ONE-DAY COURSE

Biomarker Assay Development and Application, Advanced Topics

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Course Description:

This interactive course is designed to teach participants how to approach and work through developing mass spectrometry-based biomarker analysis strategies for translational and clinical applications. It will briefly examine and blend topics on regulation; working within various invasive, semi-invasive and noninvasive matrix samples; a variety of sample preparation techniques; working with or without authentic standards; HRMS and unit resolution spectrometers and their utility; and considerations for building confidence in biomarker analysis with actual examples. This is a fast-paced course that will blend summarized, high-level introductory topics with real and novel biomarker case studies developed and experienced by the instructors. This course will spend more than half of its time within case studies, covering what worked and what did not work, with increasing complexity from small molecules to peptides, proteins and finish on "omics" and big data.

Who Should Attend:

Individuals who have experience and knowledge working with HRMS, triple quadrupoles and mass spectrometry-based quan/qual who want to develop, validate and build confidence in biomarker assays for decision making, clinical prognosis and therapeutic intervention strategies. Attendees need a practitioner level of mass spectrometry experience and would benefit from introductory level ASMS short courses including *HRMS: An Introduction*, *LC-MS/MS Method Development and Method Validation*, *Quantitative Mass Spectrometry*, and/or *Clinical Biomarkers Development and Validation*.

Basic Course Outline

1. **What is a Biomarker**
   a. Disease, prognosis and therapeutic intervention
   b. The "GLPs", GCP, CLIA and CAP guidelines
   c. Working through translation and intended purpose
   d. Matrix types and sampling (e.g. blood, plasma/serum, saliva, urine, PBMC, tissue)
   e. Sample tubes, tracking and storage
2. **Considerations**
   a. Extraction methods (IP, protein crash, LLE, SPE, and others)
   b. Stability

      c.   Selectivity, HRMS assessments
      d.   Quantitation, SRM, MRM
      e.   Sensitivity
      f.   Cost and ROI
      g.   How do we determine an assay is valid and fit for purpose?

3. **Case Studies Basic**
      a.   Targeted quantitation
      b.   Structural isomers
      c.   Offline immunoprecipitations

4. **Case Studies Advanced**
      a.   Multiplexing
      b.   Sample and matrix depletions
      c.   Working with D, 13C and 15N label substitutions/isotopologues
      d.   The "Omics" and AI/ML

About the Instructor(s):

Matthew Blatnik Ph.D. is an Associate Research Fellow and Precision Medicine Mass Spectrometry Lab Head, he has been with Pfizer for over 15 years. For the last 10 years, Matt has led a group of biomarker scientists and participated on multiple matrix teams focused on developing, translating and testing biomarker hypotheses of disease and therapeutic intervention. Several of his and his team's biomarker contributions have led to Proof of Mechanism (POM), Early Signs of Efficacy (ESOE), dose selection and label claims on several therapeutic molecules and Pfizer marketed products. His experience spans multiple therapeutic areas and diseases, a variety of biomarker modalities, sampling techniques and instrumentation including both QQQ and HRMS. Matt has numerous publications and contributions to the field and when he not talking about or exploring scientific hypotheses, he is enjoying time with family, coaching baseball and pondering the cosmos.

Brendan Tierney is a Senior Scientist in the Precision Medicine Mass Spectrometry Lab at Pfizer. He supports Pfizer's Early Clinical portfolio through the development, qualification and validation of challenging LC-MS based biomarker assays, from translation to the clinic. He has nearly 10 years of bioanalytical experience at Pfizer and has worked with a variety of QQQ and HRMS mass spectrometry platforms, numerous chromatographic systems, and too many biological matrices to count! Prior to joining Pfizer, he spent several years at a natural products drug discovery company where he used cell-based assays to guide HPLC-based isolation of biologically active compounds from fungal extracts. Outside of work, Brendan enjoys running, fishing on Long Island Sound, and spending time with his wife and family.