Mass Spec 2025: Practical Applications of Mass Spectrometry in the Biotechnology Industry

Schedule

Tuesday, 23 September, 2025

07:00-08:30 Pacific Ballroom Foyer

Registration for Mass Spec Short Course Only

Presentation type: IP - In Person

Registration for Short Course and Exhibitors only. Registration will close at 15:00.

07:30-08:30 Pacific 1-2 - B-2 Level

Rise and Dine: Breakfast for Mass Spec Short Course

Presentation type: IP - In Person

Enjoy breakfast, coffee, and networking before the short course!

08:30-12:00 Balboa Bay 1 - B-2 Level

Short Course Session I - Fundamentals of Mass Spectrometry in the Analysis of Protein Therapeutics

Presentation type: IP - In Person

This introductory course will provide an overview of the fundamentals of Mass Spectrometry, including the history of Mass Spectrometry, terminology, data interpretation and sample handling. We will include a discussion on modes of operation (parent versus fragment ion analysis), components of a current MS system, and selected applications of Mass Spec as it applies to protein analysis in the biotechnology industry. A discussion on software (basic interpretation and operation) will be presented along with a hardware discussion (strengths for various applications). A limited discussion on small molecule analysis will be presented.

Short Course Instructor:

Chris Chumsae, Bristol-Myers Squibb Company

12:00-13:00 Balboa Bay 1 - B-2 Level

Lunch

Presentation type: IP - In Person

Lunch is available for short course attendees only.

13:00-16:30 Balboa Bay 1 - B-2 Level

Short Course Session II - Applications of Mass Spectrometry to Characterize Protein Therapeutics

Presentation type: IP - In Person

The afternoon section will focus on practical industrial uses of Mass Spectrometry in the analysis of protein therapeutics as well as in Cell and Gene Therapy. The specific topics will be Intact Mass Analysis, Structural MS, Host Cell Protein ID and Peptide Mapping and Multi-Attribute Method and protein post translational modifications: detection and quantitation. The discussions will be driven by industry leaders. Two interactive segments will cover live data analysis demos of both Intact and Reduced Mass Analysis as well as Peptide Mapping Data Analysis in variety of vendors software products.

This course will review the role MS has in newer therapeutic modalities such as multi-specific, antibody-drug conjugates, cell and gene therapy (AAV, oligonucleotides). Additionally, there will be sections covering mass spec techniques which evaluate protein structure such as hydroxy radical foot-printing, cross-linking, hydrogen-deuterium exchange, top down and middle down methods and ion mobility. The increasing use of Native MS in the analysis if mis-paired Multispecifics as well as investigation of non-covalent interaction will be covered. The 2nd part of the afternoon session focuses on Multi-Attribute Method (MAM), MS in QC, PTM quantitation as well as Sequence Variant Analysis and the role of MS in Cell Line Selection.

Short Course Instructors:

Andrew Mahan, *Johnson & Johnson* Richard Rogers, *Umoja Biopharma*

Wednesday, 24 September, 2025

07:30-08:30 Pacific Ballroom Foyer

Registration for Mass Spec 2025

Presentation type: IP - In Person Registration will close at 17:00 07:30-08:30 Pacific 1-2 - B-2 Level

Rise & Dine: Breakfast

Presentation type: IP - In Person

Breakfast will be served until 09:00am Eastern

08:30-08:45 Pacific 3-4 - B-2 Level

CASSS Welcome & Mass Spec Introductory Comments

Presentation type: LS - Livestreamed

08:45-09:45 Pacific 3-4 - B-2 Level

Keynote I - Advancing Protein Analytics with Mass Spectrometry: Real-World Applications and Insights

Presentation type: LS - Livestreamed

Ping Hu, Johnson & Johnson Innovative Medicine

This presentation will cover three topics: (1) Systematic characterization of charge variants, which led to the discovery of a novel acidic variant, comprehensive structure/function characterization to assess its potential impact, and the development of a robust analytical control strategy. (2) Diverse applications of process characterization to support both protein therapeutics and gene therapy. (3) Process risk assessment to justify the analytical control strategy for marketing applications, along with the latest advancements in multi-attribute monitoring (MAM) for commercial QC testing.

09:45-10:45 Pacific 1-2 - B-2 Level

Sip & See: Posters and Exhibits

Presentation type: IP - In Person

Join us and explore the featured posters and connect with exhibitors. Take this time to engage with presenters and network with peers.

10:45-12:00 Pacific 3-4 - B-2 Level

Session I - MS Applications for Research and Early Stage Development

Jonathan (JJ) Josephs, Richard Rogers

Presentation type: LS - Livestreamed

Session Speaker:

Advancements in Separations to Enhance MS Detection: Applications From Screening to Bioanalyses of Biologics in Preclinical Drug Discovery John Tran, *Genentech, a Member of the Roche Group*

New Paradigm for Charge Variant Characterization Utilizing 'Discovery' Assisted Fractionation Strategy Yongsheng Xiao, *WuXi Biologics*

Automation and HTP Mass Spectrometry to Accelerate Biotherapeutics Discovery Steven Pomerantz, *Johnson and Johnson*

12:00-12:20 Pacific 1-2 - B-2 Level

Grab Lunch From the Exhibit Hall

Presentation type: IP - In Person

12:20-12:50 Pacific 1-2 - B-2 Level

Charge Variant Analysis of ANKTIVA® (N-803) using the Intabio ZT System I Presented by SCIEX

Presentation type: LS - Livestreamed

Session Speaker:

Brian Kawahara, Immunity Bio

12:50-13:00 Pacific 1-2 - B-2 Level

Mini-Break

Short Break to transition speakers.

13:00-13:30 Pacific 1-2 - B-2 Level

Streamlining Agile MS Workflows with Genedata Expressionist | Presented by Genedata AG

Presentation type: LS - Livestreamed

Session Speaker:

Aaron J. Cazy, Eli Lilly & Company

13:30-13:45 Pacific 1-2 - B-2 Level

Stretch Break

Presentation type: IP - In Person

Take this time to stretch, grab a beverage or visit the exhibit hall as we refresh the general session room.

13:45-15:00 Pacific 3-4 - B-2 Level

Session II - Mass Spectrometry in Cell and Gene Therapy

Anders Lund, Richard Rogers

Presentation type: LS - Livestreamed

Session Speakers:

LCMS Assays for mRNA CQAs: A Development Story

Alex Johnson, Aldevron LLC

Monitoring Intact AAV and AAV Building Blocks Through Individual Ion Mass Spectrometry

Jack McGee, ImmPro, Inc.

Employing Electron Activated Dissociation (EAD) Fragmentation to Identify Reactive N-oxide Impurities in Lipid Nanoparticles (LNPs)

Adam Crowe, *Cytiva Main*

15:00-15:30 Pacific 1-2 - B-2 Level

Sip & See: Posters and Exhibits

Presentation type: IP - In Person

Join us and explore the featured posters and connect with exhibitors. Take this time to engage with presenters and network with peers.

15:30-16:35 Pacific 3-4 - B-2 Level

Session III - MS Trends in Regulatory Research, Review and Standard

Andrew Mahan, Christopher Yu

Presentation type: LS - Livestreamed

Session Speakers:

Leveraging Mass Spectrometry Analytical Methods in FDA Cell & Gene Therapy Regulatory Submissions: Current Uses and Future Opportunities

Tiffany Lucas, *ELIQUENT Life Sciences*

Mass Spectrometry and Platform Knowledge – Regulatory Strategies for Advanced Analytical Methods

Michael Boyne, CatalystBio

16:35-18:00 Pacific 1-2 - B-2 Level

Exhibitor Reception

Presentation type: IP - In Person

Kick off the program by connecting with exhibitors and fellow attendees.

Thursday, 25 September, 2025

07:30-08:30 Pacific Ballroom Foyer

Registration for Mass Spec

Presentation type: IP - In Person

Registration will close at 17:00

07:30-08:30 Pacific 1-2 - B-2 Level

Rise & Dine: Breakfast

Presentation type: IP - In Person

Breakfast will be available until 9:00.

08:00-08:30 Pacific 3-4 - B-2 Level

Unleashing the Full Potential of High-Resolution Mass Spectrometry | Presented by SCIEX

Presentation type: LS - Livestreamed

Session Speaker:

Zoe Zhang, SCIEX

08:30-09:30 Pacific 3-4 - B-2 Level

Keynote II - Advanced Mass Spectrometry and Structural Biology Strategies to Characterize Therapeutic Proteins

Presentation type: LS - Livestreamed

Joseph Loo, University of California Los Angeles

Native mass spectrometry (MS) of proteins and protein assemblies reveals size and binding stoichiometry. Native MS and native top-down (TD) MS, i.e., fragmentation of the gas-phase protein, can be effective for deriving structural information for soluble and membrane protein complexes, and much of this information can be correlated to the solution-phase structure. TD-MS and middle down-MS (MD-MS) are emerging techniques that minimize sample preparation and preserve endogenous modifications. MD-MS can offer advantages for forced-degraded studies on mAbs and ADCs. Membrane proteins are essential for cellular functions and represent half of drug targets, but they pose a challenge for conventional structure biology methods. Sequence, higher-order structure, and lipid binding for membrane proteins can be characterized by native MS and native TD-MS. Moreover, atomic-level structural analyses of large macromolecules and protein-ligand complexes have been enhanced by tools such as X-ray crystallography and (cryo)electron microscopy. However, flexible regions, heterogeneous modifications, and bound ligands may not be readily apparent in electron density maps, for example. In such instances, native MS can offer crucial complementary information to aid the determination of the high-resolution structure. Examples of the integration of MS and crystallography/electron microscopy will be shown for nucleic acids and small protein-ligand complexes.

09:30-10:00 Pacific 1-2 - B-2 Level

Sip and See: Posters & Exhibits

Presentation type: IP - In Person

Join us and explore the featured posters and connect with exhibitors. Take this time to engage with presenters and network with peers.

10:00-11:15 Pacific 3-4 - B-2 Level

Session IV - New Technologies, Approaches and Methods

Chris Chumsae, Andrew Mahan

Presentation type: LS - Livestreamed

Session Speakers:

Rapid Online Buffer Exchange with the DynaChip X1 Platform: Enabling Simplified MS and CDMS Analysis of Large Biomolecules Mason Chilmonczyk, *Andson Biotech*

Charge Variant Analysis via icIEF-UV/MS for Enhanced Structure-Function Understanding in Complex Fc Fusion Proteins Anita Liu, *Merck & Co., Inc.*

Innovative Mass Spectrometry Solutions for Characterization of LMWS and HMWS in Early and Late-Stage Protein Therapeutic CMC Development Fatemeh Tousi, *Sanofi*

11:15-11:35 Pacific 1-2 - B-2 Level

Mini-Break: Grab Lunch for Technical Seminars

Presentation type: IP - In Person

11:35-12:05 Pacific 1-2 - B-2 Level

Simplifying Every Stage of Your Biologics Development Journey: From Advanced Characterization to Manufacturing Confidence I

Presented by Waters Corporation

Presentation type: LS - Livestreamed

Session Speaker:

Guillaume Bechade, Waters Corporation

12:05-12:15 Pacific 1-2 - B-2 Level

Mini-Break

Short break to transition speakers.

12:15-12:45 Pacific 1-2 - B-2 Level

<u>High Throughput Sample Preparation Method for MS-Based Proteomics: SPE Membrane Approaches for Peptide Cleanup and Enrichment I Presented by AFFINISEP</u>

Presentation type: LS - Livestreamed

Session Speaker:

Gabriella Gellen, AFFINISEP

12:45-13:00

Stretch Break

13:00-14:15 Pacific 3-4 - B-2 Level

Session V - Multispecifics and ADCs Characterization

Chris Chumsae, Da Ren

Presentation type: LS - Livestreamed

Session Speakers:

Diving Into the Complexities of Non-Natural Amino Acid Antibodies with Innovating Mass Spectrometry Approaches Hirsh Nanda, *Johnson & Johnson*

Applications of Mass Spectrometry in Biopharmaceutical Discovery: From Small Molecules to Proteins Aniruddha Sahasrabuddhe, *Amgen Inc.*

CDR Clipping-Induced Heterodimerization: Identification of a Novel Dimerization Mechanism in a Co-Formulated Antibody Cocktail via a Multifaceted Mass Spectrometry Approach

Andy Heindel, Regeneron Pharmaceuticals Inc.

14:15-14:45 Pacific 1-2 - B-2 Level

Sip & See: Poster & Exhibits

Presentation type: IP - In Person

Join us and explore the featured posters and connect with exhibitors. Take this time to engage with presenters and network with peers.

14:45-15:45 Pacific 3-4 - B-2 Level

<u>Session VI - Next Generation Investigator Awards</u>

Andrew Mahan, Hillary Amber Schuessler

Presentation type: LS - Livestreamed

Session Speakers:

Integrating Mass Spectrometry-Based Footprinting and Molecular Docking to Analyze Ebola Protein-Host Binding Interfaces Xinyi (Cynthia) Kuang, *Washington University in St. Louis*

Analytical Performance Profile for Host Cell Protein Characterization of a Live Attenuated Virus Vaccine Using a LC-MS Based Proteomic Approach Robert D'Ippolito, *Merck & Co., Inc.*

15:45-16:35 Pacific 3-4 - B-2 Level

Session VII - Mass Spectrometry in Higher Order Structure

Chris Chumsae, Ingo Lindner

Presentation type: LS - Livestreamed

Session Speakers:

Evaluating Antigen-Antibody Interactions: A Comparative Study of Higher-Order Structural MS Methods Silvia Ma, *Eli Lilly and Company*

Mechanistic Insights Into Non-mAb Aggregation Using MS-Cleavable Linker Laurence Whitty-Léveillé, *Merck & Co., Inc.*

16:35-16:45 Emerald 2-3 - B-2 Level and Balboa Bay - B-2 Level

<u>Transition Time to Roundtables</u>

Presentation type: IP - In Person

16:45-17:45 Emerald 2-3 - B-2 Level and Balboa Bay - B-2 Level

Roundtable Session

Presentation type: IP - In Person

Table 1 - New Mass Spec Methods to Tackle New Biotherapeutic Challenges

Table 2 - MS-Based Protein Higher Order Structure Characterization in Biologics Research and Development

Table 3 - MS of RNA and Oligonucleotides: Characterization and Quantitation of CQAs

Table 4 - MS in Cell & Gene Therapy

Table 5 - Best Practices of Extended Characterization Mass Spec Methods

Table 6 - MS for HCP

Table 7 - Multi-Attribute Method (MAM) in Development and QC

Table 8 - Best Practices for Elucidating Antibody Drug Conjugate Molecules by MS

Table 9 - Mass Spec and Predictive Stability

Table 10 - Challenges and Obstacles to True Belonging in the Workplace

Friday, 26 September, 2025

07:30-09:00 Pacific Ballroom Foyer

Registration

Presentation type: IP - In Person

Registration will close at 14:00

07:30-09:00 Pacific 1-2 - B-2 Level

Rise & Dine: Breakfast

Presentation type: IP - In Person

Breakfast is available until 9:00

Start the day off right with breakfast and coffee.

09:00-09:30 Pacific 3-4 - B-2 Level

Community Voices

Presentation type: LS - Livestreamed

09:30-10:30 Pacific 1-2 - B-2 Level

Sip & See: Posters & Exhibits

Presentation type: IP - In Person

Attendees are welcome to grab a cup of coffee, network and learn with their fellow attendees, and explore the exhibit hall.

10:30-11:45 Pacific 3-4 - B-2 Level

Session VIII - MAM for Product and Process Characterization and Quality Control

Ingo Lindner, Da Ren

Presentation type: LS - Livestreamed

Session Speaker:

Expanding MAM Horizon Beyond mAb-Based Therapeutics

Sara Carillo, National Institute for Bioprocessing Research & Training (NIBRT)

A Robust and Versatile New Peak Detection Workflow to Facilitate the Implementation of the LC-MS Multi-Attribute Method (MAM) from Research to Commercialization

Patrick Merkle, Novartis Pharma AG

MAM-MS and Proteomics-Driven Process Optimization of Sialylation in N-Glycosylated Biologics Johnathon Li, *Takeda Pharmaceutical Company*

11:45-12:00 Pacific 1-2 - B-2 Level

Mini Break: Grab Lunch for the Technical Seminar

Grab lunch on the way to the technical seminar.

12:00-12:30 Pacific 1-2 - B-2 Level

Purpose-Built Software: A Guided Analytical Workflow for the Multi-Attribute Method | Presented by Agilent Technologies, Inc.

Presentation type: IP - In Person

Session Speaker:

Melissa Sato, Agilent Technologies, Inc.

12:30-12:40 Pacific 1-2 - B-2 Level

<u>Mini Break</u>

12:40-13:10 Pacific 1-2 - B-2 Level

<u>Setting a New Standard in Biotherapeutic Characterization: Holistic Multi-Attribute Characterization of a Bispecific Molecule Leveraging Fast EThcD and Enhanced Native MS on an Orbitrap Excedion Pro BioPharma Hybrid MS | Presented by Thermo Fisher Scientific Inc.</u>

Presentation type: LS - Livestreamed

Session Speaker:

Andrew Mahan, Johnson & Johnson

13:10-14:30 Pacific 3-4 - B-2 Level

Session IX - Multi-omics in Process Development

Chris Chumsae, Christopher Yu

Presentation type: LS - Livestreamed

Session Speakers:

Combining In-Line Biocapacitance and LC-MS to Monitor and Understand Cell Culture Process in Real Time Tingting Jiang, *Merck & Co., Inc.*

Development of a 2D LC-MS Method for Host-Cell Protein Characterisation to Predict Behaviour of Vaccine Antigens in an E. Coli-Based Expression System Henry Fisher, *Labcorp Drug Development*

Unraveling the Metabolic Regulatory Mechanisms Driving Lactate Runaway in CHO Cell Cultures Using a Multi-Omics Approach Elsa Gorre, *Johnson & Johnson*

14:30-14:45 Pacific 3-4 - B-2 Level

Mass Spec 2025 Poster Award

Presentation type: LS - Livestreamed

14:45-15:00 Pacific 3-4 - B-2 Level

Closing Comments & Invitation to Mass Spec 2026

Presentation type: LS - Livestreamed