



2025 Global Labeling & Regulatory Symposium

Pre-Symposium Workshop

Developed and presented in partnership with Opus Regulatory

October 6, 2025 Kimpton Hotel Monaco Washington, DC

9:00 – 9:05 AM

Welcome Remarks, Workshop Goals

9:05 – 11:00 AM

Target Product Profile (TPP) to Target Product Label (TPL) as the Driver for Successful Development

Mary DeWaters

- Definition of the TPP
- Purpose, requirements, and value of the TPP
- Differences between the TPP and TPL
- Timelines to begin TPP/TPL to optimize Drug/Biologics Development
- Regulatory/Labeling intelligence to compose the TPL
- TPL format and content with a TPL case study

11:00 – 11:15 AM

Stretch Break

11:15 AM -
12:30 PM

Core Data Sheet / USPI / SmPC (Perspective after TPL)

Gerrit-Jan Nijveldt

Principal Consultant, Regulatory Labeling
Opus Regulatory

- Transition from TPL to CCDS - things to keep in mind
- Issues in this process:
 - Adverse reaction section in CCDS vs US and EU
 - Getting the right supporting documents
 - Class labeling how to deal with it in CCDS
 - Pooling of data for efficacy and safety

12:30 – 1:30 PM

Lunch Break

1:30 – 2:30 PM

Core Data Sheet / USPI / SmPC (continued)

Gerrit-Jan Nijveldt

Principal Consultant, Regulatory Labeling
Opus Regulatory

- Case study exercise

2:30 – 2:45 PM

Stretch Break

2:45 – 4:20 PM

Global Launch Activities (US/EU)

Lana Syatkin

Principal Consultant, Regulatory Affairs Labeling
Opus Regulatory

- Overview of EU regulations (EMA)
 - HA reviewers (i.e. Rapporteurs, PRAC, CHMP)
 - Translation activities and handoff to Member States
- Overview of US regulations (FDA)
 - HA reviewers (i.e. CDER, CBER)
 - Posting to DailyMed
- Artwork activities
- Case study exercise

4:20 – 4:30 PM

Workshop Conclusion, Final Q&A