Training Course Program

Best Practices for OINDP Pharmaceutical Development Programs
Leachables and Extractables

26-27 September 2007
Basel, Switzerland

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