



# 2023 Global Labeling & Regulatory Symposium

## Pre-Symposium Workshops

*Developed and presented in partnership with Opus Regulatory*

October 16 – 2023      Kimpton Hotel Monaco Washington, DC

*Morning Workshop Session: 8:30 am – 12:00 pm EDT*

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8:30 – 8:35 AM

### **Welcome Remarks, Workshop Goals**

8:35 – 10:15 AM

### **CCDS: The Most Critical Labeling Document**

**Gerrit-Jan Nijveldt**

Global Labeling Consultant

Opus Regulatory

#### *Key Presentation Topics:*

- Labeling and company position
- History of CCDS from CIOMS to EU PV modules
  - Use of CCDS then and now
  - How has the CCDS process evolved over time due to changed regulatory environment
- Structure and content of CCDS- think globally
  - Differences globally in ADR sections and solutions how to capture in the CCDS
  - Helpful tips for data presentation (rounding, frequency buckets, MedDRA, etc.)
- CCDS in development process
  - Role of CCDS: First to develop and approved or not (pro and con)
  - Different stages of CCDS in development
- End-to-End Labeling and impact on rules for implementation and timing of Safety Updates

10:15 – 10:30 AM

### ***Morning Break***

Morning Workshop Session: 8:30 am – 12:00 pm EDT

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10:30 – 11:15 AM

**ROW Deviations**

**Brandon Stempo**

Principal Consultant, Regulatory Affairs Labeling  
Opus Regulatory

*Key Presentation Topics:*

- Reference country label
- Assessment against the CCDS/Core position discussions
- Rounds of pushback, accepting as locally mandated HA request
- Supporting the team on HA responses
- Tracking/History of local country deviations

11:15 – 11:55 AM

**Label Meeting Preparation for Running the Best Label Working Group Meetings**

**Paul Neihouse**

Principal Consultant, Regulatory Labeling  
Opus Regulatory

*Key Presentation Topics:*

- Provide a strategic focus for Label Working Group meetings (including labeling text and topics for discussion)
- How to create a meeting environment that is collaborative, respectful, and inclusive – where everyone feels that their opinions are valued.

11:55 AM –  
12:00 PM

**Workshop Conclusion, Final Q&A**