



# 2024 Global Labeling & Regulatory Symposium

## Pre-Symposium Workshops

*Developed and presented in partnership with Opus Regulatory*

October 7, 2024      Kimpton Hotel Monaco Washington, DC

8:30 – 8:35 AM      **Welcome Remarks, Workshop Goals**

8:35 – 10:30 AM      **Adverse Reactions**

**Mark Collins**

Principal Consultant, Regulatory Affairs Labeling, Opus Regulatory

Key Discussion Topics:

- What is an adverse *event* and what is an adverse *reaction*?
- Breaking down the regulatory definitions (US/EU) of an adverse reaction
- Adding an adverse reaction to labeling
- CIOMS and safety labeling thresholds
- Breaking down (some of) the important available guidances (US/EU) related to adverse reactions
- Deciding what is an adverse reaction and challenges to that process

10:30 – 10:45 AM      ***Morning Break***

10:45 – 12:00 PM      **Establishing Key Labeling Governance**

**Julie Retzinger**

Principal Consultant, Regulatory Labeling, Opus Regulatory

Key Discussion Topics:

- CCDS Governance
- Labeling Governances
- The role of Pharmacovigilance
- The role of Quality – QMS
- Deviation Management
- Define end-to-end labeling
- Implementation into the market

12:00 – 1:00 PM      ***Lunch Break***

1:00 – 2:55 PM

**Synergy between CCDS/CCSI and Local Labeling**

**Gerrit-Jan Nijveldt**

Principal Consultant, Regulatory Affairs Labeling, Opus Regulatory

Key Discussion Topics:

- Mandatory information (CCSI) within a CCDS
- How to update a CCDS based on HA question
- Class Labeling in CCDS
- Implementation of CCDS in countries, what must be added (CCSI)
- How to deal with difference between CCDS and Local labeling
- What to track from CCDS

2:55 – 3:15 PM

***Stretch Break***

3:15 – 4:50 PM

**Pulling It All Together: Interactive Case Studies**

**Brandon Stempo - Facilitator**

Principal Consultant, Regulatory Affairs Labeling, Opus Regulatory

This section will include interactive case studies that allow workshop attendees to participate in a discussion on how to manage a challenging real-life scenario. The case study will encompass the content presented throughout the day.

4:50 – 5:00 PM

**Workshop Conclusion, Final Q&A**