



Training Course Program

Best Practices for OINDP Pharmaceutical Development Programs Leachables and Extractables

April 12-13, 2007
Chicago, IL

Day 1, 12 April 2007

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

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

*Presenters: Dan Norwood*

Introduction of Training Course Faculty

What are leachables and extractables?

Significance of leachables and extractables to OINDP pharmaceutical development programs, i.e., do you want an approval or not?

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 (9:30-10:30)

*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 (10:30-11:00)~~~~~

III. Safety Evaluation of Extractables and Leachables (11:00-12:30)

Presenters: Doug Ball and Tom Feinberg

Overview

Safety Thresholds for Leachables

Extension of Safety Thresholds to Extractables

The Analytical Evaluation Threshold

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

### IV. Analysis of Leachables and Extractables (1:15-2:15)

*Presenters: 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

### V. Characterization of Extractables (2:15-4:30)

*Presenters: Diane Paskiet*

The Controlled Extraction Study

Application of the AET for extractables

Evaluation of Controlled Extraction Study results

**End Day 1 (5:00 pm)**

**Day 2, 13 April 2007**

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

VI. Characterization of Leachables (8:30-10:00)

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

VII. Special Case Compound Classes (10:00-10:45)

Presenter: James Mullis

- Nitrosamines – origins, analysis and control
- Polynuclear Aromatic Hydrocarbons (PAHs or PNAs) – origins, analysis and control
- 2-Mercaptobenzothiazole – origins, analysis and control

~~~~~Break (10:45-11:00)~~~~~

**VIII. Quality Control and Specification Setting (11:00-12:30)**

*Presenters: 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)

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

IX. Panel Discussion/Q&A - QbD (1:15-3:00)

All Faculty and Attendees

X. Conclusions and Brief Wrap-up (3:00)

End of Training Course