



## Agenda

# *PDA TRAINING COURSE EXTRACTABLES – LEACHABLES*

*Basel  
27 – 28 February 2020*

*Dr. Piet Christiaens*

*Dr. Dennis Jenke*

*Ir. John Iannone*



# DAY 1: Morning Session

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



# DAY 1: Afternoon Session

- **PQRI PDP/ODP Chemistry Workgroup – UPDATE**
- **USP Update**
- **The Analytical Approaches, used in E/L Research**
- **The Errors one can make in Chromatographic Screening**



# DAY 2: Morning Session

- **Setting-up Extractable Studies**
- **Bridging Extractables => Leachables**
- **Setting-up Leachable Studies**
- **Toxicology 101**



# DAY 2: Afternoon Session

- **Single Use Systems in Biomanufacturing**
- **Small Volume Parenterals: E&L Considerations**
- **Large Volume Parenterals & Simulation Study Set-up**