

Safety Labeling: In-Depth Review of Important Aspects

In-depth Seminar - Instructor: A.L. Fontaine, M.D.
February 24-25, 2010 - Radisson Plaza-Warwick, Philadelphia

For Labeling/Regulatory, Pharmacovigilance, Clinical and Medical Professionals

It is recommended - but not required - to first attend our seminars "Company Core Data Sheets and Core Safety Information" or "US Prescribing Information with Highlights & US Safety Labeling," which present the most important information from a global, EU and US labeling perspective, respectively. However, our seminar "Safety Labeling – In-Depth Review of Important Aspects" is nonetheless useful without being combined with one of our other seminars.

The number of participants in this seminar will be limited.

Seminar Program

Refreshment breaks not shown

Day 1

7:30 Registration and Breakfast

8:00 Instructor's welcome, introduction of participants

8:30 Brief Recap of Important Definitions and Rules for Safety Labeling Decision Making

- Definition of "adverse reaction for the purposes of labeling"; Review of definitions used in the field of pharmacovigilance
- Definition of "clinically relevant/significant interaction"
- Threshold criteria for including adverse reactions in labeling – CIOMS guidelines, US, EU and other labeling regulations and guidelines
- How the relevance (seriousness etc.) of potential adverse reactions influences when they are added
- Definition: "Precaution", "Warning", "Contraindication"
- When to elevate risks to "Warnings and Precautions"
- When to contraindicate
- When and how to provide advice to consider avoidance
- Principles of describing the probability (frequency) of adverse reactions
- Important market-to-market differences in the application of basic labeling principles
- The effect of subjectivity on decision making

11:30 From Clinical Study Adverse Events to the Presentation of Risks in Labeling

- Understanding the main differences between decisions to add adverse reactions based on clinical study data and on spontaneous postmarketing reports
- Are clinical study adverse reactions of "superior quality"?
- Background noise and the role of individual-case causality assessment by investigators
- The effect of term-grouping and definitions
- Which data to consider when deciding if an observed event is an adverse reaction for the purposes of labeling
- Brief review of FDA's "Safety Reviewer Guidance"
- How to decide if an observed difference in rate between drug and comparator is "real"

12:15 Lunch break

1:00 From Clinical Trial Adverse Events to the Presentation of Risks in Labeling (continued)

- **Group exercise and discussion of results: From lists of events to reactions in labeling**

3:45 Allergic Reactions, Other Hypersensitivity Reactions, and Infusion Reactions – Addressing Immunogenicity

- Definition of "hypersensitivity", "hypersensitivity reactions", "allergic reactions", "anaphylactic reactions", "anaphylactoid reactions" and related terms.
- How to deal with the differences in the understanding of some terms by healthcare professionals • Review of related terms in MedDRA
- Various types of infusion reactions. How to describe them and provide meaningful advice
- Mechanisms and categorization of allergic and immune reactions
- Factors determining the immunogenicity of medicines
- How to describe immunogenicity in labeling in a way that reflects the level of concern

5:15 End of Day One

Day 2

7:30 Breakfast

3:15 Controlling Terminology in Labeling – Dealing with MedDRA's Granularity, Hierarchy and Axiality

- Review of MedDRA from a labeling perspective
- Review of key points of the MSSO's "MedDRA and Product Labeling: Best Practices' Recommendations"
- Principles of good term grouping – To which extent can we use MedDRA's "built-in" group terms
- Understanding MedDRAs axiality - allocating an adverse reaction to an appropriate SOC
- Risk communication issues associated with changeover of labeled terms from other terminologies to MedDRA
- **Group exercise and discussion of results: Rational term grouping**
- **Group exercise and discussion of results: Selecting the best SOC**

10:30 Dealing with Event Cascades – Addressing the Potential Severity of Adverse Reactions

- The difference between expectedness, labeledness, listedness and communicatedness
- Understanding regulatory event reporting rules and how they do/don't affect labeling
- When to add to labeling information about more serious or more specific outcomes
- The need to "diagnose" the adverse phenomena associated with the use of a product
- When facing a cascade of events/reactions and associated symptoms – How to decide what is the adverse reaction for the ADR table, and what to describe elsewhere or not at all
- **Group exercise and discussion of results: When and how to inform about the potential severity of adverse reactions.**

12:15 Lunch break

1:00 Selecting Adverse Reaction Frequency Categories for EU Labeling – Use of rates in US labeling

- Understanding terminology used in labeling guidelines:

Rate, frequency, probability, incidence, crude incidence rate etc.

- Understanding the "Rule of Three"
- Dealing with "background noise"
- For US labeling, how to decide where to cut off the table of common adverse reactions
- In the US and EU, are the "most common adverse reactions" really the most common adverse reactions?
- How to correctly describe the data in a US Common Adverse Reactions table
- **Group exercise and discussion of results: Exploring the limitations of the Rule of Three**
- **Group exercise and discussion of results: How to decide, for US labeling, where to cut off the table of common adverse reactions**
- **Group exercise and discussion of results: Creating a complete set of US and EU Adverse Reactions tables/lists for clinical study and postmarketing adverse reactions**

4:00 End of Seminar

Venue Information: February 24-25, 2010. Radisson Plaza-Warwick Hotel, 1701 Locust Street , Philadelphia PA 19103-United States. Phone: +1 (888) 201-1718 or +1 (215) 735-6000. For hotel room reservations, please contact the hotel directly.

Registration: By phone: Call +1(610)269.3933 By fax: Fax registration form to +1(484) 698 7706 By mail: Mail the registration form (with check, if applicable) to Pharmiceutics LLC, 109 Holly Drive, Downingtown, PA 19335, USA.

Registration Form

Please register me for the "Safety Labeling – In-Depth Review of Important Aspects and Topics" Seminar, **February 24-25, 2010** Radisson Plaza-Warwick Hotel, PA, USA - **Fee: US\$ 2,195.-** The fee includes workshop material, 2 continental breakfasts, break refreshments, 2 luncheons. The fee does not include dinner, accommodation and transportation.

The seminar is open to pharmaceutical company employees only; admission of other interested persons only on invitation by Pharmiceutics LLC.

Registration Information: £ Ms. £ Mr. £ Dr.

Name: _____

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Full payment must accompany the registration form. Registrations accompanied by a personal check must be received 2 weeks before the event. Confirmation is sent via regular mail. **Cancellations:** Cancellations made by participants within 14 days of a workshop will be subject to a 50 % cancellation fee. If the workshop is not held for any reason, Pharmiceutics LLC's liability is limited to the refund of the workshop fee.



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