

TWO-DAY COURSE, Saturday and Sunday
14 Protein Therapeutics: Practical Characterization and Quantitation by Mass Spectrometry

Instructors



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This introductory course is designed for practicing analytical scientists (new users, chromatographers, analytical chemists, protein chemists, and laboratory managers) performing/supporting recombinant protein characterization/analysis, in-process testing, quality control, quality assurance, research and development, and manufacturing. It covers the fundamental principles and practical applications of mass spectrometry (MS) for the characterization and quantitation of protein therapeutics with a focus on monoclonal antibodies including antibody-drug conjugates (ADCs). It emphasizes problem-solving skills in the areas where MS is used most extensively, for example, characterization of chemical modifications and post-translational modifications of protein therapeutics. The interpretation of protein therapeutics mass spectra will be illustrated with real case examples. This course will focus on electrospray ionization (ESI) and matrix-assisted laser desorption / ionization (MALDI) techniques in the analysis of protein therapeutics, and will survey various mass analyzer options for the characterization of protein therapeutics. A thorough coverage of approaches toward method development for both qualitative and quantitative analysis of protein therapeutics will provide a good starting point for understanding practical issues that are frequently encountered during implementation and applications of MS on protein therapeutics in the laboratory.

Major topics

Introductions to Protein Therapeutics Mass Spectrometry:

- ESI & MALDI for Protein Therapeutics
- Mass Spectra of Protein Therapeutics
- Peptide Fragmentation

Commonly Used Mass Analyzers for Analysis of Protein Therapeutics:

- Quadrupole
- Ion Trap
- Time-of-Flight
- Orbitrap
- Tandem MS (MS/MS)
- Activation Methods for Protein Therapeutics

MS Method Development for Analysis of Protein Therapeutics:

- Intact Mass Analysis
- Peptide Mapping & Analysis of ADCs
- Characterization of Higher Order Structures/HDX-MS

Characterization of Modifications in Protein Therapeutics:

- Oxidation
- Deamidation / Isomerization
- Glycosylation
- PEGylation / Conjugation
- Unknown Identification

Quantitative Analysis of Protein Therapeutics

- Sample Preparation
- Relative Quantitation of Modifications
- *In vivo* Quantitation

Prerequisite: Working knowledge of mass spectrometry and/or protein chemistry