



Agenda

PDA TRAINING COURSE EXTRACTABLES – LEACHABLES

*Rome
01-02 March, 2018*

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

- **Final Recommendations of the PQRI PDP/ODP Chemistry Workgroup**
- **ISO 10993-18 UPDATE: Material Characterization for Medical Devices**
- **USP <381> UPDATE: Elastomeric Closures - UPDATE**
- **Biodisposable & Single Use Systems**
- **USP <665> UPDATE: Plastic Components Pharmaceutical Manufacturing**
- **Toxicology 101**



DAY 2: Morning Session

- **Setting-up Extractable & Leachable Studies**
- **Understanding different Physico-Chemical Parameters in optimizing a Simulation Study Set-up**
- **Analytical Approach in E/L studies**



DAY 2: Afternoon Session

- **Small Volume Parenterals: E&L Considerations**
- **Large Volume Parenterals: E&L Considerations**
- **Closing Gap between Extractables & Leachables**
 - **Reactive Leachables**
 - **(if timing does not allow, it will be presented as a free webinar)**