2023 Global Labeling & Regulatory Symposium

Pre-Symposium Workshops

Developed and presented in partnership with Opus Regulatory

October 16 – 2023 Kimpton Hotel Monaco Washington, DC

Afternoon Workshop Session: 1:30 pm – 5:00 pm EDT

1:30 – 1:35 PM **Welcome Remarks, Workshop Goals**

1:35 – 2:30 PM **Target Product Profile (or Development Labeling US/EU)**
Kalpana Venkataraman
Principal Consultant
Opus Regulatory

Key Presentation Topics:

- Product visions with end in mind
- Reflects value propositions from diverse cross functional areas
- Incorporates both efficacy and safety considerations.
- Drives clinical and statistics to design and power the clinical trials.
- Potential local exceptions as driven by local regulations.
- Includes ideal and fallback positions

2:30 – 2:40 PM ***Stretch Break***

2:40 – 3:50 PM **US Labeling**
Paul Neihouse
Principal Consultant, Regulatory Labeling
Opus Regulatory

Key Presentation Topics:

- Submission Types
  - Prior Approval Supplements (PAS) vs. Changes Being Effected (CBE) Supplements
- Timeline development
  - Issues for Consideration
- Order of Labeling Section Development
  - Data Availability and Desire for Prototypes

- Responsibility for Labeling Section Content and Labeling Annotations
    - Functional Subject Matter Experts
    - eCTD Sections and/or Specific Final Reports
- Labeling Negotiations
    - Issues for Consideration
    - Accept health authority position vs. Support company position
- Print at Risk Labeling Artwork
    - Issues for Consideration

3:50 – 4:00 PM ***Stretch Break***

4:00 – 4:55 PM **EU Labeling**

Gerrit-Jan Nijveldt
Global Labeling Consultant
Opus Regulatory

Key Presentation Topics:

- Short introduction of content of SmPC (QRD Template)
    - *Comparison with USPI*
- Readability testing - when and how
- Translation process
- Electronic SmPC - SPL like system (HL7)

4:55 – 5:00 PM **Workshop Conclusion, Final Q&A**