DIA

Global Labeling Conference

Short Courses: April 23 | Conference: April 24-25
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM CO-CHAIRS

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Gerrit-Jan Nijveldt, Msc
Senior Director of Labeling
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Overview

Labeling is a critical tool for the safe and effective use of prescription drugs, biologics, and medical devices. Its purpose is to convey the essential information needed by providers, patients, and payers to make decisions about product access, prescription, and use. Today's environment of increasingly complex labeling regulations and guidances is especially challenging for products marketed in multiple regions, which demand worldwide consistency of prescribing and patient information. This Conference provides a forum for regulators and industry to update their knowledge of local and global labeling-related policies and to examine the impact of changes on regulatory compliance.

Highlights

- Two half-day short courses to extend your learning
- Labeling updates from around the globe
- Engage outside of session rooms at the Networking Reception on Tuesday
- Examination of key changes, such as the safety labeling submission requirements of the revised EU GVP Module IX
- Representatives from regulatory agencies in multiple regions including the US, EU, Japan, Canada, Australia, Latin America, the Middle East, and Africa

Who should attend?

Professionals from biopharmaceutical and device companies, regulatory authorities, CROs, and consulting agencies involved in:

- Labeling
- Clinical Safety/pharmacovigilance
- Pharmacoepidemiology
- Regulatory affairs/drug review and approval process
- Medical affairs and communications
- Medical writing
- Clinical research and development
- Product research and development alliances
- Quality control/quality assurance

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Discuss new labeling-related developments and regulations (e.g., Canada, EU, Japan, Asia, Latin America, Middle East, Africa, and US)
- Describe the impact of proposed changes to regional and global labeling requirements and implications for labeling practice and processes
- Analyze the impact of current and proposed global and region-specific labeling policies for combination products, biosimilars, and generic drugs on labeling development and product lifecycle practices
- Assess the advantages and limitations of various labeling processes and document management systems commonly used in companies
- Describe global labeling compliance expectations and best practices

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Type of Activity: Knowledge

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Participants are able to receive an ACPE statement of credit for daily attendance. **No partial credit will be awarded.**

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If you would like to receive a statement of credit, you must attend the entire conference (and/or short course), sign in each day at the DIA registration desk upon arrival, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning Wednesday, May 9.

Continuing Education Credit Allocation

Short Course 1: ***EU Inspections and Audit Readiness Plans:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-052-L04-P

Short Course 2: ***Writing Good Core Data Sheets and Supporting Documentation – Performing Rational Deviation Management:*** Pharmacy 3.5 contact hours or .35 CEUs, UAN: 0286-0000-18-053-L04-P

Conference Day One: Pharmacy 7 contact hours or .7 CEUs, UAN: 0286-0000-18-054-L04-P

Conference Day Two: Pharmacy 6.25 contact hours or .625 CEUs, UAN: 0286-0000-18-055-L04-P

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| Schedule At-A-Glance

SHORT COURSES | MONDAY, APRIL 23		ROOM
7:30AM-5:00PM	Short Course Registration	Brookside Foyer
8:30AM-12:00PM	**Short Course 1:** EU Inspections and Audit Readiness Plans	Brookside AB
1:00-5:00PM	**Short Course 2:** Writing Good Core Data Sheets and Supporting Documentation – Performing Rational Deviation Management	Brookside AB

DAY ONE | TUESDAY, APRIL 24		ROOM
7:00AM-5:15PM	Registration	Brookside Foyer
7:00-7:45AM	Continental Breakfast in the Exhibit Hall	White Oak
7:45-8:00AM	**Welcome and Opening Remarks**	Brookside AB
8:00-8:30AM	**Late-Breaking Presentation:** Will Brexit Impact the Business of Life Science Companies in the EU?	Brookside AB
8:30-10:30AM	**Session 1:** Updated Global Regulations and Guidances (Including Canada and Australia)	Brookside AB
10:30-11:00AM	Refreshments, Exhibits, and Networking Break	White Oak
11:00AM-12:30PM	**Session 2:** EU Labeling Updates	Brookside AB
12:30-1:45PM	Luncheon, Exhibits, and Networking	White Oak
1:45-3:15PM	**Session 3:** US Updates	Brookside AB
3:15-3:45PM	Refreshments, Exhibits, and Networking Break	White Oak
3:45-5:15PM	**Session 4:** Japan and Asia Updates	Brookside AB
5:15-6:15PM	Networking Reception	White Oak

DAY TWO | WEDNESDAY, APRIL 25		ROOM
7:00AM-3:45PM	Registration	Brookside Foyer
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking	White Oak
8:00-8:05AM	**Opening Remarks**	Brookside AB
8:05-9:30AM	**Session 5:** Latin America, Middle East, and Africa Labeling Updates	Brookside AB
9:30-11:00AM	**Session 6:** Impact of EU GVP Module IX on Global Labeling Governance	Brookside AB
11:00-11:30AM	Refreshments, Exhibits, and Networking Break	White Oak
11:30AM-1:00PM	**Session 7:** Combination Products and Medical Device Labeling	Brookside AB
1:00-2:00PM	Luncheon, Exhibits, and Networking	White Oak
2:00-3:30PM	**Session 8:** Labeling Process, Document Management Systems, and Databases	Brookside AB
3:30-3:45PM	**Wrap-up**	Brookside AB

SHORT COURSES | MONDAY, APRIL 23

7:30AM-5:00PM

Short Course Registration

**Short Courses require a separate registration fee*

8:30AM-12:00PM

Short Course 1: EU Inspections and Audit Readiness Plans

Instructors

Megann Looker, Director, EU/RoW Labeling and Advertising/Promotion, Global Regulatory Affairs, Jazz Pharmaceuticals, United Kingdom

Kiernan Trevett, PhD, Senior GPvP Inspector, MHRA, United Kingdom

If you were notified today, would your organization be ready for an EU inspection of its pharmacovigilance system? With the recent shift to risk-based inspections, do you know what health authority inspectors look for when they conduct safety inspections? And what is the role of the labelling team in the process? This short course focuses on the preparations necessary for labeling teams in the EU ahead of pharmacovigilance inspections. Industry representatives will discuss the goals of end-to-end labeling compliance oversight. The MHRA Inspectorate will share their extensive and well-documented pharmacovigilance inspection process and their perspectives on inspection readiness and common findings.

At the conclusion of this short course, participants should be able to:

- Describe considerations from industry on pharmacovigilance inspection readiness
- Discuss the Inspector perspective on common findings and areas for improvements in compliance

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1:00-5:00PM

Short Course 2: Writing Good Core Data Sheets and Supporting Documentation – Performing Rational Deviation Management

Instructors

A. Leander Fontaine, MD, President, Pharmiceutics, LLC.

Barbara Lachmann, MD, Senior Advisor, Center of Excellence Product Information, Barbara Lachmann Labeling Consulting, Germany

Rie Matsui, RPh, Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc., Japan

This short course discusses common shortfalls of Company Core Data Sheet (CCDS) content and supporting rationales/documentation that have implications for regulatory acceptability of proposed safety labeling changes. Improvement strategies are presented and evaluated in interactive practice exercises. In addition, the short course explores rational strategies for accepting or refuting local labeling deviations from Company Core Safety Information (CCSI) content.

At the conclusion of this short course, participants should be able to:

- Describe common shortfalls of CCDS content and supporting rationales/documentation
- Explain why these shortfalls limit regulatory acceptability of proposed safety labeling changes
- Discuss ways to improve CCDS content and supporting rationales/documentation
- Explain when proposed local labeling or CCSI content may have to be changed to ensure sufficient similarity

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DAY ONE | TUESDAY, APRIL 24

7:00AM-5:15PM — **Registration**

7:00-7:45AM — **Continental Breakfast in the Exhibit Hall**

7:45AM-8:00AM — **Welcome and Opening Remarks**

Su-Yueh Lin, MS, Regulatory Labeling Consultant, Independent Consultant

8:00-8:30AM — **Late-Breaking Presentation:** Will Brexit Impact the Business of Life Science Companies in the EU?

Elisabethann Wright, Partner, Hogan Lovells International LLP, Belgium

After briefly reviewing the history of Brexit, this presentation discusses its likely practical implications for the life science industries and how companies can prepare for "unknown" implications.

8:30-10:30AM — **Session 1:** Updated Global Regulations and Guidances (Including Canada and Australia)

Session Chair
Mark A. Collins, PhD, MBA, Global Labeling Lead, CSL Behring

This session reviews recent updates to global regulations and guidances and an update on the Structured Product Monograph (SPM) initiative in Canada. A representative from Health Canada has been invited and the session also contains an industry viewpoint.

Recent Changes to the Product Information Requirements in Australia and New Zealand
Mark A. Collins, PhD, MBA, Global Labeling Lead, CSL Behring

Adverse Reactions in Regional Labeling and Investigator Brochures: Inconsistent Expectations
A. Leander Fontaine, MD, President, Pharmiceutics, LLC.

The Canadian Structured Product Monograph (SPM) Initiative
Craig Anderson, Business Analyst, Health Canada

The Canadian Structured Product Monograph (SPM) Initiative from an Industry Perspective
Luiza Madeira, Consultant, Global Labeling Department, Eli Lilly Canada Inc., Canada

10:30-11:00AM — **Refreshments, Exhibits, and Networking Break**

11:00AM-12:30PM — **Session 2:** EU Labeling Updates

Session Chair
Megann Looker, Director, EU/RoW Labeling and Advertising/Promotion, Global Regulatory Affairs, Jazz Pharmaceuticals, United Kingdom

This session will cover the latest developments in the eLabeling arena, as well as an overview of recent guidance updates and the latest thinking on regional labeling strategy.

Introduction to the EMA Action Plan
Deborah Bebbington, BSc, Vice President, Head, Global Labeling, Bayer, United Kingdom

Envisioning the Future of Labeling Through Digitization of Information and the Current Environment for eLabeling
Nisha Modha, Regulatory Labeling Site Head – Welwyn, Roche Products Limited, United Kingdom

EU Timelines for MAAs and Linguistic Review – How, When, and What
Megann Looker, Director, EU/RoW Labeling and Advertising/Promotion, Global Regulatory Affairs, Jazz Pharmaceuticals, United Kingdom

Evaluation of the SmPC and the Impact to Regional Labels
Hayley Parker, PhD, Senior Director, Head, Global Labeling, Vertex Pharmaceuticals

12:30-1:45PM — **Luncheon, Exhibits, and Networking**

1:45-3:15PM

Session 3: US Updates

Session Chair
Paula Hudson, RPh, Director, Global Regulatory Affairs - Labeling, Eli Lilly and Company

This session provides information on labeling-related regulatory guidances and current expectations that are essential for those involved in drafting and maintaining US labeling throughout its lifecycle.

SPL Updates
Herbert O'Brien, Senior Local Labeling Registration Manager, Bayer HealthCare Pharmaceuticals Inc.

Insights and Learnings from the FDA REdI Conference
Gina Monteiro, Manager, US and Canada Labeling, Eli Lilly and Company

Adverse Reaction Section of the USPIA.
Leander Fontaine, MD, President, Pharmiceutics, LLCAdverse Reaction Section of the USPI

Barbara Lachmann, MD, Senior Advisor, Center of Excellence Product Information, Barbara Lachmann Labeling Consulting

3:15-3:45PM

Refreshments, Exhibits, and Networking Break

3:45-5:15PM

Session 4: Japan and Asia Updates

Session Chair
Rie Matsui, RPh, Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc., Japan

This session will present the new labeling regulations for Japan, issued in June 2017 as the first such update in 20 years. All Japanese labels must be updated according to the new regulations, and necessary preparations for the potential impact of the new regulation on global labeling will be discussed. This session will also provide PMDA initiatives in Asia and updates on important labeling-related regulatory trends in Asia, including China, Singapore, Korea, and Vietnam.

New Labeling Regulations in Japan and PMDA Initiatives in Asia
Shinobu Uzu, Chief Safety Officer, PMDA, Japan

Labeling in Asia: A Dynamic Landscape
Rie Matsui, RPh, Director, Regional Labeling Head for Asia, International Labeling Group, Pfizer Japan Inc., Japan

Panel Discussion and Q&A

5:15-6:15PM

Networking Reception

DAY TWO | WEDNESDAY, APRIL 25

7:00AM-3:45PM

Registration

7:00-8:00AM

Continental Breakfast, Exhibits, and Networking

8:00-8:05AM

Opening Remarks

Session Co-Chairs
Sudip S. Parikh, PhD, Senior Vice President and Managing Director, DIA Americas
Steven W. Bass, PhD, President, Bass Biopharm Consulting Group, LLC

8:05-9:30AM

Session 5: Latin America, Middle East, and Africa Labeling Updates

Session Chair
Gerrit-Jan Nijveldt, Msc, Senior Director, Labeling, Sanofi

This session will discuss the requirements for labeling submission and regulatory agency approval in the Latin America and Middle East/Africa regions. Labeling strategies, including the use of shared labeling processes within some of the Latin American and Middle East/Africa countries, and the use and need for approved reference labeling prior to submission to agencies in some of the countries will be explored.

Labeling in LATAM Region
Olga Lucia Anzola, BPharm, Head Center of Expertise Labeling LATAM, Sanofi, Colombia

Labeling in Africa/Middle East Region
Nathalie Cunha-Da-Silva, Management Associate, Regulatory Excellence and Countries Management, Africa Middle East Region, Sanofi, France

9:30-11:00AM

Session 6: Impact of EU GVP Module IX on Global Labeling Governance

Session Chair
A. Leander Fontaine, MD, President, Pharmiceutics, LLC.

This session discusses the potential implications of the safety-labeling submission requirements added to the revised EU GVP Module IX on companies' global labeling actions, policies, and processes.

The Revised GVP Module IX and its Potential Impact on Global Labeling Processes - Introduction
Barbara Lachmann, MD, Senior Advisor, Center of Excellence Product Information, Barbara Lachmann Labeling Consulting, Germany

Understanding the Labeling-Related Requirements of the Revised GVP Module IX
Elisabethann Wright, Partner, Hogan Lovells International LLP, Belgium

The New Labeling Submission Requirements in GVP Module IX – A USA Legal Point of View
Lynn Mehler, Partner, Hogan Lovells

Panelists
Joining the speakers

Shinobu Uzu, MSc, Chief Safety Officer, PMDA, Japan
Deborah Bebbington, BSc, Vice President, Head, Global Labeling, Bayer Healthcare PLC, United Kingdom
Kiernan Trevett, PhD, Senior GPvP Inspector, MHRA, United Kingdom
Paula Hudson, RPh, Director, Global Regulatory Affairs - Labeling, Eli Lilly and Company

11:00-11:30AM

Refreshments, Exhibits, and Networking Break

11:30AM-1:00PM

Session 7: Combination Products and Medical Device Labeling

Session Chair
Su-Yueh Lin, MS, RPh, Regulatory Labeling Consultant, Independent Consultant

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. The regulatory experience for a recently FDA-approved combination product involving mobile app will also be presented.

Current Regulations and Guidance and a Process Overview for Developing the Labeling for a Drug-Device Combination Product
Ryan McGowan, Associate Director, Combination Products, AstraZeneca

Human Factors and Labeling/IFU Development
James Meehan, Associate Principal Scientist – Human Factors, AstraZeneca, United Kingdom

Case Study: Regulatory Experience for a Drug-Device Combination Product Involving a Mobile App
Michael Fahmy, MS, Director, Global Labeling Strategy and Regulatory Affairs, Otsuka Pharmaceutical Development & Commercialization, Inc.

1:00-2:00PM

Luncheon, Exhibits, and Networking

2:00-3:30PM

Session 8: Labeling Process, Document Management Systems, and Databases

Session Chair
Gerrit-Jan Nijveldt, MSc, Senior Director, Labeling, Sanofi

Up-to-date data management systems are increasingly important to comply with SPL requirements in the US and IDMP in the EU, especially for the labeling function, which must look at the complete set of data needed for global compliance. Labeling groups also frequently employ content authoring systems to consistently apply the data and updates in regulatory documents. This session will discuss the advantages and limitations of content authoring, its relation to data management, and the downstream use of systems that can integrate content and data as possible tracking tools for countries/affiliates.

End-to-End Labeling – A Vision for the Future
Jun Dong, PhD, Director, Business Partner for Global Regulatory Affairs and Development, R&D IT, Sanofi

Transforming the Labeling Process: How an R&D Approach to Innovation Can Fuel the Future State
Executive Director, Shimon Yoshida, PhD, Head, International Labeling Group, Worldwide Safety and Regulatory, Pfizer Inc

Structured Authoring as a Tool for Globalization
Julie Reitzinger, RN, MBA, Senior Director - Global Labeling and CCDS, Astellas PharmaStructured Authoring as a Tool for Globalization

Camiel Hoogendoorn, MSc, Consultant IDMP, Iperion / Astellas Pharma, Netherlands

3:30-3:45PM

Wrap-up

Session Chair
Gerrit-Jan Nijveldt, Msc, Senior Director, Labeling, Sanofi

3:45PM

Conference Adjourned