



## **Training Course Program**

### **Best Practices for OINDP Pharmaceutical Development Programs Leachables and Extractables**

**26-27 September 2007  
Basel, Switzerland**

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#### **Day 1, 26 September 2007**

~~~~~**Light Breakfast (8:30 am)**~~~~~

#### **I. Introduction and Overview (9:00-9:30)**

*Presenter: Dan Norwood*

Introduction of Training Course Faculty

What are leachables and extractables?

Significance of leachables and extractables to OINDP pharmaceutical development programs

Overview of pharmaceutical development process

Quality by Design concepts

Overview of training course

Feedback from trainees regarding course outline and content

#### **II. OINDP Container Closure Systems (9:30-10:45)**

*Presenters: Michael Ruberto and Doug Ball*

Container closure systems components and their selection - QbD

Container closure system suppliers

Evaluation of information available from suppliers

Early safety assessment of potential leachables – case studies and interaction of analytical chemists and toxicologists

~~~~~**Break and Open Discussion (10:45-11:15)**~~~~~

### III. Analysis of Leachables and Extractables (11:15-12:30)

*Presenter: Dan Norwood*

Principles of Trace Organic Analysis

Analytical techniques for identification of extractables and leachables

What does it mean to “identify” an extractable or leachable?

Identification criteria for extractables and leachables

Quantitation of extractables and leachables

~~~~~**Lunch (12:30-1:15)**~~~~~

### IV. Characterization of Extractables (1:15 – 2:45)

*Presenter: Diane Paskiet*

The Controlled Extraction Study

Application of the AET for extractables

Evaluation of Controlled Extraction Study results

~~~~~**Break (2:45 – 3:00)**~~~~~

### V. Special Case Compound Classes (3:00-4:00)

*Presenter: Jamie Mullis*

Nitrosamines – origins, analysis and control

Polynuclear Aromatic Hydrocarbons (PAHs or PNAs) – origins, analysis and control

2-Mercaptobenzothiazole – origins, analysis and control

**End Day 1**

**Day 2, 27 September 2007**

~~~~~Light Breakfast (8:30 am)~~~~~

**VI. Characterization of Leachables (9:00–10:30)**

*Presenter: Tom Feinberg*

- Analytical method development for leachables
- Validation of analytical methods for leachables
- Application of the AET for leachables
- Leachables testing on formal stability programs
- Correlation of leachables and extractables

~~~~~Break (10:30-10:45)~~~~~

**VII. Safety Evaluation of Extractables and Leachables (10:45-12:00)**

*Presenter: Doug Ball*

- Overview
- Safety Thresholds for Leachables
- Extension of Safety Thresholds to Extractables
- The Analytical Evaluation Threshold

~~~~~Lunch (12:00-12:45)~~~~~

**VIII. Quality Control and Specification Setting (12:45-2:15)**

*Presenter: Terry Tougas*

- Control of leachables through control of extractables
- Analytical methods for routine quality control of extractables
- Validation of analytical methods for routine quality control of extractables
- Establishing extractables specifications and acceptance criteria (process capability analysis, statistical approaches)
- Establishing leachables specifications and acceptance criteria (process capability analysis, statistical approaches)

**IX. Regulatory Requirements for Leachables and Extractables – A European Perspective (2:15-3:15)**

*Presenter: Stefan Leiner*

**End of Training Course**