2023 Global Labeling & Regulatory Symposium

Developed and presented in partnership with Opus Regulatory

October 17 – 18, 2023
Kimpton Hotel Monaco – Washington, DC

Course Description

This a one-of-a-kind comprehensive labeling education symposium 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, roundtable discussions, case studies, and collaborative sessions, each meticulously planned to provide the best experience for symposium participants.

Course Day 1: Tuesday, October 17, 2023 **#**

8:30 – 8:45 AM **Welcome Remarks**

8:45 – 10:00 AM **Keynote Presentation:** **S1**
"FDA's Roadmap to Patient-Focused Outcome Measurement in Clinical Trials"

Laurie Burke, MPH
Founder of LORA Group, LLC
Former Dir., FDA's Study Endpoints & Labeling Development Group

Roundtable Discussion:

Vishal Bhatnagar, MD
Associate Director, Patient Outcomes
FDA Oncology Center of Excellence

Julie Batal, MBA, JD
VP, Regulatory Labeling, Advertising & Promotion, Compliance & Operations
bluebird bio

Omar Perez, PhD, RAC
Head of Medical Diagnostics, US Medical Affairs, Oncology
AstraZeneca

Donald Patrick, PhD
Professor Emeritus, Health Systems and Population Health
University of Washington School of Public Health

10:00 – 10:15 AM ***Stretch Break***

Course Day 1: Tuesday, October 17, 2023
continued

10:15 – 11:30 AM **Comparison of Labeling Work for Large vs. Small Pharma** **S2**

Presentation:
"Labeling to Support Large Pharma"

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

Presentation:
"Labeling to Support Small Pharma"

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

11:30 – 11:45 AM ***Stretch Break***

11:45 AM – 1:00 PM **Oncology Labeling Initiatives** **S3**

Presentation:
"Oncology Labeling Philosophy & Initiatives"

William Pierce, PharmD, MPH, BCPS
Associate Director, Oncology Labeling
FDA Oncology Center of Excellence

Presentation:
"Oncology Center of Excellence: Project Orbis"

Shaily Arora, PharmD
Executive Regulatory Science Director, TDR
AstraZeneca

Presentation:
"Oncology Center of Excellence: Companion Diagnostic Labeling"

Reena Philip, PhD
Associate Director, Biomarkers and Precision Oncology
FDA Oncology Center of Excellence

1:00 – 2:15 PM **Networking Luncheon**

Course Day 1: Tuesday, October 17, 2023
continued

2:15 – 3:45 PM **Labeling During a Public Health Emergency** **S4**

Presentation:
"Introduction to US and EU Emergency Use Regulations"

Nina El-Badry, M.S., RAC (US, EU)
Senior Regulatory Advisor, Regulatory and Quality Affairs Division
Biomedical Advanced Research and Development Authority (BARDA)
Department of Health and Human Services (DHHS)

Case Study:
"EUA Labeling: Vaccine Case Study"

Colleen McGraw
Senior Director, Global Regulatory Labeling
Moderna

Presentation:
"EUA Labeling: Treatment Case Study"

Karen Ciprero
Senior Director, Global Labeling
Merck & Co., Inc.

3:45 – 4:00 PM ***Stretch Break***

4:00 – 5:15 PM **Device Labeling: Instructions for Use (IFU)** **S5**

Presentation:
"Development of an IFU: Human Testing Factors"

Kellie Taylor, PharmD, JD
Executive Director, CMC Regulatory Affairs
Regeneron

Presentation:
"IFU as a Labeling Document: Global/Core IFU

Gerrit Nijveldt
Principal Labeling Consultant
Opus Regulatory, Inc.

Case Study:
"Instructions for Use Labeling Case Study"

Mike Fahmy
Executive Director
Otsuka Pharmaceutical Development & Commercialization

5:15 – 5:30 PM **Closing Remarks: Day 1**

6:00 – 7:30 PM ***Evening Networking Reception*** *Hosted by Opus Regulatory*
Paris Ballroom

Course Day 2: Wednesday, October 18, 2023

8:30 – 8:45 AM **Welcome Remarks**

8:45 – 10:00 AM **Development of ADR Sections** **S6**

Virtual Session

Presentation:
"Development of ADR Sections for US/EU/Core Labeling"

Leander Fontaine, MD
Owner
pharmiceutics, LLC

Presentation:
"CIOMS MedDRA Labeling Grouping (MLG)"

Dr. Ilona Große-Michaelis
Senior Medical Dictionary Expert, Bayer AG
CIOMS Working Group Member - MedDRA Labeling Groupings

10:00 – 10:15 AM ***Stretch Break***

10:15 – 11:30 AM **Development of Atypical Efficacy Section Data** **S7**

Presentation:
"Inclusion of Secondary and Exploratory Endpoints in Labeling"

Joe Sison
Labeling Director, Merck & Co., Inc.

Presentation:
"Patient Reported Outcomes in Labeling"

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

11:30 – 11:45 AM ***Stretch Break***

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

Presentation & Case Study:
"Target Labeling (US): Importance of Label as Driver"

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

Presentation & Case Study:
"Role of Labeling Team in CCDS Development"

Vijay Sammeta, MD, MBA
Senior Director Global Labeling Strategy, Sanofi

Course Day 2: Wednesday, October 18, 2023
continued

1:00 – 2:15 PM **Networking Luncheon**

2:15 – 3:45 PM **Labeling Compliance** **S9**

Presentation:
"Labeling Compliance: Overview, Operations, and Tracking"

Mary Beth Wilusz
Head, Regulatory Labeling Operations and Compliance
Daiichi Sankyo, Inc.

Presentation:
"How to Prepare for an Audit/Inspection from Labeling Perspective"

Julie Batal, MBA, JD
VP, Regulatory Labeling, Advertising & Promotion, Compliance & Operations
bluebird bio

3:45 – 4:00 PM **Program Conclusion**