TWO-DAY COURSE, Saturday and Sunday

Protein Therapeutics: Practical Characterization and Quantitation by Mass Spectrometry

Instructors

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This introductory course is designed for analytical scientists or interested professionals who would like to learn in depth knowledge about fundamental principles and current practice of protein therapeutics analysis by mass spectrometry and related techniques in pharmaceutical industry. It provides a comprehensive up to date description of different instrumentation platforms in mass spectrometry, and to a lesser degree, in liquid chromatography and electrophoresis techniques that are commonly used in industry. Various modalities of protein therapeutics already commercialized and those promising ones, their unique characteristics, quality attributes, and technical challenges for their analysis will be presented. The basic concepts of protein therapeutics discovery and development, such as critical steps in candidates screening and maturation, phases of clinical trials, process development, analytical development, protein therapeutics manufacturing, regulatory considerations and associated strategies will be covered extensively. This short course emphasizes on real world problems and practical solutions with case studies in the areas where MS is used extensively, such as molecular profiling of post-translational modifications, degradation pathways, structure-function relationship, critical quality attributes that are at the center of protein therapeutics characterization. Real case examples supporting drug discovery, process development, method development, formulation development, and commercial manufacture investigation by both qualitative and quantitative analysis of protein therapeutics will be presented.

Main Topics

<u>Introduction to Protein Mass Spectrometry</u>

- ESI & MALDI for protein molecular ionization
- Intact mass profile and deconvolution
- Tandem mass spectrometry and peptide identification
- Fragmentation techniques
- Top-down and bottom up
- Commonly used mass analyzers for protein molecules
- Ion mobility mass spectrometry

<u>Other related techniques</u>

- Commonly used liquid chromatography techniques for protein analysis
- Commonly used electrophoresis techniques for protein analysis

<u>Discovery process for protein therapeutics</u>

- Hybridoma, phage display, and B-cell cloning
- Candidate screening and maturation
- Antibodies, ADCs, bispecifics, fusion proteins, and PEGylated proteins
- Glycan and glycopeptide analysis

<u>Process development for protein therapeutics</u>

- Small molecular vs large molecule drugs
- Cell line development
- Upstream and downstream processes
- Process development and analytical development

<u>Applications and real case studies</u>

- Peptide Mapping & post-translational modifications
- Characterization of Higher Order Structures/HDX-MS
- Degradation pathways
- PEGylation / Conjugation / ADCs

Quantitative Analysis of Protein Therapeutics

- Sequence variants
- ADCs
- Host cell protein analysis
- Size and charge variants analysis
- Structure-function relationship
- Forced degradation studies
- Disulfide bond linkages
- Stable domain analysis

MS in quality control environment

- Multi-attribute methods