



Agenda

PDA TRAINING COURSE EXTRACTABLES – LEACHABLES

*Venice
21 – 22 March 2019*

Dr. Piet Christiaens

Dr. Dennis Jenke

Ir. John Iannone



DAY 1: Morning Session

- **Introduction & Regulatory Aspects of E/L**
- **Polymers 101 – Glass 101**
- **The Mechanism of Polymer Leaching**



DAY 1: Afternoon Session

- **PQRI PDP/ODP Chemistry Workgroup**
- **ISO 10993 Part 18 - Chemical Characterization for medical devices**
- **Toxicology 101**
- **The Analytical Approaches, used in E/L Research**



DAY 2: Morning Session

- **Setting-up Extractable & Leachable Studies**
- **Errors In Screening & How to address them**
- **USP UPDATE**
- **E/L For Biodisposable and Single Use systems**



DAY 2: Afternoon Session

- **Small Volume Parenterals: E&L Considerations**
- **Large Volume Parenterals & Simulation Study Set-up**
- **Closing Gap between Extractables & Leachables**