Global Labeling 2016

Essential Updates on Worldwide Regulations and Guidelines

Short Courses: September 11 | Conference: September 12–13 | Omni Shoreham Hotel | Washington, DC

PROGRAM CO-CHAIRS

Steven W. Bass, PhD
President
Bass Biopharm Consulting Group LLC

Su-Yueh Lin, MS, RPh
Senior Director, Head of Regulatory Labeling
Regeneron Pharmaceuticals Inc.

PROGRAM COMMITTEE

Barbara Fanelli, MS, MSc
Associate Adjunct Professor
Temple University School of Pharmacy

A. Leander Fontaine, MD
President
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Barbara Lachmann, MD
Senior Advisor, Center of Excellence Product Information
Barbara Lachmann Labeling Consulting, Germany

Megann Looker
Regulatory Associate Director Labeling
Jazz Pharmceuticals, United Kingdom

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

Gerrit-Jan Nijveldt, MSc
Senior Director of Labeling
Sanofi US

Junko Sato
Office Director, Office of International Cooperation
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Overview

Labeling is a critical tool for the safe and effective use of prescription and non-prescription drugs, biologics, and medical devices. The labeling conveys the essential information needed by payers, providers, and patients to make decisions about access, prescription, and use of these products. In an environment of increasingly complex labeling requirements, this conference provides a forum for regulators and industry to update their knowledge of local and global labeling-related policies, and to share processes, tools, and approaches to ensure effective and compliant labeling.

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

Highlights

- Networking Reception, Monday, September 12, 5:00-6:00PM
- Six tabletop exhibitors
- Discussions with industry and agency experts from around the world
- Numerous networking opportunities

This program has been developed in collaboration with the Regulatory Affairs Community-Labeling Working Group.

Message from Program Co-Chairs

Dear Colleagues,

On behalf of the Program Committee and the Labeling Working Group of the DIA Regulatory Affairs Community, we are pleased to welcome you to DIA's *Global Labeling 2016: Updates on Worldwide Regulations and Guidelines* conference. As this is the program committees' fifth conference over the past six years, we can personally attest to the continuity of this conference's goal of being a forum for sharing global regulatory and policy updates and real-world approaches to ensure compliant global labeling practices

Over the years we have been fortunate to have had significant participation from the FDA, Health Canada, the EMA, and the PMDA in Japan, as well as from our global labeling colleagues throughout the biopharmaceutical industry. This conference will continue this tradition as we present to you the recent updates and changes to labeling regulations and guidance documents in the EU, Canada, Japan, Asia, and the US, with added features to address labeling for Generic and Biosimilar Product Labeling and labeling for Combination Products. We will also assess how to best incorporate new patient labeling requirements into effective patient labeling and obtain insights for use of innovative package design for pharmaceutical products.

In addition, we have enlisted a unique panel, consisting of various heads of labeling, to discuss the role of the labeling group in an ever-changing regulatory affairs environment and how these groups can make a positive impact on labeling strategy and operations in their organizations.

We're also excited to be offering two short courses this year. One will discuss how to go from an "Investigator Brochure to Worldwide Labeling", emphasizing different rules for generating adverse reactions for various regulatory documents, and the other addressing the "Impact of Pharmacovigilance Inspections on the Global Labeling Process".

We look forward to seeing you and discussing with you how some of our industry's best practices can work for you to manage various aspects of the global labeling process.

Steven W. Bass, PhD
President
Bass Biopharm Consulting Group LLC

Su-Yueh Lin, RPh, MS
Senior Director, Head of Regulatory Labeling
Regeneron Pharmaceuticals Inc.

Schedule At-A-Glance

SHORT COURSES | SUNDAY, SEPTEMBER 11

9:00AM-5:00PM	Short Course Registration
10:00AM-1:00PM	Short Course 1: From Investigator's Brochure to Worldwide Labeling
2:00-5:00PM	Short Course 2: Pharmacovigilance Inspections and the Impact on Labeling

DAY ONE | MONDAY, SEPTEMBER 12

7:15AM-5:00PM	Registration
7:15-8:15AM	Continental Breakfast, Exhibits, and Networking
8:15-8:30AM	Welcome and Opening Remarks
8:30-10:30AM	Session 1: Global Labeling Issues and Updates: US and Canada
10:30-11:00AM	Refreshments, Exhibits, and Networking Break
11:00AM-12:30PM	Session 2: The Role of the Labeling Group in a Changing Regulatory Affairs Environment
12:30-2:00PM	Networking Luncheon
2:00-3:00PM	Session 3: Labeling for Combination Products and Devices
3:00-3:30PM	Refreshments, Exhibits, and Networking Break
3:30-5:00PM	Session 4: Innovative Package Design and Labeling
5:00-6:00PM	Networking Reception

DAY TWO | TUESDAY, SEPTEMBER 13

7:30AM-5:00PM	Registration
7:30-8:15AM	Continental Breakfast, Exhibits, and Networking
8:15–8:30AM	Welcome to Day Two
8:30-10:00AM	Session 5: Global Labeling Issues and Updates: EU and Asia
10:00-10:30AM	Refreshments, Exhibits, and Networking Break
10:30AM-12:00PM	Session 6: Biosimilars and Generics Labeling
12:00-1:00PM	Networking Luncheon
1:00-2:30PM	Session 7: Patient Labeling: Global View Part One
2:30-3:00PM	Refreshments and Networking Break
3:00-4:45PM	Session 8: Patient Labeling: Global View Part Two
4:45-5:00PM	Summary and Closing Remarks

Learning Objectives

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

- Discuss new labeling-related developments in Canada, European Union, Japan, Asia, and the US
- Compare and contrast packaging regulations/guidance among global regions including the US, EU, Asia, and Canada
- Describe the new US initiatives with structured product labeling
- Describe the impact of proposed changes to regional and global patient labeling requirements
- 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 life cycle practices
- Discuss how labeling groups can work effectively and increase their impact within a variety of organization structures

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program (short course and conference) is designated for 16 contact hours or 1.6 continuing education units (CEU's).

ACPE Credit Requests MUST BE SUBMITTED by October 25, 2016

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. 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 1.3 CEUs for the meeting. 0.3 CEUs will be offered for each Short Course. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the conference (short course, if applicable), complete the "Verification of Attendance" form located in your conference folder, turn in your form to the registration desk at the conclusion of the meeting, 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 on **Monday, September 26.**

To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
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Continuing Education Credit Allocation

Name	Contact Hours	CEUs	UAN
Short Course 1: From Investigator's Brochure to Worldwide Labeling:	2.75	.275	0286-0000-16-097-L04-P
Short Course 2: Pharmacovigilance Inspections and the Impact on Labeling	2.75	.275	0286-0000-16-098-L04-P
Session 1: Global Issues and Updates: US and Canada	1.5	.150	0286-0000-16-099-L04-P
Session 2: The Role of the Labeling Group in a Changing Regulatory Affairs Environment	1.5	.150	0286-0000-16-102-L04-P
Session 3: Labeling for Combination Products and Devices	1.0	.100	0286-0000-16-101-L04-P
Session 5: Global Issues and Updates: EU and Asia	1.5	.150	0286-0000-16-100-L04-P
Session 6: Biosimilars and Generics Labeling	1.5	.150	0286-0000-16-103-L04-P
Session 7: Patient Labeling: Global View Part One	2.0	.200	0286-0000-16-104-L04-P
Session 8: Patient Labeling: Global view Part Two	1.25	.125	0286-0000-16-105-L04-P

ACPE credit is not available for the following sessions:
Welcome and Opening Remarks
Session 4: Innovative Package Design and Labeling

DIA Learning

Increase the level of your statistical knowledge

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Broken into **Five modules** and taught by experienced statisticians:

1	2	3	4	5
Statistical Modeling	**Survival Analysis & Non-Inferiority Trials**	**Bayesian Principles**	**Adaptive Designs**	**Multiplicity & Data Mining**
October 6 12:00-1:30 PM ET	October 13 12:00-1:30 PM ET	October 20 12:00-1:30 PM ET	October 27 12:00-1:30 PM ET	November 3 12:00-1:30 PM ET

Short on time? *Each module can be completed during lunch.*

To Register, DIAglobal.org/ISACT

9:00AM-5:00PM **Short Course Registration**

10:00AM–1:00PM Short Course 1

From Investigator's Brochure to Worldwide Labeling

Instructors

A. Leander Fontaine, MD
President
Pharmiceutics, LLC.

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

This short course will provide you with an essential understanding of the decision making principles for selecting adverse reactions for the purposes of Core Safety information and local submission labeling, and of the differing rules for generating adverse reaction frequency information. This knowledge will be helpful to labeling and regulatory affairs professionals, pharmacovigilance, and clinical professionals, as well as biostatisticians, in avoiding frequent mistakes resulting from inappropriate application of definitions from the realm of clinical trial safety reporting.

Learning Objectives:

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

- Discuss the differences in the criteria for selecting adverse reactions for labeling, and suspected adverse reactions for regulatory reporting from clinical trials
- Describe the conceptual differences between Development Core Safety Information and Reference Safety Informatio
- Outline the various approaches to generating adverse reaction frequency information for labeling
- Select a list of adverse reactions for labeling, based on adverse event data from clinical trials

2:00-5:00PM Short Course 2

Pharmacovigilance Inspections and the Impact on Labeling

Instructors

Megann Looker
Regulatory Associate Director Labeling
Jazz Pharmaceuticals, United Kingdom

Gerrit-Jan Nijveldt, MSc
Senior Director of Labeling
Sanofi US

Vijay Sammeta, MD, MBA
Senior Director Regulatory Labeling
Sanofi

Panel Discussion
Joining the Speakers

Michelle L. Halliez
Associate Vice President
of Global Labeling
Sanofi

Julie Retzinger
Senior Director, CCDS and Labeling,
Operating Platforms, Regulatory Affairs
Astellas Pharma Inc.

The labeling process within a company is subject to a pharmacovigilance inspection, and the inspection findings will have an impact on the labeling. This short course will present the perspectives of industry and the regulatory inspector on how to prepare for the inspection and what can be done to answer major findings.

Learning Objectives:

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

- Discuss the importance for regulatory and global labeling of an EMA PV inspection
- Describe how to prepare for the inspection and what questions to expect
- Identify the impact on Regulatory and Global Labeling of the EMA PV inspection, bringing back to company valuable information on EMA PV inspection and impact on Regulatory Labeling

MONDAY, SEPTEMBER 12

7:15AM-5:00PM **Registration**

7:15-8:15AM **Continental Breakfast, Exhibits, and Networking**

8:15-8:30AM **Welcome and Opening Remarks**

Sudip Parikh
Senior Vice President and Managing Director
DIA

Su-Yueh Lin, MS, RPh
Senior Director, Head of Regulatory Labeling
Regeneron Pharmaceuticals Inc.

8:30-10:30AM **Session 1: Global Labeling Issues and Updates: US and Canada**

Session Chair

A. Leander Fontaine, MD
President
Pharmiceutics, LLC.

This session provides updates on important labeling-related regulatory developments in the US and Canada that are essential for those involved in drafting US and Canadian labeling. The discussion will also explore the importance of these developments for core and worldwide labeling.

US Proposed E-Labeling Rule

Dora W. Cohen, MS, MSc
Executive Director, Global Labeling
Amgen Inc.

Pregnancy and Lactation Labeling Rule Updates (US)

Tamara Johnson, MD, MS
Acting Team Leader, Division of Pediatrics and Maternal Health, Office of New Drugs
CDER, FDA

Updates on the Use of Structured Product Labeling and the Indexing Initiative

Lonnie D. Smith
Policy Analyst, Office of Operations, Office of Information Management, Office of the Commissioner
FDA

Implementation of the Plain Language Labeling (PLL) Regulations in Canada

Veronica Yip
Senior Regulatory Project Manager
Health Canada (RPMD)

The 2016 Canadian Product Monograph Guidance

Michelle Remillard
Manager, Health Products and Food Branch
Health Canada

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

11:00AM-12:30PM **Session 2: The Role of the Labeling Group in a Changing Regulatory Affairs Environment**

Session Chair

Gerrit-Jan Nijveldt, MSc
Senior Director of Labeling
Sanofi US

Labeling is described as the most important part of the dossier. The methods and concepts for labeling development vary across industry and there is a need to ensure the importance of this role is maintained. This interactive session will discuss the strategic role of the persons responsible for labeling development and the maintenance process.

Panelists

Theresa Brunone, MA, MS
Manager, Global Labeling
GlaxoSmithKline

Dora W Cohen, MS, MSc
Executive Director, Global Labeling
Amgen Inc.

Mark A. Collins, PhD, MBA
Senior Director, Risk Management and International Labeling Advisor
Endo Pharmaceuticals Inc.

Michelle L. Halliez
Associate Vice President of Global Labeling
Sanofi

Julie Retzinger, MBA, RN
Senior Director, CCDS and Labeling, Operating Platforms, Regulatory Affairs
Astellas Pharma Inc.

12:30-2:00PM **Networking Luncheon**

2:00-3:00PM

Session 3: Labeling for Combination Products and Devices

Session Chair

Su-Yueh Lin, MS, RPh
Senior Director, Head of Regulatory Labeling
Regeneron Pharmaceuticals Inc.

Discuss regulatory and labeling requirements for the increasing number of drugs that are combined with device-based delivery systems, or drug-device combination products. Human Factor Studies (HFS) provide key information to describe the safe and effective use of the device component, and are also important in plans for labeling of combination products in development. This session will describe the process for the HFS and the associated draft guidances from FDA and MHRA.

Human Factors Engineering

Valerie Fenster
Senior Manager, Human Factors Engineering, Device Technologies
Amgen Inc.

Labeling for a Combined Medicinal Product or Medical Device

Tara Baer
Senior Managing Consultant
NAVITAS

3:00-3:30PM Refreshments, Exhibits, and Networking Break

3:30-5:00PM

Session 4: Innovative Package Design and Labeling

Session Chair

Mark A. Collins, PhD, MBA
Senior Director, Risk Management and International Labeling Advisor
Endo Pharmaceuticals Inc.

This session includes invited speakers from industry, FDA, and Health Canada to provide a balanced view of packaging issues. The industry portion will discuss considerations and challenges when developing the packaging materials, including timing (when to start), branding, and regional differences. Regulatory perspectives include insights from an FDA Safety Reviewer, and a discussion on Canada's draft guidance, "Good Label and Packaging Practices Guide (2015)".

Considerations to be Taken When Developing the Packaging Materials

Anthony Bantug, MS
Principal Engineer, Packaging Engineering and Labeling
Amgen

Common Deficiencies in Container Labels and Carton Labeling for Biological Products

LCDR Jibril Abdus-Samad, PharmD
Labeling Reviewer, Office of Biotechnology Products, Office of Pharmaceutical Quality CDER, FDA

Application of the Good Label and Packages Practices Guide For Prescription Drugs in the Therapeutic Products Directorate's Review of Mock-Up Labels

Veronica Yip
Senior Regulatory Project Manager
Health Canada (RPMD)

5:00-6:00PM Networking Reception

TUESDAY, SEPTEMBER 13

7:30AM-5:00PM **Registration**

7:30-8:15AM **Continental Breakfast, Exhibits, and Networking**

8:15-8:30AM **Welcome to Day Two**

8:30-10:00AM **Session 5: Global Labeling Issues and Updates: EU and Asia**

Session Chair

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

The regulatory perspective on key labeling-related developments in the EU will be addressed, as well as the relationship of the pharmacovigilance risk assessment to labeling updates. Representatives of the PMDA will discuss the latest labeling updates from Japan, and labeling trends in the broader Asia region will be examined from the industry perspective.

Pharmacovigilance Risk Assessment

Victoria O'Keefe
Benefit Risk Scientific Assessor
Medicines and Healthcare Products Regulatory Agency,
United Kingdom

EU Updates: Regulations Perspective

Megann Looker
Regulatory Associate Director Labeling
Jazz Pharmaceuticals, United Kingdom

Patient Labeling in Japan and Asia

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

Japan Labeling Updates and Labeling Trends in Asia

Takashi Misu
Office of Safety II
Pharmaceuticals and Medical Devices Agency (PMDA)

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

10:30AM-12:00PM **Session 6: Biosimilars and Generics Labeling**

Session Chair

Paula Hudson, RPh
Director, Global Regulatory Affairs
Eli Lilly and Company

The regulatory landscape for biosimilars and generics is evolving and are hot topics of interest for our industry. This session will describe the challenges and discussion points that are being debated with the FDA in the draft guidance on Labeling for Biosimilars and the Generic Labeling rule. In addition, the EU perspective and experiences for biosimilars will be shared and compared with the FDA draft guidance.

US Generics Labeling

Joseph P. Thomas, JD, PharmD, RPh
Chair of Life Sciences Group and Co-Chair, Litigation
Ulmer & Berne LLP

US Draft Biosimilars Labeling Guidance

David H. Dorsey, JD, MA
Senior Director, Americas Head Global Regulatory Policy and Intelligence
Janssen Research and Development LLC

Biosimilars Labeling

Bruce Leicher, JD
Senior Vice President and General Counsel
Momenta Pharmaceuticals, Inc.

Panel Discussion

Joining the Speakers

A. Leander Fontaine, MD
President
Pharmiceutics, LLC

Julie Retzinger, RN, MBA
Senior Director, CCDS and Labeling, Operating Platforms, Regulatory Affairs
Astellas Pharma Inc.

12:00-1:00PM **Networking Luncheon**

1:00-2:30PM

Session 7: Patient Labeling: Global View Part One

Session Chair

Shinobu Uzu, MPharm
Chief Safety Officer
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

This session provides updates on patient labeling in the EU, Canada, and Asia. EU Patient labeling initiatives will be discussed from the industry point of view, and Health Canada will discuss its ongoing initiative on Plain Language Labeling. In addition, the patient labeling landscape in Asia, including Japan, will be explained.

Patient Labeling Initiatives – EU

Megann Looker
Regulatory Associate Director Labeling
Jazz Pharmaceuticals, United Kingdom

Canada's Patient Medication Information (Part III of the Product Monograph)

Michelle Remillard
Manager, Health Products and Food Branch
Health Canada

Patient Labeling in Japan and the Asian Market

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

2:30-3:00PM Refreshments and Networking Break

3:00-4:45PM

Session 8: Patient Labeling: Global View Part Two

Session Chair

Dora W. Cohen, MS, MSc
Executive Director, Global Labeling
Amgen Inc.

Patient labeling in the US has been evolving for years. The FDA continues to work with stakeholders in developing a single, standardized Patient Medication Information (PMI) document to promote the safe and effective use of prescription medication. Innovations in Internet-driven technologies that target information to patients require additional guidance. FDA and industry experts will discuss regulations, guidances, any potential updates, and offer insights in how to best prepare patient labeling.

Patient Labeling Information 2016 Update

Morgan Walker, PharmD, MBA
Patient Labeling Reviewer
FDA

Patient Medication Information Update

Elisabeth Walther, PharmD, JD
Regulatory Counsel
FDA

Patient Labeling Considerations for Mobile Medical Applications and Software

Ann Robards, MS
Labeling Consultant
Eli Lilly and Company

US Patient Labeling: The Impact on Consumer Promotion and Communication Activities

Tracy D. Rockney, JD
Co-Founder and Managing Partner
OneSource Regulatory

4:45-5:00PM

Summary and Closing Remarks

Gerrit-Jan Nijveldt, MSc
Senior Director of Labeling
Sanofi US

5:00PM

Conference Adjourned

Exhibiting Companies

- Gilead Sciences
- i4i
- Intagras, Inc.
- MakroCare
- Opus Regulatory, Inc.
- Schlafender Hase

DIA

Combination Products Conference 2016

Current, evolving, and future pathways

Increasing use of and interest in innovative combination products is raising significant challenges for regulators and the industries they regulate. This conference will:

- Examine policy and regulation of combination products
- Discuss recent organizational developments and review process improvements that address the unique regulatory needs of combination products
- Explore current and future opportunities for use of drugs and devices together
- Highlight the evolving potential of convergence across FDA's centers, as piloted by the Oncology Center of Excellence

Visit DIAglobal.org/Combo16

Washington, DC

October 24
Short Course

October 25-26
Conference

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