

11th Annual

MEDICAL DEVICE & DIAGNOSTIC LABELING CONFERENCE

SEPTEMBER 22-23, 2021 | Chicago, IL

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DISTINGUISHED PRESENTERS INCLUDE:

NOTIFIED BODY SPEAKERS:

Florianne Torset-Bonfillou

Director of Regulatory, Quality & Education, Lead Auditor

GMED NORTH AMERICA

Julien Senac

Global Director - IVD Focus Team

TÜV SÜD

MEDICAL DEVICE & DIAGNOSTIC INDUSTRY SPEAKERS:

Mary-Zane Addy

Director, Label Design & User Information Development

BECTON DICKINSON

Aimee Wright

Labeling Manager, Global Labeling

ZIMMER BIOMET

Roger Peterson

Manager, Global Labeling Systems

ARTHREX

Giulia Paolucci

MDR Expert

NOVARTIS

Ardi Batmanghelidj

President

INNOVATUM

Chris Heckert

Director, Labeling Solutions

NETWORK PARTNERS

Dawn Fowler

Director of UDI/Master Data Management

MASIMO

Alejandro Manunta

Manager, Packaging & Labeling Center of Excellence

INTEGER

Amy Kosbau

Labeling Engineer

INTEGER

Debra Horn

Labeling Specialist II, Global Labeling

SMITHS MEDICAL

Georges Hakim

Senior Director RA/QA, Managing Director

LEICA MICROSYSTEMS SWITZERLAND

Shital Bhammar

Senior Manager of Labeling Design

BLUEBIRD BIO

Mercedes Bayani

Global VP, Clinical & Regulatory Affairs

BIONESS

Cristal Salinas

Senior Manager, Global Regulatory Labeling

SEKISUI DIAGNOSTICS

Richard Korn

Senior Manager, Technical Communication

MEDTRONIC

Ken Legault

President

ENLABEL GLOBAL SERVICES

Anoop Padival

Senior Manager, Strategic Global Labeling,

Regulatory Affairs

ABBVIE

Dan Koenig

Content Strategist

ARGOS MULTILINGUAL

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DAY ONE AGENDA | WEDNESDAY, SEPTEMBER 22, 2021

8:00 REGISTRATION & WELCOME COFFEE

8:45 CHAIRPERSON'S OPENING REMARKS

Ken Legault, President, ENLABEL GLOBAL SERVICES

9:00 NOTIFIED BODY INTERVIEW: SHEDDING LIGHT ONTO PRESSING AREAS OF CONCERN WITH MDR & IVDR COMPLIANCE

With numerous provisions pertaining to labels, instructions for use, implant cards and more, the MDR as well as IVDR continue to create challenges for medical device and diagnostic manufacturers, eager to ensure compliance. This interview format will enable the audience to address specific questions to the notified body speakers ahead of the event, in order to see areas of uncertainty clarified through responses provided live, in an interactive format, ensuring a high level of deliverable content to participants.

INTERVIEWEES: Florianne Torset-Bonfillou GMED NORTH AMERICA

Julien Senac, TÜV SÜD

INTERVIEWER:

Roger Peterson, ARTHREX

9:45 CHAPTER: LEARNING FROM PEERS' EXPERIENCES IN SUCCESSFULLY ACHIEVING MDR & IVDR CERTIFICATION

- Data gathering, formatting & submission
- EUDAMED strategy plan & adjustments
- Audit findings impacting labeling & remediation
- Ease of communication with NB & corporate teams
- Overall timeline for certification completion

PART 1 - MDR CE: LABELING TEAM LESSONS LEARNED

Roger Peterson, Manager, Global Labeling Systems, ARTHREX

10:30 COFFEE & NETWORKING BREAK

11:00 PART 2 - IVDR CE: LABELING TEAM LESSONS LEARNED

Cristal Salinas, Senior Manager, Global Regulatory Labeling SEKISUI DIAGNOSTICS

11:45 SYSTEM ARCHITECTURE TO COMPLY WITH UDI RULES ON THE INTERNATIONAL LEVEL

- Developing a UDI strategy to fit multiple market requirements:
 - » European Union
 - » Asian countries
 - » Further markets worldwide
- Opportunities in enabling flexibility in the UDI process design
- Expediting updates & upgrades to the system for ongoing compliance

Giulia Paolucci, MDR Expert, NOVARTIS

12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

2:00 EUDAMED: ENSURING READINESS DESPITE ONGOING AREAS OF UNCERTAINTY

- Implementation status & use of available modules
- Process design to manage large number of attributes & data
- EUDAMED strategy & plan rationale for notified body reviews

Dawn Fowler, Director of UDI/Master Data Management, MASIMO

2:45 ANALYSIS OF COUNTRY-SPECIFIC DATA SUBMISSION PORTALS & LABELING STRATEGY ALIGNMENT

- Review of recent requirements in:
 - » China
 - » South Korea
 - » Taiwan
 - » The Netherlands
- Challenges in developing market-specific submission strategies
- Process design opportunities to expedite & sustain submissions

Mercedes Bayani, Global VP, Clinical & Regulatory Affairs, BIONESS

3:30 COFFEE & NETWORKING BREAK

4:00 DELAYED LABELING: PRINTING LABELS FOR INVENTORIED PRODUCT TO MEET COUNTRY-SPECIFIC REQUIREMENTS

- Configuring the label system to print country-specific labels in the warehouse or distribution center
- Extending the quality system
- Managing country-specific labeling
- Accounting for post-manufacturing labels

Chris Heckert, Director, Labeling Solutions - NETWORK PARTNERS

4:45 PANEL DISCUSSION: OPTIMIZING THE MANAGEMENT OF INCREASINGLY HIGH VOLUMES OF DATA

- Ongoing escalation of data volumes pertaining to labeling teams
- Insights into data management system opportunities & solutions
- Continuous tailoring & upgrading of data management process
- Common pitfalls in sustaining large amounts of data & practical advice

Dawn Fowler - MASIMO

Debra Horn - SMITHS MEDICAL

Anoop Padival - ABBVIE

5:30 CLOSING REMARKS & COCKTAIL HOUR SPONSORED BY ENLABEL GLOBAL SERVICES



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DAY TWO AGENDA | THURSDAY, SEPTEMBER 23, 2021

8:15 REGISTRATION & COFFEE

8:45 CHAIRPERSON'S OPENING REMARKS

Dan Koenig, *Content Strategist*
ARGOS MULTILINGUAL

9:00 BREXIT IMPACT ON LABELING & ADJUSTING TO NEW REQUIREMENTS

- Recognition of:
 - » CE mark in the UK
 - » UKCA & UKNI in the EU
- UK provisions specific to labeling materials
- Ongoing grey areas pertaining to labeling

Debra Horn, *Labeling Specialist II, Global Labeling*
SMITHS MEDICAL

9:30 SWIXIT: CLARIFYING NECESSARY CHANGES TO LABELING MATERIALS

- Recent developments & impact on labeling
- Focus on swiss-based economic operators
- Necessary partners established in the territory
- Currently remaining areas of uncertainty

Georges Hakim, *Senior Director RA/QA, Managing Director*
LEICA MICROSYSTEMS SWITZERLAND

10:00 COFFEE & NETWORKING BREAK

10:30 ENSURING LABEL COMPLIANCE IN A CONTINUOUSLY CHANGING REGULATORY ENVIRONMENT

- Composing with increasing country-specific requirements
- Regulatory intelligence strategies to stay abreast of changes
- Addressing multiple markets with a single, tailorable strategy

Alejandro Manunta, *Manager, Packaging & Labeling Center of Excellence*
INTEGER

11:00 CONSIDERATIONS FOR END-TO-END LABELING IMPLEMENTATION & OPTIMIZATION

- Comparing varying perspectives into end-to-end labeling
- Needs assessment: Full implementation versus upgrade
- Technology solutions & related cost considerations
- Common execution missteps & lessons learned

Aimee Wright, *Labeling Manager, Global Labeling*, **ZIMMER BIOMET**
Ardi Batmanghelidj, *President*, **INNOVATUM**

11:45 PANEL DISCUSSION: FUTURE OF LABELING & INNOVATIONS IN LABEL/IFU CONTENT DELIVERY

- Innovative pathways for label & IFU delivery
- New trends & possibilities with e-labeling
- Outlook into where technology is headed

MODERATOR: Ken Legault - ENLABEL GLOBAL SERVICES

PANELISTS:

Alejandro Manunta - INTEGER

Shital Bhammar - BLUEBIRD BIO

Richard Korn - MEDTRONIC

Cristal Salinas - SEKISUI DIAGNOSTICS

12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:45 EXCHANGE GROUPS: SHARING TACTICS FOR OPTIMAL IFU LAYOUT, DESIGN & CONTENT

- Optimizing real-estate management with large volumes of data
- Best practices in displaying critical information for end-users
- Incorporating user feedback in IFU updating & improvement

Amy Kosbau, *Labeling Engineer*, **INTEGER**

2:30 VIRTUAL & REMOTE LABELING WORKFLOW MANAGEMENT

- Impact of shift into remote workforce on labeling operations
- Creating efficiencies all while working remotely
- Tasks to keep virtual vs. in-person moving forward

Mary-Zane Addy, *Director, Label Design & User Information Development*
BECTON DICKINSON

3:15 CLOSING REMARKS & CONFERENCE CONCLUSION



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ATTENDEE PROFILE:

Executives working within Medical Device Corporations concerned with the appropriate development, design and delivery of labels and instructions for use of medical products, as well as meeting evolving regulatory guidance will be best suited to attend and take high value out of attending this meeting.

Job titles for this meeting include:

- Labeling
- Regulatory Affairs
- Technical Writing
- Document Control
- Localization/Translation
- Quality Assurance/QMS

PREVIOUS ATTENDEES INCLUDE:

R&D Project Manager, **Abbott**
Prgm Dir. Global RA/Labeling, **Advanced Sterilization Products**
Labeling Graphics Supervisor, **AngioDynamics**
Manager of Global Labeling Systems, **Arthrex inc**
Senior Manager, Global Regulatory Affairs, Labeling, **Baxter**
Technical Writing Manager, **Baylis Medical Company**
Director, Labeling, **Becton Dickinson**
Localization Project Coordinator, **BioFire Diagnostics**
Quality Engineer, **Biomerics**
Labeling & Technical Comm. Manager, **Biosense Webster**
Regulatory Operations, **Cantel Medical**
Sr. Labeling Project Manager, **Cardinal Health**
Manager RA International & Labelling, **Carl Zeiss Meditec**
Manager, Regulatory Affairs, **Cook Biotech**
Global Labeling Manager for Regulatory Affairs, **Cook Medical**
Labeling Team Manager, **Cordis**
Project Manager (IVD Expert), **DEKRA Certification B.V.**
Sr Manager R&D Labeling, **Fresenius Kabi**
Content Labeling Director, **FUJIFILM Sonosite**
Director of Regulatory & Quality, **GMED North America**
Sr. Director Community Engagement, Healthcare, **GS1 Global**
Senior Manager, Labeling, **Hollister**
Principal Technical Writer, **Imricor Medical Systems Inc**
Manager, Packaging & Labeling Center of Excellence, **Integer**
Graphic Labeling Designer, **KavoKerr**
Director of UDI/Master Data Management, **Masimo**
Senior Manager, Technical Communication, **Medtronic**
Labeling Ops Manager, **Philips Image Guided Therapy Systems**
Global Operations Manager, Labeling, **Roche Diagnostics**
Senior Manager, Global Regulatory Labeling, **Sekisui Diagnostics**
Supervisor, Labeling, **Smiths Medical**
VP Quality & Regulatory, **SP Medical A/S**
Product Labeling Group Leader, **STERIS**
Global Director - IVD Focus Team, **TÜV SÜD**
Director - Regulatory Operations, **Vyair Medical**
Project Manager for Product Labeling, **W.L. Gore & Associates**
and many more!



Join our LinkedIn Group

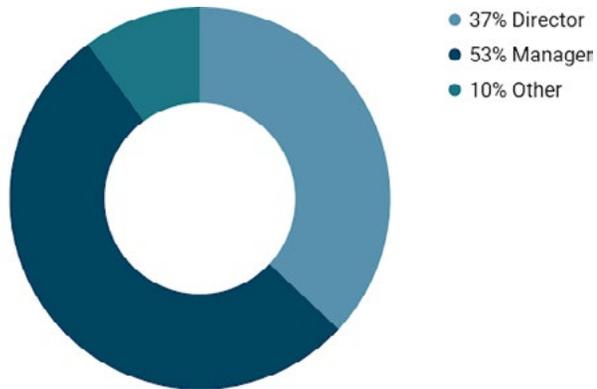
Start a conversation focused on learnings from the meeting's modules with fellow participants in our **LinkedIn Group!** Keep exchanging insights and best practices among peers, and take the opportunity to meet with delegates who focus on similar challenges to brainstorm together on topics that matter to you!



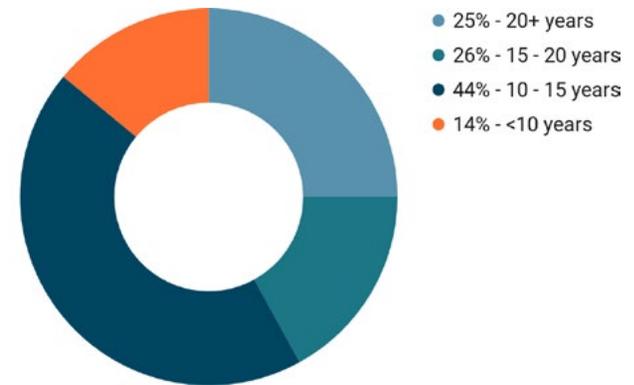
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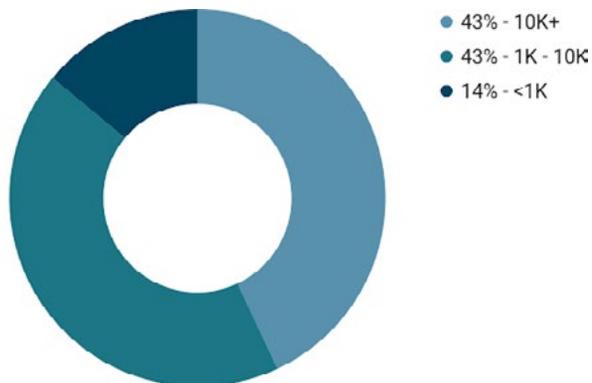
ATTENDEES BY JOB TITLE:



ATTENDEES BY YEARS OF EXPERIENCE:



ATTENDEES BY COMPANY SIZE:



INDUSTRY VERTICAL:

