Product Benefit-Risk Through Global Labeling Governance & Compliance - 2017

October 5 – 6, 2017 • Arlington, VA

Thursday, October 5, 2017

7:30 – 8:15 AM — ***Registration and Continental Breakfast***

8:15 – 8:30 AM — **PERI Welcome and Course Overview**
Lauren Kirk, Course Manager
The Pharmaceutical Education and Research Institute, Inc.

8:30 – 10:00 AM — **Session 1**

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Presentation — ***Global Labeling Systems: General Architecture and Common Challenges***
Dr. med Leander Fontaine - Pharmiceutics, LLC

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- Establishing a common view at the end-to-end process and terminology for the purposes of this conference
- Key areas for discussion highlighted

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Presentation — ***The Impact of the EU GVP Guidelines on Safety Labeling Governance***
Barbara Lachmann, MD – Barbara Lachmann Labeling Consulting

- Regulatory Requirements
- EU GVP Guidelines – PV Systems, PSMF, Inspections, Audits, Signal Management
- Process Documentation

Presentation — ***Global Safety Labeling: Expectations from a PV Point of View***
JP Clement, MD – JP Clement Consulting, LLC

- How PV expectations shape CCDS content
- Labeling performance expectations from a global and regional PV viewpoint
- Essential deliverables to PV

10:00 – 10:30 AM — ***Morning Break***

10:30 AM – 12:00 PM — **Session 2**

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Presentation
Group Discussion
Faculty Panel — ***Aligning Pharmacovigilance and Labeling Processes/Committees***
Debra McNaughton – Pfizer, Inc.
Boris Jankowski – Johnson & Johnson
JP Clement, MD – JP Clement Consulting, LLC
Julie Retzinger – Astellas
Elizabeth Moyle – BioMarin

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- Combining or separating decision-making/governance structures
- Coordinating decision-making to increase efficiency
- Aligning safety labeling with other PV action workstreams
- What are “safety-labeling changes”?

Presentation

Best Practices to Achieve Safety Labeling Consistency
Dr. med Leander Fontaine - Pharmiceutics, LLC
Barbara Lachmann, MD – Barbara Lachmann Labeling Consulting
Elizabeth Moyle – BioMarin

- Consistency targets (what is "similar enough")?
- Root causes of inconsistences (at HQ and affiliate level)
- How to make consistent implementation outcomes easier to achieve?

12:00 – 1:15 PM ***Lunch Break***

1:15 – 2:45 PM **Session 3**

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Presentation
Group Discussion
Faculty Panel

Process Reliability and Efficiency at the Headquarters Level
Boris Jankowski – Johnson & Johnson
Jan Myers – Celgene
Debra McNaughton – Pfizer

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- What are the most consequential risks of an unreliable process?
- Typical root causes of failure
- Tips for improving process reliability and efficiency
- What to do if there is no dedicated labeling group?

Presentation

Tracking and Documentation from Initial Trigger to Dispatch of Updated Core Labeling
Dr. med Leander Fontaine - Pharmiceutics, LLC
Julie Retzinger – Astellas
Debra McNaughton - Pfizer

- The consequences of upstream tracking failures
- The challenges of "upstream tracking"
- How to make/keep things trackable?
- The very minimum: a low-tech solution

2:45 – 3:00 PM ***Afternoon Break***

3:00 – 4:00 PM **Session 4**

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Presentation

The Complexities of Implementation Tracking - Overview
Boris Jankowski – Johnson & Johnson
Paula Hudson – Eli Lilly & Company

- Factors that determine tracking complexity
- Tracking data vs implementation world-map vs deviation-management records
- How deep to track? By whom?
- Prerequisites for efficient tracking
- The need for auditing

4:00 – 5:00 PM ***Open Exhibitor Time***

Friday, October 6, 2017

7:30 – 8:15 AM — ***Continental Breakfast***

8:15 – 10:00 AM — **Session 5**

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Presentation

Deviation Management
Jan Myers – Celgene
Dr. med Leander Fontaine - Pharmiceutics, LLC

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- Deviation decisions – major source of workload – need for efficiency
- Formal- vs. informal decision-making
- Typical business rules for deviation management
- When to give in?
- How to document what we did?

Presentation
Group Discussion
Faculty Panel

How To Do Implementation Tracking?
Boris Jankowski – Johnson & Johnson
Paula Hudson – Eli Lilly & Company

- Granularity of tracking
- What to track for demonstration of system performance?
- What to track for "diagnostic" purposes?
- How to process, present and evaluate tracking results?
- Acting on tracking findings
- When to audit and what to audit?

10:00 – 10:30 AM — ***Morning Break***

10:30 AM – 12:00 PM — **Session 6**

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Presentation

Covering the Entire Portfolio of Product Types
Boris Jankowski – Johnson & Johnson
Dr. med Leander Fontaine - Pharmiceutics, LLC

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- Scope of the overall labeling governance system
- Which types of products or regulatory constellations require special features?
- What to do with local-only products
- Assigning responsibilities and auditing

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Presentation

Approaches to Govern Patient labeling and IFU Documents
Terry Brunone – GlaxoSmithKline
Paula Hudson – Eli Lilly & Company

- The challenges of patient labeling governance
- What to do if a product does not have HCP labeling in some markets?
- Patient labeling governance approaches
- Approaches to governing Instructions for Use (IFU)
- The challenges of IFU governance

Presentation

Improving CCDS, CCSI, and Supporting Documentation
Dr. med Leander Fontaine - Pharmiceutics, LLC
Barbara Lachmann, MD – Barbara Lachmann Labeling Consulting

- What to do in CCDS/CCSI to help with governance?
- How to design supporting rationales/documentation to maximize implementability of labeling changes

12:00 – 1:00 PM **_Lunch Break_**

1:00 – 3:00 PM **Session 7**

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Interactive Group Workshop

End-to-End Simulation for Global Labeling Updates
Entire Course Faculty

- Typical tasks under an end-to-end global labeling process,
- Demonstration of different scenarios
- Demonstration of potential tracking challenges

3:00 PM **_Adjournment_**