Connecting People, Science and Regulation

AGENDA

PDA WORKSHOP
EXTRACTABLES – LEACHABLES

Brussels
13-14 March, 2014

Dr. Piet Christiaens

DAY 1: Morning Session

- **Regulatory Aspects of E/L**
- **Polymers 101 – Glass 101**
- **The Mechanism of Polymer Leaching**
- **Analytical Approach for E/L testing**

DAY 1: Afternoon Session

- **Analytical Approach in E/L testing (continued, when necessary)**

- **Closing the GAP between extractables & Leachables**

- **Presentation Ingrid Markovic:**

  "Regulatory Perspective on Extractables & Leachables in Biologics: Quality Considerations"

DAY 2: Morning Session

- **Setting-up Extractable & Leachable Studies**
- **E/L studies for Parenterals**
- **E/L studies for Single-Use systems**

DAY 2: Afternoon Session

- **E/L studies for Large Volume Parenterals**
- **E/L studies for Blow-Fill-Seal Applications**
- **E/L Studies for Lyophilized Drug Products**