



## Fiber-Optic Advanced Training Course

**When:** May 14–15, 2019

**Where:** NEW Training Facility @ Pion,  
10 Cook Street, Billerica, MA 01821

**Contact:** [sales@pion-inc.com](mailto:sales@pion-inc.com) for registration and logistics

**Note:** Please bring your own laptop for the training course. We will install the AuPRO software version 5.5 for the group discussion.

### Tuesday, May 14<sup>th</sup>

- 8:30 – 9:00** Attendee Arrival and Breakfast
- 9:00 – 9:15** Introduction to Pion and personnel
- 9:15 – 10:15** **Method Development Part 1: Getting started with the technology and basic considerations (Shawn Burgess)**
- Introduction to Pion Fiber Optic instruments
  - Principles and challenges of *in situ* concentration measurements
  - Pathlength selections
  - Generating good standard curve, “Blue Standards”
  - Baseline correction algorithms
  - 2<sup>nd</sup> derivative spectroscopy
  - Calculation settings
  - Sample Blank
- 10:15– 10:30** **Break**
- 10:30 – 11:00** **User Case Study #1 (Amanda Pluntze, Lonza Pharma and Biotech):**  
Pushing the Limits: Detection at <math><1\mu\text{g/mL}</math>
- 11:00 – 11:30** **Method Development Part 2: Advanced considerations (Oksana Tsinman)**
- Spectral shape analysis
  - Blank and Reference Channel
  - Can standard curve be prepared in different media
  - Supersaturation considerations
  - Media conversion experiments
- 11:30 – 12:15** **Interactive Group Discussion #1: Fiber Optic Method Development**  
Recognizing issues, understanding and troubleshooting the data
- 12:15 – 1:15** **Lunch (provided)**
- 1:15 – 2:00** **Towards in vivo predictive dissolution – Flux Measurements (Konstantin)**



- Tsinman)**
- Understanding the principles and driving forces of the flux
  - Flux configurations
  - Calculation and interpretation of flux data
  - In vivo predictions using flux data
- 2:00 – 2:45**     **Flux Measurements: Analytical work behind the scene (Oksana Tsinman)**
- Detecting artifacts
  - Membrane-exciipient compatibility
  - Ensuring membrane integrity
  - Dual component flux
  - Potential limitation of the flux measurement
- 2:45 – 3:00**     **Break**
- 3:00 – 3:45**     **Group Discussion #2: Practical aspects of flux measurements**
- Recognizing issues, understanding and troubleshooting the flux experiments and media change experiments
- 3:45 – 4:15**     **User Case Study #2 (Brent Hilker, CoreRx):**
- Targeted Drug Delivery Through A Submerged Mucosal Membrane
  - Low Volume USP Protein Dissolution
  - Nano Particle Targeted Drug Delivery.
  - Improving Franz Cell Development/Analysis for Topical Cream
- 4:15 – 4:45**     **Introduction of AuPRO Version 6: Recent Advances in Pion Technology (Konstantin Tsinman)**
- Dealing with more than 2 components—multicomponent regression analysis
  - Scatter modelling—can we estimate particle size from the shape of baseline?
  - Creating Reports
  - Standards for nanoparticles and colloids
  - Automating flux calculations
- 4:45 – 5:15**     **Q&A / Roundtable**
- 5:30 – 7:00**     **Social hour**



## Wednesday, May 15<sup>th</sup>

- 8:30 – 9:00**      **Attendee Arrival and Breakfast**
- 9:00 – 9:45**      **Zero intercept Method: Principles and Applications of ZIM (Konstantin Tsinman)**
- Dual-component dissolution
  - Monitoring for spectral consistency
  - Solubility of nanoparticles
  - Liquid-liquid phase separation (LLPS)
- 9:45 – 10:30**      **Group Discussion #3**  
Practical aspects of ZIM method implementation – interactive practice. Nanoparticles solubility, dual-component dissolution, LLPS.
- 10:30 – 10:45**      **Break**
- 10:45 – 11:15**      **User Case Study #3 (Doran Pennington, Dispersol)**  
MacroFlux Dissolution for Generic Drug Product Development of a Poorly Soluble Drug
- 11:15 – 11:30**      **Introduction to Pion Service Group (Shawn Burgess)**
- 11:30 – 12:15**      **Pion FO in GMP Environment, DissoPRO software (Shawn Burgess)**
- Fiber optic in regulated environment
  - DissoPRO and 21 CFR Part 11 compliance
  - Validating fiber optic dissolution methods
  - DissoPRO software package
  - Preview of the next revision of DissoPRO
- 12:15 – 1:15**      **Lunch (provided)**
- 1:15 – 2:00**      **Group Discussion #4**  
Practical aspects – interactive data analysis, different aspects. Data files for troubleshooting.
- 2:00 – 2:30**      **Advanced Tools: Dissolution Curve Analysis (Konstantin Tsinman)**
- Relations between dissolution, solubility, particle size, and hydrodynamics
  - Intrinsic dissolution rate (IDR) measurements
  - Predicting disk IDR from powder dissolution experiments
  - Effective particle size estimation from the powder dissolution profile
- 2:30 – 2:45**      **Break**
- 2:45 – 4:00**      **Track 1: FO and Flux Lab Demo (optional for all interested participants)**  
**Track 2: FO in Compliant Environment, GMP considerations round table**  
**Closing the Training Course**