



2025 Global Labeling & Regulatory Symposium

Developed and presented in partnership with Opus Regulatory

October 7 – 8, 2025

Kimpton Hotel Monaco – Washington, DC

Course Description

This is a one-of-a-kind comprehensive labeling education symposium that explores both fundamental labeling skills and specialized concepts, including current events and new regulatory initiatives. Throughout the two-day program, global experts from big pharma and small pharma will lead several dynamic sessions; faculty for this program also include current and former FDA representatives, academics, and consultant presenters. The program features a blend of interactive presentations, panel discussions, case studies, and collaborative sessions, each meticulously planned to provide the best experience for symposium participants.

Course Day 1: Tuesday, October 7, 2025

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7:30 – 8:30 AM

Check in & Continental Breakfast

8:30 – 8:45 AM

Welcome Remarks

8:45 – 10:10 AM

Regulatory Collaboration

S1

8:50 – 9:10 AM **Presentation:** Regulatory Strategy and Labeling**Jody L Roth, PMP, RAC**Senior Vice President Global Regulatory Affairs
Immunovant9:10 – 9:30 AM **Presentation:** Ad Promo and Labeling**Mark Gaydos**Head of Labeling, Advertising & Promotion
Global Regulatory Science
Moderna9:30 – 9:50 AM **Presentation:** Creating Cross-Function Working Groups and Workstreams**Talia Ben David**

BMS

9:50 – 10:10 AM **Panel Q&A**

Course Day 1: Tuesday, October 7, 2025 *continued*

10:10 – 10:25 AM **Stretch Break**

S2

10:25 – 11:45 AM **Unique Labeling: Session 1**

10:30 – 10:50 AM **Presentation:** Case Study: Using RWE in Pediatric Oncology

Deepali Hattangadi

Senior Manager, Labeling Strategy
Amgen

10:50 – 11:10 AM **Presentation:** Cross-Labeling for the Combination Use of Targeted Therapies in Oncology

Mathieu Jacob

Global Labelling Strategy Director
AstraZeneca

11:10 – 11:30 AM **Presentation:** Case Study: Cell and Gene Therapy

Julie Batal

Vice President, Regulatory Science
bluebird bio

11:30– 11:45 AM **Panel Q&A**

11:45 – 11:55 AM **Stretch Break**

11:55 AM – 1:15 PM **Human Factors/Labeling Integration**

S3

12:00 – 12:20 PM **Presentation:** Industry Human Factors Engineer Presentation

Kellie Taylor

Regeneron

12:20 – 12:40 PM **Presentation:** Case Study: Combination Product with Device

Seema Yadav

Sanofi

12:40 – 1:00 PM **Presentation:** Case Study: Core IFU

Gerrit-Jan Nijveldt

Principal Consultant, Regulatory Labeling
Opus Regulatory

1:00 – 1:15 PM **Panel Q&A**

Course Day 1: Tuesday, October 7, 2025 *continued*

1:15 – 2:30 PM **Networking Luncheon** *sponsored by Basil Systems*

2:30 – 3:50 PM **Unique Labeling: Session 2**

S4

2:35 – 2:55 PM **Presentation:** Case Study: Co-Development/Working with a Business Partner

Melissa Smart

Director, Global Labeling Product & Initiative Leader
Johnson and Johnson

2:55 – 3:15 PM **Presentation:** Patient Reported Outcomes in US Oncology Labels –
Landscape Review

Marina Robin, PharmD

Labelling Strategy Manager
Oncology Global Regulatory Affairs
AstraZeneca

3:15 – 3:35 PM **Presentation:** Radiopharmaceutical Diagnostic Labeling

Courtney Portik, MPH, RAC

Regulatory Affairs Senior Manager, Labeling
GE Healthcare

3:35 – 3:50 PM **Panel Q&A**

3:50 – 4:05 PM **Stretch Break**

4:05 – 5:15 PM **Developing Global Patient Labeling**

S5

4:10 – 4:35 PM **Presentation:** Labeling Strategy: US Fundamentals, Best Practices

Michelle Pearson

Director, Global Labeling
Merck & Co., Inc.

4:35 – 5:00 PM **Presentation:** Labeling Strategy: EU Fundamentals, Best Practices

Heather Hammond

Senior Director, Regulatory Labeling
Regeneron

5:00 – 5:15 PM **Panel Q&A**

Course Day 1: Tuesday, October 7, 2025

5:15 PM **Closing Remarks: Day 1**

6:00 – 7:30 PM ***Evening Networking Reception***
**Optional Paris Ballroom, Hotel Monaco*

“Drinks and Demos” with attendees and invited vendors:

- Basil Systems
- Dr. Evidence

Course Day 2: Wednesday, October 8, 2025

7:30 – 8:30 AM **Check in & Continental Breakfast**

8:30 – 8:35 AM **Welcome Remarks**

8:35 – 9:55 AM **Clinical Studies: Impact to Labeling**

S6

8:40 – 9:00 AM **Presentation:** US Clinical Section 14 – Assessing Endpoints With Your Teams

Vicki Demby, PhD

Senior Vice President, Global Regulatory Affairs and Quality
Third Arc Bio

9:00 – 9:20 AM

Presentation: Building the EU Clinical Section

Elise Lefebvre

Labeling Strategy Director
Daiichi Sankyo

9:20 - 9:40 AM

Presentation: Industry Case Study Across Markets

Jessica Nguyen, PharmD

Director, Strategic Global Labeling
AbbVie

9:40 – 9:55 AM **Panel Q&A**

9:55 – 10:10 AM **Morning Break**

Course Day 2: Wednesday, October 8, 2025 *continued*

10:10 – 11:30 AM	<u>Labeling Procedures</u>	S7
10:15 – 10:35 AM	Presentation: Coordination of Label Development Process Aligned with Module Documents	
	Colleen McGraw Sr. Director, Global Regulatory Labeling Moderna	
10:35 – 10:55 AM	Presentation: Industry Labeling Deviations – Impact to Core	
	Yaroslav Ivanov Sr. Director, Global Labeling Strategy, Marketed Product Development Bristol Myers Squibb	
10:55 – 11:15 AM	Presentation: Case Study: Navigating Product Information Negotiations with Business Partners	
	Ann Jasniewski Director, Regulatory Labeling Cytokinetics	
11:15 – 11:30 AM	Panel Q&A	
11:30 – 11:45 AM	<u>Stretch Break</u>	
11:45 AM – 1:05 PM	<u>Development Labeling</u>	S8
11:50 AM – 12:10 PM	Presentation: TPP to TPL: With the Patient in Mind	
	Princy John Sanofi	
12:10 – 12:30 PM	Presentation: Reality Check – Moving from wish list to data supported (TPL to Draft CCDS)	
	Tina Marks Merck & Co., Inc.	
12:30 – 12:50 PM	Presentation: Adverse Drug Reactions (ADRs) in EU:	
	Elise Lefebvre Daiichi Sankyo	
12:50 – 1:05 PM	Panel Q&A	

Course Day 2: Wednesday, October 8, 2025 *continued*

1:05 – 2:30 PM

Roundtable Luncheon

Gather with colleagues and debate key challenges, issues, or best practices! Tables will be assigned a concept, topic, and/or vendor to foster collaboration and discussion.

2:30 – 3:50 PM

FDA Insight: In-Depth Discussion on US Drug Interactions Guidance

S9

Eric Brodsky, MD

Director, Labeling Policy Team, Office of New Drugs
US Food and Drug Administration

Extended Q&A with FDA

3:50 – 4:00 PM

Program Wrap Up & Conclusion