



Global BioPharmaceutical Resources, Inc.

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Best Practices for the Management of Extractables and Leachables

Course Leader: E.J. Smith, Ph.D., Packaging Science Resources, LLC

Thursday, February 9, 2012

7:30am-8:30am **Continental Breakfast & Registration**

- 8:30am-10:30am
- 1. Purpose of E&L Studies**
 - 2. E&L Regulations**
 - 3. Identification of Materials that Require E&L Studies**

Description: Introduction to the Management of Extractables & Leachables

10:30am-11:00am **Refreshment Break**

- 11:00am-12:30pm
- 1. Identification of Potential Leachables from Rubber, Glass, and Plastic Components**
 - 2. Compendial & Standards Tests**

Description: Extractables from typical packaging components & materials and required compendial testing will be discussed.

12:30pm-1:30pm **Lunch Break**

- 1:30pm-3:00pm
- 1. Types of Extractables Studies**
 - 2. The Design & Execution of Extractables Studies**

Description: The purpose and types of extractables studies and the design of a study based on current best practices will be presented.

3:00pm-3:30pm **Refreshment Break**

- 3:30pm-5:00pm
- 1. The Leachables Study**
 - 2. Review of E&L Process**

Description: The analysis of drug typical products for leachables and a leachables study protocol will be reviewed as part of the complete E&L process.

5:00pm-5:30pm **Discussion including Q&A**