DIA

Global Labeling Conference

Live Virtual Conference: April 20-21

PROGRAM COMMITTEE CO-CHAIRS

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Advisor, Global Regulatory Affairs
Eli Lilly and Company

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Executive Director, Regulatory Labeling and Promotion
Intercept Pharmaceuticals, Inc.

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Vice President, Head Labeling
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Head of Global Labeling, Global Regulatory Affairs
Vertex Pharmaceuticals

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Bass Biopharm Consulting Group, LLC

Leander Fontaine, MD
President
Pharmiceutics, LLC

Overview

DIA's *Global Labeling Conference* is designed for professionals in medical product labeling and related disciplines as they work to develop and manage clear and accurate labeling information for the safe and effective use of prescription drugs, biologics, and medical devices. The efforts of these professionals are key to providing essential information needed by providers, patients, and payers to make decisions about product access, prescription, and use. Influences such as digital technology, patient centricity, evolving product classes, and changing regulations require the use of informed, systematic approaches throughout the labeling cycle to ensure the development and availability of current, compliant information in all regions where products are marketed.

This conference provides a forum for exchange among regulators and industry peers to update their knowledge of key local and global labeling policies and to examine the impact of changes on regulatory compliance. Most importantly, through interactive discussions with expert panels and peer-to-peer exchange, participants will share approaches, processes, and tools to ensure the availability of effective labeling content meeting the needs of patients, consumers, and prescribers.

Who Should Attend

Professionals involved in:

- Labeling
- Regulatory Affairs/Drug Review and Approval Process
- Clinical Safety/Pharmacovigilance
- Pharmacoepidemiology
- Medical Affairs and Communications
- Medical Writing
- Clinical Research and Development
- Product Research and Development Alliances
- Quality Control/Quality Assurance
- Marketing/Advertising/Promotion

Virtual Schedule At-A-Glance

DAY ONE | MONDAY, APRIL 20

7:45-8:00AM	**Welcome and Opening Remarks**
8:00-8:30AM	**Keynote Address:** The New Age of Automation – A Glimpse to the Future of Global Labeling
8:30-10:20AM	**Session 1:** Digital Labeling and Panel Discussion
10:20-10:25AM	Break
10:25-11:15AM	**Session 1:** Digital Labeling and Panel Discussion Continued
11:15AM-12:00PM	Break
12:00-1:30PM	**Session 2:** Tracking and Compliance
1:30-1:45PM	Break
1:45-2:45PM	**Session 3:** Current Labeling Landscape
2:45-3:15PM	**Case Study Spotlight:** Live PRA Health Sciences Exhibitor Interview and Q&A

DAY TWO | TUESDAY, APRIL 21

7:45-8:00AM	**Opening Remarks**
8:00-9:30AM	**Session 4:** Emerging Labeling Markets/Growth Markets: What You Must Know to Manage Globally
9:30-9:40AM	Break
9:40-11:10AM	**Session 5:** Strategic Labeling Approaches
11:10-11:15AM	Break
11:15AM-12:45PM	**Session 6:** Real World Evidence Framework
12:45-1:15PM	Break
1:15-2:45PM	**Session 7:** Combination Product and Device Labeling
2:45-3:00PM	Wrap-Up

Learning Objectives

At the end of this conference participants should be able to:

- Discuss regional and global developments of labeling regulations/guidances, including digital, drug-device combination, and advanced therapy products, and their impact on company processes
- Describe early labeling strategies and their role in product differentiation/marketing plans
- Identify approaches for including patient perspectives and RWD in the creation of labeling content for regulatory approval and patient communication
- Describe use of end-to-end tracking and compliance metrics to improve labeling processes and communications
- Discuss management of reference label, patient labeling, and "beyond the label" information across global regions, including growth markets
- Summarize recent audit trends and how peers monitor labeling implementation and address challenges

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 11.75 contact hours or 1.175 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY JUNE 5, 2020

If you are claiming ACPE credit for this event you must:

1. Complete a Verification of Attendance Form
2. Send back to **NAEvents@DIAglobal.org** by April 28, 2020
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DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by May 5, 202020, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**.

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As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 1.2 CEUs for this conference. Participants must complete the entire conference in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending The 2020 Advertising and Promotion Regulatory Affairs Conference, please complete your state's application for credit and submit accordingly. If you require additional information, please contact **CE@DIAglobal.org**

DIA Disclosure Policy

It is DIA's policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the handout materials.

Continuing Education Credit Allocation

Global Labeling Conference – Day One: 5.5 contact hours or .55 CEUs
Global Labeling Conference – Day Two 6.25 contact hours or .625 CEUs

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VIRTUAL DAY ONE | MONDAY, APRIL 20

7:45-8:00AM

Welcome and Opening Remarks

Session Chair
Su-Yueh Lin, MS, RPh, Executive Director, Regulatory Labeling & Promotion, Intercept Pharmaceuticals

Speaker
Robin Weinick, PhD, SVP/MD Americas and Global Program Officer, DIA

8:00-8:30AM

Keynote Address: The New Age of Automation – A Glimpse to the Future of Global Labeling

Session Chair
Su-Yueh Lin, MS, RPh, Executive Director, Regulatory Labeling & Promotion, Intercept Pharmaceuticals

The advancement of automation has profoundly affected how R&D activities are performed across the industry. The global, multi-functional, high volume, and complex nature of Labeling makes it an ideal candidate for disruption from automation. This session will provide a view into the potential future of Labeling, highlighting the organizational benefits from this future. The session will also include details on steps the industry can take to achieve this future.

Speakers
William Carter, MBA, PMP, Senior Manager, Deloitte

Mukesh Singhal, MBA, Senior Manager, Deloitte

8:30-10:20AM

Session 1: Digital Labeling and Panel Discussion

Session Chair
Rie Matsui, RPh, Senior Director, International Labeling Asia, Regulatory Affairs, Pfizer, Japan

Session Co-Chair
Deborah Bebbington, Vice President, Head Labeling, Bayer, United Kingdom

There are many on-going initiatives of digital labeling across regions such as European Union, Japan, Canada and Singapore, although paper labeling is still required in majority of countries. eLabeling will help to deliver the latest labeling information immediately in efficient and customer friendly way for patients safety. Also, eLabeling is driven by the acceleration of digital disruption and must consider patient-centricity. In this session, the current landscape of eLabeling initiatives for future digital health across regions will be shared and will be discussed from regulators' and industry's point of view.

Speaker (Pre-recorded)
Shinobu Uzu, MSc, PHARMA, Senior Executive Director, PMDA, Japan

Update on Health Canada's XML Product Monograph Project
Craig Anderson, Senior Expert, Program Delivery, Health Canada

European Product Information – ePI Hot Air or Real Opportunities?
Aimad Torqui, Director Global Regulatory Policy and Chair of IATF, MSD, Belgium

The Electronic Patient Leaflet Project (e-PIL): A Pioneer Pilot in Belgium and Luxembourg
Nathalie Lambot, DrSc, MPharm, RPh, Expert Santé Publique – Clinical Trials and Regulatory Affairs, pharma.be, Belgium

Electronic Labeling: A U.S. Perspective
Mark Hendrickson, MS, Senior Director, Leavitt Partners

Asia Updates for E-Labeling
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, Japan

10:20-10:25AM

Break

10:25-11:15AM **Session 1:** Digital Labeling and Panel Discussion Continued

Session Chair
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, Japan

Session Co-Chair
Deborah Bebbington, Vice President, Head Labeling, Bayer, United Kingdom

There are many on-going initiatives of digital labeling across regions such as European Union, Japan, Canada and Singapore, although paper labeling is still required in majority of countries. eLabeling will help to deliver the latest labeling information immediately in efficient and customer friendly way for patients safety. Also, eLabeling is driven by the acceleration of digital disruption and must consider patient-centricity. In this session, the current landscape of eLabeling initiatives for future digital health across regions will be shared and will be discussed from regulators' and industry's point of view.

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Nathalie Lambot, DrSc, MPharm, RPh, Expert Santé Publique – Clinical Trials and Regulatory Affairs, pharma.be, Belgium

Electronic Labeling: A U.S. Perspective
Mark Hendrickson, MS, Senior Director, Leavitt Partners

Asia Updates for E-Labeling
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, Japan

11:15AM-12:00PM **Break**

12:00-1:30PM **Session 2:** Tracking and Compliance

Session Chair
Theresa Brunone, MA, MS, Compliance Director, Global Labeling, GlaxoSmithKline

Session Co-Chair
Paula Hudson, RPh, RAC, Advisor, Global Regulatory Affairs, Eli Lilly and Company

End to end tracking of labeling submissions is a pharmacovigilance activity [tracking from signal identification/validation through regulatory submission/approval and finally through the creation of production packaging artwork and product distribution] and a source of many potential areas for opportunities for miscommunications and delays to product availability in the hands of the patients. A wide variety of solutions exist across the pharmaceutical, biologics, and device industries. We will look at what is implemented in various companies for governance and tracking, and where the pain points are for future improvements in tracking and labeling compliance.

Connected Labeling: The Final Frontier in Content Management
David Gwyn, MBA, Vice President, Life Sciences, North America, Amplexor

Labeling Tracking
Nya Feldthus, MS, Global Labeling Implementation Consultant, Eli Lilly and Company, Denmark

Timely Implementation Monitoring
Shannon Leber, MA, MBA, Associate Director, GRA Quality and Compliance, Janssen Pharmaceuticals

Timely Implementation Monitoring
Kathleen Salazar, MA, MBA, Head, Global Labeling Operations, Global Labeling COE, Janssen Research and Development/Johnson & Johnson

1:30-1:45PM **Break**

1:45-2:45PM

Session 3: Current Labeling Landscape

Session Chair
Paula Hudson, RPh, RAC, Advisor, Global Regulatory Affairs, Eli Lilly and Company

Session Co-Chair
Su-Yueh Lin, MS, RPh, Executive Director, Regulatory Labeling and Promotion, Intercept Pharmaceuticals

Labeling organizations have similar struggles at different times across the labeling process. It is always helpful to hear how other companies have addressed issues to gain insight for improving your own processes. This panel made up of consultants and industry labeling professionals will provide their views on several relevant labeling topics and also allow participants to share their perspectives.

Panelists
Deborah Bebbington, Vice President, Head Labeling, Bayer, United Kingdom

Gerrit-Jan Nijveldt, MSc, Labeling Consultant, EASi

Hayley Parker, MSc, PhD, Head of Global Labeling, Global Regulatory Affairs, Vertex Pharmaceuticals

Theresa Brunone, MA, MS, Compliance Director, Global Labeling, GlaxoSmithKline

2:45-3:15PM

Case Study Spotlight: Live PRA Health Sciences Exhibitor Interview and Q&A

Session Chair
Bill Allman, Chief Digital Officer, DIA

Speaker
Tara Baer, Executive Director, Global Labeling, PRA Health Science

Do you understand the philosophy of core labeling and global labeling regulations? This rare interview reviews case studies in in labeling content development and document review, project management, process review and redesign, labeling operations and compliance. Find out how companies are developing local labeling, strategically supporting Target Product Labeling, and managing global compliance.

VIRTUAL DAY TWO | TUESDAY, APRIL 21

7:45-8:00AM

Opening Remarks

Session Chair
Paula Hudson, RPh, RAC, Advisor - Global Regulatory Affairs, Eli Lilly and Company

8:00-9:30AM

Session 4: Emerging Labeling Markets/Growth Markets: What You Must Know to Manage Globally

Session Chair
Theresa Brunone, MA, MS, Compliance Director, Global Labeling, GlaxoSmithKline

Session Co-Chair
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, Japan

This session will focus on labeling concepts such as the reference label, patient labeling, and beyond the label information, and how they are addressed across the world. In emerging markets, seeking clarity on what is required for each of these related elements can reduce the challenges of managing affiliates. The session will explore this and other labeling concepts you must know to successfully manage labeling in global markets.

Speaker
Shinobu Uzu, MSc, PHARMA, Senior Executive Director, PMDA, Japan

Labeling Challenges in Africa: An Industry Perspective
Francis Karanja, MSc, RPh, Regulatory Affairs Director, GlaxoSmithKline, Kenya

Labeling Challenges in Africa: An Industry Perspective
Chi-Sing Nip, MBA, PHARMA, PharmD, Product Development Regulatory, PDR, Hoffmann-La Roche Limited, Canada

What's the Role of Patients in Patient Labeling?
Meredith Smith, PhD, MPA, Director, Risk Management, Global Drug Safety, Alexion Pharmaceuticals, Inc.

9:30-9:40AM

Break

9:40-11:10AM

Session 5: Strategic Labeling Approaches

Session Chair
Paula Hudson, RPh, RAC, Advisor, Global Regulatory Affairs, Eli Lilly and Company

Labeling associates can provide value to their organizations by working with key stakeholders early in the product development stages to develop labeling that can help with market entry and product differentiation. This session will provide some examples on how this can be accomplished.

Early Phase Drug Labeling Development
Michael Roesner, MS, Senior Labeling Associate, Eli Lilly and Company

Global Target Labeling
Maria Sandrino-Meinz, MS, Deputy Director Labeling, Global Labeling, Bayer Healthcare Pharmaceuticals

Integrating Health Literacy into the Development of Patient Labeling and Promotional Material
Karen Ciprero, MS, Director, Global Labeling, Merck & Co., Inc.

Integrating Health Literacy into the Development of Patient Labeling and Promotional Material
Kevin Stark, MBA, RAC, Director, Office of Promotion and Advertising Review, Regulatory Affairs, Merck & Co.

11:10-11:15AM

Break

11:15AM-12:45PM

Session 6: Real World Evidence Framework

Session Chair
Hayley Parker, MSc, PhD, Head of Global Labeling, Global Regulatory Affairs, Vertex Pharmaceuticals

Industry and regulators are striving to ensure patient needs and perspectives are included in the information provided to patients as well as in the information used to approve new products or expansion of labeling for approved products. How can industry Labeling Organizations facilitate the creation of label content generated from patient focus groups, RWE, and/or RWD? This session will provide insight as to how this can be done.

Real World Evidence and Real World Data
Denise Globe, MHS, PhD, Vice President, Global Real World Evidence, Vertex Pharmaceuticals

Patient Experience in Oncology Product Labeling
Vishal Bhatnagar, MD, Associate Director for Patient Outcomes, Oncology Center of Excellence, CDER, FDA

Real World Evidence: A Case Study
Thomas Kilker, MS, Director and Interim Head, Regulatory Affairs Labeling, Jazz Pharmaceuticals

12:45-1:15PM

Break

1:15-2:45PM

Session 7: Combination Product and Device Labeling

Session Chair
Su-Yueh Lin, MS, RPh, Executive Director, Regulatory Labeling and Promotion, Intercept Pharmaceuticals

Session Co-Chair
Gerrit-Jan Nijveldt, MSc, Labeling Consultant, EASi

The labeling for drug-device combination products - drugs that are combined with device-based delivery systems - continues to evolve as a topic of interest for the industry. This session will discuss the current guidance and regulations for combination product labeling in the US and EU. Useful information on combination product labeling development from conceptualization to agency approval will be provided from industry and regulator perspectives. Some key elements of the medical device regulation (MDR) will also be presented as the May 2020 deadline for the implementation is approaching.

Labeling for (Drug-)Device Products and FDA Draft Guidance for Instruction for Use
Gerrit-Jan Nijveldt, MSc, Labeling Consultant, EASi

Human Factors Engineering for Combination Products
Martin McLoughlin, PhD, Head of Device Development, Global Product Development and Supply, Bristol-Myers Squibb

Speaker
Gina Monteiro, Advisor, Eli Lilly

2:45-3:00PM

Wrap-Up

Session Chair
Gerrit-Jan Nijveldt, MSc, Labeling Consultant, EASi