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 regulatory bodies; selecting appropriate biomarkers; working within various invasive, semi-invasive and noninvasive matrix samples; HRMS and unit resolution mass spectrometers and their utility; and considerations for building confidence in decision-making biomarkers, with actual examples. This is a fast-paced course that will merge summarized, high-complexity and introductory topics with real and novel biomarker case studies. Over half of the course content is focused on case studies and discussions of learnings and applications, with complexity increasing from small molecules to peptides, proteins, "omics" and big data.

Who Should Attend:

Individuals who have experience, knowledge and/or interest in mass spectrometry-based biomarker applications, working with HRMS and triple quadrupole systems who want to further their skills in the development, validation and execution of decisional biomarker assays. Attendees need direct hands-on experience operating and developing mass spectrometry-based assays. The course will also cover biology and biochemistry topics as they pertain to biomarker samples and biomarker decision making. A reasonable interest and/or understanding of basic biology and biochemistry is recommended.

Basic Course Outline:

1) **Intro to Biomarkers and Regulatory Considerations**
   a. **Biomarkers are multifaceted**
   b. **Disease, prognosis and therapeutic intervention biomarkers**
   c. **GCP, CLIA, CAP and LDT guidelines**

2) **Selecting a Biomarker**
    a. How do we decide on a biomarker?
    b. Translation and intended purpose of our biomarker
    c. Matrix types and sampling types
    d. Sample tubes, tracking and storage
3) **Assay Development Considerations**
    a. Sample extraction methods
    b. Stability
    c. Selectivity and HRMS
    d. Quantitation and HRMS vs. QQQ
    e. Sensitivity and thought experiments vs. actual experiments
    f. Are we fit-for-purpose?
4) **Case Studies - Basic**
    a. Targeted quantitation
    b. Structural isomers
    c. Offline immunoprecipitations
5) **Case Studies - Advanced**
    a. Multiplexing
    b. Sample and matrix depletions
    c. Working with D, 13C and 15N labeled surrogate analytes
    d. Omics and pushing the boundaries

About the Instructors:

Matthew Blatnik Ph.D. is an Immunology Associate Director of Precision Medicine at AbbVie and has over 16 years' big pharma experience developing, translating, testing and leading biomarker strategies for clinical decision making. Several of Matt's contributions have led to the development of new medications for the treatment of disease, new therapeutic indications, therapeutic dose selections, label claims and a more comprehensive understanding of the molecular basis of disease in heterogeneous patient populations. Matt's biomarker experience spans multiple therapeutic areas and diseases, a mixture of laboratory head and strategy lead roles, business development and broad applications of mass spectrometry to the field of clinical sciences. When Matt is not talking about or exploring scientific hypotheses, he is enjoying time with family, coaching youth baseball and pondering the cosmos.

Brendan is a Principal Scientist leading the Translational Clinical Sciences - Clinical Biomarker Technologies LC-MS Lab at Pfizer. His lab 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 over 11 years of bioanalytical experience at Pfizer and has worked with a variety of QQQ and HRMS mass spectrometry platforms, numerous chromatographic systems, and is especially interested in the application of minimally invasive sampling techniques in bioanalysis. He is graduate of the University of Connecticut where he earned a Bachelor's degree in Molecular and Cell Biology and a Master's Degree in Applied Genomics. Outside of work, Brendan enjoys running, fishing on Long Island Sound, and spending time with his wife and three children.