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 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 14th

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**

- 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
- 2nd derivative spectroscopy
- Calculation settings
- Sample Blank

10:15– 10:30 ***Break***

10:30 – 11:00 **User Case Study #1 (TBD)**

11:00 – 11:30 **Method Development Part 2: Advanced considerations**

- 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**

- 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**

- Detecting artifacts
- Membrane-excipient 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 (TBD)**

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 15th

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 (TBD)**

11:15 – 11:30 **Introduction to Pion Service Group**

11:30 – 12:15 **Pion FO in GMP Environment, DissoPRO software**

- 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**

- 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