2024 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 **#**

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
Immunovant

9:10 – 9:30 AM **Presentation:** Ad Promo and Labeling

Mark Gaydos
Moderna

9:30 – 9:50 AM **Presentation:** Global Artwork & Packaging: Exploring the “When” and “How”

Speaker Invited

9:50 – 10:10 AM **Panel Q&A**

10:10 – 10:25 AM ***Stretch Break***

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

S2

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

10:30 – 10:50 AM **Presentation:** Case Study: Rare Disease Therapy

Speaker Invited

10:50 – 11:10 AM **Presentation:** Cross-Labeling for Combination Products: Case Study of Targeted Therapies in Oncology

Speaker Invited

11:10 – 11:30 AM

Presentation: Case Study: Cell and Gene Therapy

Julie Batal
bluebird bio

11:30 AM – 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

Speaker Invited

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

Carine Thions
Argenx

1:00 – 1:15 PM **Panel Q&A**

1:15 – 2:30 PM **Networking Luncheon**

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

S4

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

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

Melissa Smart
Johnson and Johnson

2:55 – 3:15 PM **Presentation:** Biosimilars

Speaker Invited

3:15 – 3:35 PM **Presentation:** Radiopharmaceuticals

Courtney Portik
GE Healthcare

3:35 – 3:50 PM **Panel Q&A**

3:50 – 4:05 PM **Stretch Break**

4:05 – 5:25 PM **Patient Labeling** **S5**

4:10 – 4:30 PM **Presentation:** US Labeling Strategist: Fundamentals, Best Practices

Speaker Confirmed
Merck & Co., Inc.

4:30 – 4:50 PM **Presentation:** Patient Reported Outcomes – Landscape Review

Marina Robin
AstraZeneca

4:50 – 5:10 PM **Presentation:** EU Labeling Strategist: Fundamentals, Best Practices

Heather Hammond
Regeneron

5:25 – 5:30 PM **Closing Remarks: Day 1**

Course Day 1: Tuesday, October 7, 2025

6:00 – 7:30 PM
**Optional*

Evening Networking Reception
Paris Ballroom, Hotel Monaco

"Drinks and Demos" with attendees and invited vendors.

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**

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

Vicki Demby
Adlai Nortye

9:00 – 9:20 AM **Presentation:** Building the EU Clinical Section

Elise Lefebvre
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 **Labeling Procedures** **S7**

10:15 – 10:35 AM **Presentation:** Industry Labeling Deviations – Impact to Core

Speaker Invited

10:35 – 10:55 AM **Presentation:** Case Study: Document Management/Track Changes

Speaker Invited

10:55 – 11:15 AM **Presentation:** Coordination of module doc development and review vs. Label development and review/Timelines, QC Check, Annotations Check/ Management review

Colleen McGraw
Moderna

11:15 – 11:30 AM **Panel Q&A**

11:30 – 11:45 AM **Stretch Break**

11:45 AM – 1:00 PM **Development Labeling** **S8**

11:50 AM – 12:15 PM **Presentation:** Commercial Presenter: TPP – Wish Lists

Speaker Invited

12:15 – 12:45 PM **Presentation:** TPP to TPL // Labeling Presenter: Reality Check – Moving from wish list to data supported (TPL to Draft CCDS)

Speaker Confirmed
Merck & Co., Inc.

12:45 – 1:00 PM **Panel Q&A**

1:00 – 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.

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

S9

2:30 – 3:50 PM **Addressing Challenges Within Safety Labeling Sections**

2:35 – 3:10 PM **Presentation:** DDI: Reviewing New FDA Guidance, Case Study

Speaker Invited

3:10 – 3:35 PM **Presentation:** Adverse Drug Reactions (ADRs) in EU: How do we assign it in safety?

Speaker Invited

3:35 – 3:50 PM **Panel Q&A**

3:50 – 4:00 PM **Program Wrap Up & Conclusion**