DIA

Global Labeling Conference

Virtual Short Courses: April 1 | Virtual Conference: April 4-5

PROGRAM COMMITTEE CO-CHAIRS

Su-Yueh Lin, MS, RPh
Vice President of Operation
BRIM Biotechnology, Inc., Taiwan

Kathleen Salazar, MA, MBA
Head, Global Labeling Implementation, Global Labeling COE
Janssen Research & Development/Johnson & Johnson
Program Committee

Deborah Bebbington
Head, RA Labeling
Bayer Plc, United Kingdom

Theresa Brunone, MA, MS
Head-Labelling Compliance and Implementation, Global Labeling
GlaxoSmithKline

Lauren Brunke, PharmD, RPh
Senior Director – GRA-NA Global Labeling Department (GoLD)
Eli Lilly and Co

Megann Looker
Executive Director, Head of Global Labeling
Jazz Pharmaceuticals, United Kingdom

Rie Matsui, RPh
Senior Director, Regional Labeling Head for APAC
Pfizer R&D Japan G.K., Japan

Gerrit Nijveldt, MSc
Global Consultant Labeling
Opus Regulatory

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

PROGRAM ADVISORS

Steve Bass, PhD
President
Bass Biopharm Consulting Group, LLC

Leander Fontaine, MD
President
Pharmiceutics, LLC.

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.

DIA is offering a virtual conference for the *Global Labeling Conference* that allows you to view all the session recordings from the comfort of your own home/office. Can't make all the sessions live? You will receive access to the On Demand library with your registration for 2 months post-conference.

Highlights & Features

- Two Preconference Short Courses:
  - **Short Course 1:** Global Labeling – The Basics of Core Datasheet
  - **Short Course 2:** Beyond the Basics of the Core Data Sheet: A Practical Approach to Regional Considerations

Schedule At-A-Glance

SHORT COURSE | FRIDAY, APRIL 1

Sessions are held in ET

8:30AM-12:00PM	**Short Course 1:** Global Labeling – The Basics of Core Datasheet
1:00-5:00PM	**Short Course 2:** Beyond the Basics of the Core Data Sheet: A Practical Approach to Regional Considerations

DAY ONE | MONDAY, APRIL 4 — WHAT'S HAPPENING AND WHAT'S TRENDING IN LABELING

8:30-9:45AM	**Welcoming Remarks and Session 1:** Current and Future Labeling Landscape
9:45-10:15AM	**Break, Visit the Virtual Exhibit Hall**
10:15-11:45AM	**Session 2:** Digital Labeling
11:45AM-12:45PM	**Break, Visit the Virtual Exhibit Hall**
12:45-1:45PM	**Session 3:** Labeling Markets
1:45-2:30PM	**Non-CE/Sponsored Case Study: ComplianceAuthor™ for Global Labeling**
2:40-3:55PM	**Session 4:** Value of Metrics and Human Performance in Labeling Development and Day 1 Closing Remarks

DAY TWO | TUESDAY, APRIL 5 — HANDS ON LABELING WORK

8:30-9:45AM	**Welcome to Day 2 and Session 5:** Strategies for Development Labeling
9:45-10:15AM	**Break, Visit the Virtual Exhibit Hall**
10:15-11:45AM	**Session 6:** Patient Centricity
11:45AM-12:45PM	Break, Visit the Virtual Exhibit Hall
12:45-1:45PM	**Session 7:** Non-Traditional Data – Labeling versus Promotion
1:45-2:15PM	**Refreshments, Exhibits, and Networking Break**
2:15-3:30PM	**Session 8:** Combination Products and Medical Device Labeling and Closing Remarks

Learning Objectives

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

- Identify the key labeling requirements in major markets
- Discuss the concept of digital labeling and forms it may take in making product information available to patients and prescribers
- Examine the regulations supporting drug prescribing information in Latin America and the Caribbean and identify the changes in UK MHRA regulations as a result of Brexit – both those that are new and still in transition
- Identify key submission and implementation metrics that can be used to track labeling changes globally
- Explain the value of labeling during drug development from a global and local perspective
- Describe the opportunities and challenges of patient-centric drug labeling for all stakeholders
- Describe the different types of non-traditional data and the possibility and pros/cons for inclusion in labeling or promotional materials
- Describe the latest information regarding the current regulations and guidance for combination product and medical device labeling in the US and EU

Continuing Education Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to **16.75** contact hours or **1.675** continuing education units (CEU's). Type of Activity: Knowledge.

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MAY 20, 2022

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 **Friday, May 20, 2022**, 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**.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .7* CEUs for this program.

Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

***IACET CEUs are only available for Short Courses.**

Continuing Education Credit Allocation

April 1, 2022 – Virtual Short Course 1: Global Labeling – The Basics of Core Datasheet 3.25 contact hours or .325 CEUs; Type of Activity: Knowledge; UAN: 0286-0000-22-034-L04-P IACET: .3 CEUs

April 1, 2022 – Virtual Short Course 2: Beyond the Basics of the Core Data Sheet: A Practical Approach to Regional Considerations 3.5 contact hours or .35 CEUs; Type of Activity: Knowledge; UAN: 0286-0000-22-035-L04-P IACET: .4 CEUs

April 4, 2022 - Global Labeling Conference – Day One: 5 contact hours or .5 CEUs Type of Activity: Knowledge; UAN: 0286-0000-22-036-L04-P

April 5, 2022 - Global Labeling Conference – Day Two: 5 contact hours or .5 CEUs Type of Activity: Knowledge; 0286-0000-22-037-L04-P

TO ACCESS MY TRANSCRIPT

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

Statement of Credit

If you would like to receive a statement of credit for the days you attend the **live** virtual short course(s), you must virtually attend the short course(s), in their entirety, achieve a passing score of 80% or better on the post-assessment, and complete the program evaluation and request CE credit online through My Transcript (see instructions below).

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must attend each day the conference, in their entirety, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation, and request CE credit online through My Transcript (see instructions below). 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 **Tuesday, April 19, 2022.**

If you are claiming ACPE credit for the live virtual conference you must:

1. Complete a CE Verification of Attendance Form
2. Return it to CE@diaglobal.org by **April 12, 2022**
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Tuesday, April 19, 2022**

SHORT COURSE | FRIDAY, APRIL 1

8:30AM-12:00PM

Virtual Short Course 1: Global Labeling – The Basics of Core Datasheet

Session Co-Chairs
Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

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

Session Description
This half-day short course will present the basic labeling requirements for global labeling documents. It will cover the concept of the Company Core Data Sheet (CCDS), the impact inside and outside of the company, and how local labeling changes and regulatory requirements may have an impact on CCDS. In addition, we will discuss the consequence for a company of having a CCDS and how that will impact local labeling and labeling departments.

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

- Demonstrate a basic understanding of concept core labeling
- Describe the use and impact of core labeling during development
- Identify the impact of core labeling on local labeling such as US, EU, and Japan Labeling
- Apply basic knowledge of core labeling implementation and deviations

Instructors

Audrey Anderson, MS, Head - Labeling (US Hub) & US Labeling Strategy, Pharmaceuticals, Bayer

Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

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

1:00-5:00PM

Virtual Short Course 2: Beyond the Basics of the Core Data Sheet: A Practical Approach to Regional Considerations

Session Co-Chairs
Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

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

Session Description
This Short Course is intended to build on the Basic understanding of Company Core Datasheets. It will provide a practical experience to illustrate the regional (e.g. EU, US and Japan) considerations which can influence CCDS decision making. The course will consider key core safety sections of the labeling and the impact of Agency labeling requests. The course will be based around case studies.

At the conclusion of this short course, participants should be able to
- Identify core safety topics which differ between regions
- Identify common regional core safety topics for inclusion into a CCDS
- Identify potential impact of health authority HA requests on CCDS texts

Instructors
Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

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

Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

DAY ONE | MONDAY, APRIL 4 WHAT'S HAPPENING AND WHAT'S TRENDING IN LABELING

8:30-9:45AM **Welcoming Remarks and Session 1:** Current and Future Labeling Landscape

Session Co-Chairs
Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

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

The session will provide a foundational overview of the key labeling requirements in major markets. It will highlight some of the more recent and upcoming regulations that influence labeling decision making. It will touch upon some of the most common challenges encountered when managing labeling on a global level. It will also discuss some of the implications and considerations for personalized medicines in comparison to traditional medicines.

Speakers
Tomoko Oshawa, PhD, Director of Office of Informatics and Management for Safety Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Misti Link, PMP, Regulatory Labeling Director, Vertex Pharmaceuticals

9:45-10:15AM **Break, Visit the Virtual Exhibit Hall**

10:15-11:45AM **Session 2:** Digital Labeling

Session Co-Chairs
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, R&D Japan G.K., Japan

Kathy Salazar, MA, MBA, Head, Global Labeling Implementation, Global Labeling COE, Janssen Research & Development/Johnson & Johnson

Session Description
Fueled largely by the COVID-19 pandemic, the acceleration and enhancement of digitalization in the pharmaceutical industry has been unprecedented, including digital/electronic labeling. This session will explore the benefits, status, and current developments around digital/electronic labeling for patients and healthcare professionals across regions. This session will include perspectives from regulators and industry representatives and will cover the opportunities and hurdles of introducing digital/electronic labeling.

Speaker
Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, R&D Japan G.K., Japan

ePI Principle and Set-up Project
Elizabeth Scanlan, MSc, PhD, Scientific Communication Officer European Medicines Agency, Netherlands

Speakers
Giovanna Ferrari, PhD, Regional Labelling Lead, Senior Director, Pfizer, United Kingdom

Tomoko Osawa, PhD, Director of Office of Informatics and Management for Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Patrick Maher, PharmaLedger ePI use case Co-Lead / Senior Operations Manager SPT/ TEP, Novartis, Switzerland

---

11:45-12:45PM — **Break, Visit the Virtual Exhibit Hall**

12:45-1:45PM — **Session 3:** Labeling Markets

Session Co-Chairs
Deborah Bebbington, Head, RA Labeling, Bayer Plc, United Kingdom

Theresa Brunone, MA, MS, Head-Labelling Compliance and Implementation, GlaxoSmithKline

Session Description
The details of labelling regulations vary greatly between markets. In some regions, multi-market guidelines have been developed to aid markets in creation and management of labelling. This session will illustrate examples of changes in regulatory strategy in areas beyond US, EU and Japan including the evolution of drug prescribing information regulations in Latin America and the Caribbean, and in Australia.

Regulation of Drug Prescribing Information in Latin America and the Caribbean
Urimara Argotti-Rodriguez, MBA, Regional Regulatory Policy LATAM Region, Global International Regulatory Policy, Productos Roche S.A. DE C.V., Mexico

Regulation of Drug Prescribing Information in Latin America and the Caribbean
Mariana Ramírez-Telles, PharmD, Drug Regulatory Affairs Specialist, Roche Central America and the Caribbean, Costa Rica

Speaker
Jalpa Patel, PhD, Associate Director (ROW Labeling Lead), Vertex Pharmaceuticals (Europe) Ltd, United Kingdom

---

1:45-2:30PM — **Non-CE/Sponsored Case Study: ComplianceAuthor™ for Global Labeling**

2:40-3:55PM — **Session 4:** Value of Metrics and Human Performance in Labeling Development and Day 1 Closing Remarks

Session Co-Chairs
Lauren Brunke, PharmD, RPh, Senior Director – GRA-NA Global Labeling Department (GoLD), Eli Lilly and Co

Theresa Brunone, MA, MS, Head-Labelling Compliance and Implementation, Global Labeling, GlaxoSmithKline

Session Description
The Value of Metrics and Human Performance session will explore how different companies track compliance of labeling changes globally. This session will highlight examples of internal labeling governance groups that are being used to oversee and influence compliance of submission and implementation metrics on a global scale. The session will also include a presentation on a unique approach of applying human error analysis during labeling development and how setting people up for success can unlock opportunities to reduce the risk of human error.

Value of Metrics
Kelly Toetz, Consultant, Regulatory Process Owner, Eli Lilly and Company

Human Error Analysis in Labeling Development
Francesca Dickins, Lead Consultant (Regulatory), Eli Lilly and Company, United Kingdom

Speaker
Julie Avery, Company Secretary, Chatham Consulting LTD, United Kingdom

8:30-9:45AM

Welcome to Day 2 and Session 5: Strategies for Development Labeling

Session Chair
Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

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

Session Description
This session will discuss labeling throughout drug development from a global and local (e.g., US, EU, Japan) perspective. This session will include a discussion on when to start the process, the needed resources for global submissions, effective strategies and how to negotiate with your company to include labeling department in discussions. This session will include examples from different companies and case studies followed by a Q&A.

Moderators
Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

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

Panelists
Vijay Sammeta, Sanofi

Parul Shukla, **RPh**, Associated Director, Global Labeling, Bayer U.S.

Suzanna Leacy, Director, Global Labeling Development, GSK, United Kingdom

9:45-10:15AM

Break, Visit the Virtual Exhibit Hall

10:15-11:45AM

Session 6: Patient Centricity

Session Co-Chairs
Kathy Salazar, MA, MBA, Head, Global Labeling Implementation, Global Labeling COE, Janssen Research & Development/Johnson & Johnson

Rie Matsui, RPh, Senior Director, Regional Labeling Head for APAC, Pfizer, R&D Japan G.K., Japan

Session Description
Pharmaceutical labeling contains important product information that helps enable appropriate prescribing decisions to be made, as well as the safe and effective use of prescribed products. With patients increasingly involved in their own healthcare decisions and outcomes, there is a need to develop patient-focused product information that is both understandable and accessible across a varied group of product end-users. This session will describe insights and approaches to creating patient centric pharmaceutical labeling and supporting development of health literacy across users of patient product information to help ensure engagement and understanding of patients who use our products.

Speakers
Kim Quaintance-Lunn, Vice President, US Regulatory Lead, Regulatory Affairs Americas

Meredith Y. Smith, PhD, MPA, FISPE, Director, Risk Management, Global Patient Safety, Alexion Astra Zeneca Rare Disease

Health Literacy: Educating Patients Beyond the Label Itself, Impact of Labeling Development
Annlouise Assaf, **PhD, MS, FISPE**, Senior Director, Patient Health Activation Expert, Pfizer Inc

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

11:45AM-12:45PM **Break, Visit the Virtual Exhibit Hall**

12:45-1:45PM **Session 7:** Non-Traditional Data – Labeling Versus Promotion

Session Co-Chairs
Su-Yueh Lin, MS, RPh, Vice President of Operation, BRIM Biotechnology, Inc., Taiwan

Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

Session Description
Explore and discuss the use and placement of the non-traditional data (e.g., long term extension study data, open labeling study data, RWE, etc.) in labeling and promotion. Application of the "consistent with the FDA-required labeling" final guidance will be presented. A panel discussion will provide an interactive learning experience using case studies to help drive the conversation and determine the appropriate course of action.

Speakers
Micheline Awad, MBA, Senior Director, Regulatory Affairs – Advertising, Promotions, and Labeling, Turning Point Therapeutics, Inc.

Heather Hammond, MSc, Associate Director, Regulatory, Labeling, Regeneron

1:45-2:15PM **Break, Visit the Virtual Exhibit Hall**

2:15-3:30PM **Session 8:** Combination Products and Medical Device Labeling and Closing Remarks

Session Co-Chairs
Su-Yueh Lin, MS, RPh, Vice President of Operation, BRIM Biotechnology, Inc., Taiwan

Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

Session Description
This session will discuss the current guidance and regulations for combination product labeling in the US and EU. Useful information on combination product and medical device labeling development from conceptualization to agency approval will be provided with perspectives from industry and regulator.

Speakers
Karthik Balasubramanian, **PhD, MS**, Vice President, CMC & Technical Operations, Verrica Pharmaceuticals

Jason Flint, MBA, PMP, Associate Director for Human Factors Reviewer, CDER, OSE, OMERPM, DMEPA, FDA

Gerrit Nijveldt, MSc, Global Consultant Labeling, Opus Regulatory

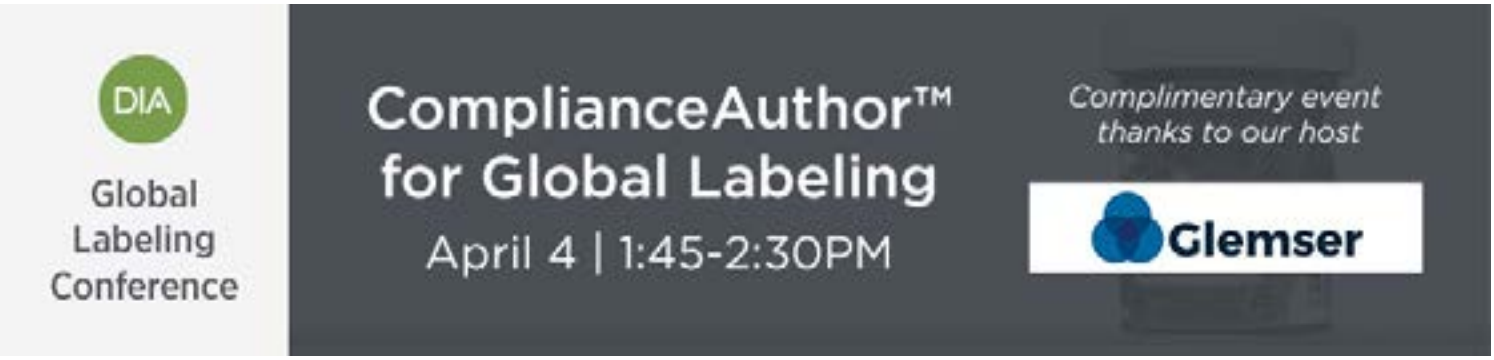
Global Labeling Conference Exhibitor Sponsored Event

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full conference. These sponsored sessions are separate to the conference content included in registration. Upon completion of your RSVP a login link will be sent to you for the session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services.

DAY ONE | MONDAY, APRIL 4

Sessions held in ET

1:45-2:30PM Non-CE/Sponsored Case Study: ComplianceAuthor™ for Global Labeling



Glemser has modernized Global Labeling with ComplianceAuthor™, a system designed to overlay your existing infrastructure and allow for streamlined label capabilities. We leverage advancements in machine learning and artificial intelligence to make structure product labeling easy.

Featured Topics will include:

- ComplianceAuthor™ use case (build once, use many)
- A new generation of problem solving for the industry
- Easy to implement with an overlay strategy where everybody wins (users, IT, regulatory)

All registered attendees for the DIA Global Labeling Conference who attend the case study will receive a $10USD Amazon Gift Card after the conference.

Ray Glemser, PhD, CEO and Executive Consultant, Glemser Technologies

Cathy Herbert, Senior Vice President, Arria Natural Language Generation

Separate RSVP is required. ***Click here to RSVP.***