2024 Global Labeling & Regulatory Symposium

Developed and presented in partnership with Opus Regulatory

October 8 - 9, 2024
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 8, 2024 **#**

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

8:30 – 8:45 AM **Welcome Remarks**

8:45 – 10:10 AM **Establishing Labeling Governance and Process** **S1**

8:50 – 9:10 AM **Presentation:** Small Pharma – No Labeling Presence

Jody L Roth, PMP, RAC
Senior Vice President Global Regulatory Affairs
Immunovant

9:10 – 9:30 AM **Presentation:** Medium Pharma – Establishing Labeling Model

Christina McGahan
Senior Director, Global Labeling
Otsuka Pharmaceutical Development & Commercialization

9:30 – 9:50 AM **Presentation:** Large Pharma – "Well Oiled Machine"

Kelly Treonze
Executive Director, Global Labeling Therapeutic Areas
Merck & Co., Inc.

9:50 – 10:10 AM **Panel Q&A**

10:10 – 10:25 AM ***Stretch Break***

Course Day 1: Tuesday, October 8, 2024 *continued*

10:25 – 11:45 AM **Patient-Reported Outcomes & Real-World Evidence in Labeling** **S2**

10:30 – 10:50 AM **Presentation:** Case Study: FDA Review of RWE in Breast Cancer Therapy

Catherine Lerro, PhD, MPH
Senior Pharmacoepidemiologist
Oncology Center of Excellence
US Food and Drug Administration

10:50 – 11:10 AM **Presentation:** Academic Perspective: Patient-Reported Outcomes in Labeling

Ari Gnanasakthy, MBA, MSc
Principal Scientist, Patient-Centered Outcome Assessment
RTI Health Solutions

11:10 – 11:30 AM **Presentation:** FDA Perspective/Update on Patient-Reported Outcomes

Vishal Bhatnagar, MD
Associate Director, Patient Outcomes
Oncology Center of Excellence
US Food and Drug Administration

11:30 AM – 11:45 AM **Panel Q&A**

11:45 – 11:55 AM ***Stretch Break***

11:55 AM – 1:15 PM **Labeling Lifecycle Concepts** **S3**

12:00 – 12:20 PM **Presentation:** What is End-to-End Labeling – How Does It Evolve?

Vijay Sammeta, MD, MBA
Head, Global Regulatory Affairs Labeling
Daiichi Sankyo

12:20 – 12:40 PM **Presentation:** Deviation Management and Tracking Tools

Kelly Treonze
Executive Director, Global Labeling Therapeutic Areas
Merck & Co., Inc.

12:40 – 1:00 PM **Presentation:** Preparing for the World of E-Labeling

Sima Desai
Senior Director Global Labeling
Sanofi

1:00 – 1:15 PM **Panel Q&A**

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

Course Day 1: Tuesday, October 8, 2024 *continued*

2:30 – 3:50 PM **The Importance of Development Labeling** **S4**

2:35 – 2:55 PM **Presentation:** Labeling Perspective on TPL – *When should it start, Who is responsible, How is it done (example)*

Vijay Sammeta, MD, MBA
Head, Global Regulatory Affairs Labeling
Daiichi Sankyo

2:55 – 3:15 PM **Presentation:** TPL in Phase II – Impact to Protocol Development and SAP

Heather Hammond, BPharm, MSc
Director, Regulatory Labeling
Regeneron

3:15 – 3:35 PM **Presentation:** Label as Driver Case Study – *The evolution of label messaging. How did we start and where did we land?*

Thomas Kilker
Director, Regulatory Affairs Labeling
Jazz Pharmaceuticals

3:35 – 3:50 PM **Panel Q&A**

3:50 – 4:05 PM **Stretch Break**

4:05 – 5:25 PM **FDA Key Labeling Initiatives** **S5**

4:10 – 4:40 PM **Presentation:** Oncology Center of Excellence (OCE) Updates / Labeling Initiatives (Project Renewal, Oncology Labeling Priorities)

William Pierce, PharmD, MPH, BCPS
Associate Director, Oncology Labeling
Oncology Center of Excellence
US Food and Drug Administration

4:40 – 5:25 PM **FDA Panel Discussion / Q&A**

Doris Auth
Vishal Bhatnagar, MD
Catherine Lerro, PhD, MPH
William Pierce, PharmD, MPH, BCPS
US Food and Drug Administration

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

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

Join us for drinks and hors d'oeurves after a long day of learning! Relax and mingle with participants and faculty, as well as connect with representatives from Docuvera, one of our supporting sponsors.

Course Day 2: Wednesday, October 9, 2024

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

8:30 – 8:40 AM **Welcome Remarks**

8:40 – 10:00 AM **Labeling for Challenging Populations** **S6**

8:45 – 9:05 AM **Presentation:** Pediatrics Case Study - Impact to Labeling

Laurie Cooker, PhD
Director, Strategic Global Labeling
AbbVie

9:05 – 9:25 AM **Presentation:** Rare Disease Case Study

Kathy Bradley
Global Labeling Director
AstraZeneca

9:25 - 9:45 AM **Presentation:** Companion Diagnostics – Global Case Study

Heather Hammond, BPharm, MSc
Director, Regulatory Labeling
Regeneron

9:45 – 10:00 AM **Panel Q&A**

10:00 – 10:20 AM **Morning Break**

10:20 – 11:40 AM **Oncology Safety Labeling** **S7**

10:25 – 10:55 AM **Presentation:** Oncology Overview of FDA Adverse Reaction Guidance for SARs, Dosage Modifications, and Low Incidence Adverse Reactions

William Pierce, PharmD, MPH, BCPS
Associate Director, Oncology Labeling
Oncology Center of Excellence, US Food and Drug Administration

10:55 – 11:25 AM **Presentation:** Local Country Labeling Impact to Company Core Data Sheet

Mark A. Smith
Director, Global Labeling Strategy
Bristol Myers Squibb

11:25 – 11:40 AM **Panel Q&A**

Course Day 2: Wednesday, October 9, 2024 *continued*

11:40 – 11:50 AM **Stretch Break**

11:50 AM – 1:10 PM **Instructions for Use Labeling** **S8**

11:55 AM – 12:25 PM **Presentation:** IFU as Global Labeling Document and Human Factor Testing

Gerrit Nijveldt
Principal Labeling Consultant
Opus Regulatory, Inc.

12:25 – 12:55 PM **Presentation:** Instructions for Use Labeling Case Study

Mike Fahmy
Executive Director
Otsuka Pharmaceutical Development & Commercialization

12:55 – 1:10 PM **Panel Q&A**

1:10 – 2:25 PM **Networking Luncheon**

2:25 – 3:50 PM **Label Negotiations** **S9**

2:30 – 3:00 PM **Presentation:** FDA Perspective: *How are labeling negotiations managed, Advice to sponsor, Roles and responsibilities*

Doris Auth, PharmD
Associate Director for Labeling
Oncology Center of Excellence
US Food and Drug Administration

3:00 – 3:30 PM **Presentation:** Industry perspective: *Preparing and managing label negotiations, best practices, and common considerations*

Jamie Park
Global Labeling Lead
Pfizer

3:30 – 3:50 PM **Panel Q&A**

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