minimize industry impacts
- Pushing regulatory bodies in emerging markets to incorporate e-Labeling guidelines

Colleen O'Keeffe, International Regulatory Affairs Manager
CareFusion/BD

9:45 Case Study

Mitigating Risk through Labeling to Avoid Recalls and Additional Costs

- Troubleshooting new complexities international markets bring to risk management
- Incorporating risk mitigation in labeling design
- Selecting metrics to best measure label effectiveness
- Establishing practices to manage recalls while not overextending resources, timelines, and costs

10:30 Networking Break

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:

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

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

Erin Salbilla, Manager – Respiratory Solutions Labeling
CareFusion

Laura Torok, Program Manager
Smiths Medical

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 GUDID submission to increase supply chain agility
- Looking beyond distribution: Understanding UDI healthcare implications

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

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

IMPLEMENTING COST-SAVING MEASURES WITH DUAL-FUNCTIONALITY

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
- Underscoring 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 Stynen, 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 in 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 forgoing 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

SILVER SPONSORS:

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.

Loftware 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, Loftware'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 topline 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

PRISYM 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, PRISYM ID empowers its clients to safeguard their reputation by ensuring compliance, removing risk and significantly reduce costs by eliminating recalls through labeling errors.

BRONZE SPONSORS:

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 assessements and more.

EXHIBITORS:

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.

Merrill Brink International is a leading provider of specialist translation services with tailored solutions for medical device, pharmaceutical, clinical research organizations (CROs) and regulatory consultants. Merrill Brink is certified to ISO 9001:2008, ISO/IEC 27001:2005, ISO 13485:2003 and compliant to ISO 14971:2007 and ISO 17100:2015.

MEDIA PARTNERS:

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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.

Managed Care delivers high-interest articles and features developed through original research and writing. Its editorial mission is to advise managed markets physicians, pharmacists, and executives on the integration of the business and medical aspects of the rapidly changing managed care market. A strict fact-checking and peer-review process assures the accuracy and relevance of editorial content.

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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