Mass Spec 2023: Practical Applications of Mass Spectrometry in the Biotechnology Industry

Schedule

Tuesday, 5 September, 2023

9:00-10:00am

VIEW NOW: Co-Chair Chris Chumsae Invites You to Mass Spec 2023

Chris Chumsae Invites You

View Now

10:00-11:00am Burnham Office (Floor 2) Registration for Mass Spec Short Course

Registration for Short Course and Exhibitors only. Registration will close at 17:00 CDT.

11:00am-2:30pm LaSalle (Floor 4)

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

Therapeutics

Co-Chairs: Anders Lund, Richard Rogers

Short Course

This introductory course will provide an overview of the fundamentals of mass spectrometry, including the history of mass spectrometry (MS), 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.

The Short Course is informative and interactive. Please expect to participate in the conversation. Lunch and breaks are included.

2:30-3:00pm LaSalle (Floor 4)

Mind the Moment: Snack & Refresh Break

Attendees should take this time to grab something refreshing, stretch, take a quick inside walk. Use this time to process and regroup.

3:00-6:00pm LaSalle (Floor 4)

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

Co-Chairs: Anders Lund, Richard Rogers, Melissa Sherman Short Course

Welcome back to session II of the Short Course. This interactive course is designed to be an interactive experience. Please expect to participate in the discussion.

The course will focus on practical industrial uses of mass spectrometry in the analysis of protein therapeutics. Examples from the published literature will be used to demonstrate the current uses of MS in various areas of protein pharmaceutical development including formulation studies, process development, and scale-up studies. The specific topics will be Intact Mass Analysis, HDX, Host Cell Protein ID, and protein post-translational modifications: detection and quantitation.

Breaks will be included.

Wednesday, 6 September, 2023

7:00-7:30am Burnham Office (Floor 2)

Registration for Mass Spec 2023 & HOS 2023

Registration will close at 17:00 CDT.

Stop by and Say "Hi" to CASSS Staff Members Carolyn, Mikaela, Lauren, Necoya and the newest Team Member and CASSS Executive Director, Dave Bergeson.

7:00-7:30am Discover Room (Floor 2)

Diverse Voices: Emerging Professionals Breakfast Chat (NEW!)

Diverse Voices Breakfast Chat

Diversity is not a *color*. It is who is represented in the workplace, research, and society. Examples include gender diversity, age diversity, ethnic diversity, physical ability and neurodiversity.

Equity: Fair treatment for *all people* resulting in equality. The unique circumstances of each person is considered, treatment is adjusted accordingly to ensure the end result is equal.

Inclusion: *How* the workforce experiences the workplace and to what degree organizations embrace *all* employees and enable them to make meaningful contributions. Inclusive cultures ensure that all voices are heard.

Speaker:

Emmanuel Cudjoe, Yale University (Former Bristol-Myers Squibb Company)

7:30-8:45am Explore Room (Floor 2)

Rise & Dine: Breakfast

Start the day off right with breakfast and coffee. You may also view e-posters from your device and visit the Exhibit Hall before the sessions start!

New this year: Plug and Play Poster Sessions! Presenters will plug their laptop into a 40" HD monitor and present their abstract on screens instead of boards!

Breakfast will be served until 09:00 AM CDT.

7:30-8:45am Sip Room (Floor 2)

The CASSS Quiet Room

CASSS is pleased to welcome you to the CASSS Quiet Room. The Quiet Room is a space where our attendees can regroup, relax and think. A tranquil space to provide a short period of down-time for those that need a moment of self-care to stay at their best and be prepared for the stimuli of the conference. The CASSS Quiet room will be open daily from 7:30 AM - 5:00 PM on each day of HOS and Mass Spec.

The room may NOT be used for the following:

- Cell phone conversations and meetings with others (please do not use any electronic devices in the quiet room)
- Talking or interrupting others that may be present
- Gathering or socializing
- Eating or drinking (no food or beverage allowed)
- Any types of noise or unnecessary light

Anyone not adhering to the above will be asked to leave the Quiet Room. Please be mindful of others and may the calm be with you.

8:45-9:00am Grand Ballrooms 1-3 (Floor 2)

CASSS Welcome & Mass Spec Introductory Comments

Mass Spec 2023 Co-Chair Welcomes You Back!

Presented by: Chris Chumsae, Bristol-Myers Squibb Company

View Now

9:00-10:00am Grand Ballrooms 1-3 (Floor 2)

Keynote Session I: Quantitative Proteomics for Understanding Histone Mutations in Human Disease

Co-Chairs: Chris Chumsae Keynote Presentation

Quantitative Proteomics for Understanding Histone Mutations in Human Disease (45 minutes) Q&A (15 minutes)

Session Speaker: Benjamin Garcia, Washington University in St. Louis

10:00-10:15am Grand Ballrooms 4-6 (Floor 2)

Sip Break

Take a quick break to grab a cup of coffee and stretch. Come back in 15-minutes for our next session. Today poster sessions will start in the afternoon.

10:15-11:50am Grand Ballrooms 1-3 (Floor 2)

Session I: Molecular Design, Developability and Biotransformation

Co-Chairs: Jason Rouse, John Valliere-Douglass

Session Speakers:

Importance of Disulfide Bond re-arrangement in vitro and in vivo: Evidence and Approaches to Address It

Franta Hubálek, Novo Nordisk A/S

Development of a Rapid and Automated, Compliance Ready Workflow for Full Sequence Coverage of RNAi Therapeutics

Jennifer Nguyen, Alnylam Pharmaceuticals

Elucidation, Characterization and Monitoring of a Unique Tyrosine Sulfation Post-Translational Modification During Bispecific Antibody Process Development and Scaleup

David Mahon, Bristol-Myers Squibb Company

11:50am-12:00pm Grand Ballrooms 4-6 (Floor 2)

Meet & Eat: What's for Lunch?

Mass Spec attendees should grab their lunch and beverages and return to the general session room if they plan on attending the lunch and learns.

*The Technical Seminars are not part of the HOS Symposium.

12:00-12:30pm Grand Ballrooms 1-3 (Floor 2)

Technical Seminar: Presented by SCIEX

Presented by: SCIEX

Technical Seminar Lunch & Learn Sessions are for Mass Spec attendees only. HOS attendees and those not wishing to attend should grab their lunch and proceed to the Explore Room (Floor 2).

12:30-1:00pm Grand Ballrooms 1-3 (Floor 2)

Technical Seminar: Presented by GenNext Technologies, Inc.

Presented by: GenNext Technologies, Inc.

Technical Seminar Lunch & Learn Sessions are for Mass Spec attendees only. HOS attendees and those not wishing to attend should grab their lunch and proceed to the Explore Room (Floor 2).

1:00-1:55pm Grand Ballrooms 4-6 (Floor 2)

Sip & See Posters: Session I & Exhibits

Poster Presentation

After lunch, take your coffee or beverage of choice and visit the Poster Hall to chat with authors about their posters. You may also go online and view any e-posters and video presentations. Creating a badge by clicking on your profile in the upper right, will allow you to comment on e-submissions. If the author has also created a badge, they will be notified of comments (if they allowed permissions). You may view e-posters and any e-poster video submissions 24/7 during the Symposium.

NEW ONSITE: Plug & Play Poster Presentations! No more Poster Boards. Bring your presentation on your laptop or thumb drive and plug into the HD Screen that will be available to display your poster and to show anything else during your presentation!

Please be sure to visit our Exhibitors. Without the support of these vendors, our strategic and program partners, Mass Spec would not be possible. See what products and services they have to offer.

1:55-2:45pm Grand Ballrooms 1-3 (Floor 2)

<u>Featured Joint Keynote Presentation: Hacking Structural Biology for Drug Delivery Using Protein</u> <u>Footprinting Based Mass Spectrometry</u>

Co-Chairs: Galahad Deperalta Keynote Presentation

Joint Keynote Presenter Mark R. Chance Has a Message for You

Mark Chance: Why Attend CASSS MS/HOS 2023

2:45-3:30pm Grand Ballrooms 4-6 (Floor 2)

Sip & See Networking Break: Poster Session II & Exhibits

Visit the exhibit hall and posters. Return to the general session room for the last session of the day, a joint plenary session with HOS attendees.

3:30-6:00pm Grand Ballrooms 1-3 (Floor 2)

Session II: Emerging Mass Spectrometry Technologies for HOS

Co-Chairs: George Bou-Assaf, Ingo Lindner

Session Speakers:

High-Order Structure Characterization of Membrane Proteins Using Benzoyl Fluoride Footprinting

Mengqi Chai, Washington University in St. Louis

In Depth Characterization of Biologics Through a Combination of Mass Spectrometry and Molecular Modeling

Naresh Chennamsetty, Bristol-Myers Squibb Company

Protein Footprinting for Structural Biology in Complex Model Systems

Lisa Jones, University of California San Diego

Complementary Backbone and Side Chain Analysis of Drug - Protein Interactions Combining Hydrogen/Deuterium Exchange and Protein Oxidative Mass Spectrometry

Yan Sun, Albert Einstein College of Medicine

6:00-8:00pm Raised Roof Bar (Floor 3)

Mix & Mingle Welcome Reception: Mass Spec 20th Anniversary

Join us as we celebrate 20 years of CASSS Mass Spec! Let's Mix & Mingle at the Raised Rooftop Bar. Grab a lovely libation and some savory bites. Catch up with co-workers, make new connections and wind down from Day 1 with the CASSS staff and Scientific Organizing Committee of both Mass Spec and HOS. See You There!

Thursday, 7 September, 2023

7:00-8:00am Burnham Office (Floor 2)

Registration for Mass Spec

Registration will close at 17:00 CDT.

7:15-8:45am Discover Room (Floor 2)

Diverse Voices: Emerging Professionals Breakfast Chat (NEW!)

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Equity: Fair treatment for *all people* resulting in equality. The unique circumstances of each person is considered, treatment is adjusted accordingly to ensure the end result is equal.

Inclusion: *How* the workforce experiences the workplace and to what degree organizations embrace *all* employees and enable them to make meaningful contributions. Inclusive cultures ensure that all voices are heard.

7:30-8:45am Explore Room (Floor 2)

Rise & Dine: Breakfast

Start the day off right with breakfast and coffee. You may also view e-posters from your device and visit the Exhibit Hall before the sessions start!

New this year: Plug and Play Poster Sessions! Presenters will plug their laptop into an HD monitor and present their abstract on screens instead of boards!

Breakfast will be served until 09:00 AM CDT.

8:45-8:50am Grand Ballrooms 1-3 (Floor 2)

Welcome & Introductory Comments

Co-Chairs: Frances Namuswe

8:50-9:50am Grand Ballrooms 1-3 (Floor 2)

<u>Keynote Session III: Mass Spectrometry Enables More Definitive Process & Product Development Towards Well-Characterized Biotherapeutics: A Personal Account</u>

Co-Chairs: Frances Namuswe

Session Speaker:

Mass Spectrometry Enables More Definitive Process & Product Development Towards Well-Characterized Biotherapeutics: A Personal Account

Jason Rouse, Pfizer, Inc.

9:50-10:20am Grand Ballrooms 1-3 (Floor 2)

Sip Break

Visit the Exhibit Hall, take a quick stretch or walk break or visit the Quiet Room located in the Root Office. The Quiet Room will be available during the conference for relaxation and anyone neurodivergent or neurodiverse. Please do not use the quiet room for phone calls or working. This room is strictly for CALM and Quiet.

10:20-11:55am Grand Ballrooms 1-3 (Floor 2)

Session III: Mass Spectrometry in Gene and Cell Therapy

Co-Chairs: Anders Lund, Christopher Yu

Session Speakers:

Applications of Mass Spectrometry in CRISPR based Cell Therapy and Gene Editing Therapy Bo Yan, Beam Therapeutics

LC-MS/MS as a Potency Assay for mRNA Vaccines

Aline Dörrbaum, BioNTech SE

Proteomic Approaches for Characterization of Live Biotherapeutic Escherichia coli Nissle Products from Fermentation to Therapeutic Activity

Steven Bruckbauer, Synlogic Operating Company

11:55am-12:05pm Grand Ballrooms 4-6 (Floor 2)

Mini-Break: Grab Lunch for Vendor Showcase

Mass Spec Attendees should grab their lunch from the Exhibit Hall and proceed back into General Session room for the Vendor Showcase. *HOS attendees may grab lunch and proceed to the Explore Room.

12:05-12:35pm Grand Ballrooms 1-3 (Floor 2)

Mass Spec 20th Anniversary Vendor Showcase ~ Presented by Waters Corporation

Presented by: Waters Corporation

Mass Spec attendees should grab their lunch and beverages and return to the general session room if they plan on attending the vendor showcase.

*The vendor showcases are not part of the HOS Symposium.

12:35-1:05pm Grand Ballrooms 1-3 (Floor 2)

Mass Spec 20th Anniversary Vendor Showcase ~ Presented by MOBILion Systems, Inc.

Presented by: MOBILion Systems, Inc.

HOS attendees should grab their lunch and proceed to the meal room to eat.

1:05-1:35pm Grand Ballrooms 4-6 (Floor 2)

Sip & See: Poster & Exhibits III

Visit the poster hall, view and discuss e-posters on monitors and chat with presenters about their research or latest scientific findings.

1:35-2:05pm Grand Ballrooms 4-6 (Floor 2)

Sip & See: Poster & Exhibits Session IV

Visit the poster hall, view and discuss e-posters on monitors and chat with presenters about their research or latest scientific findings.

2:05-2:55pm Grand Ballrooms 1-3 (Floor 2)

The Regulator Panel: Can We Talk?

Featured Panelists:

Wayne Hicks, CBER, FDA Frances Namuswe, CDER, FDA Sarah Rogstad, CDER, FDA

2:55-4:20pm Grand Ballrooms 1-3 (Floor 2)

Session IV: Next Generation Investigators

Co-Chairs: Douglas Richardson, Sarah Rogstad

Session Speakers:

Streamlined IP-RP-LCMS Workflow for siRNA Characterization and Routine Impurity Profiling Chen-Chun Chen, Eli Lilly and Company

Understanding Problems in Biologics Expression by Studying Intracellular Product Quality Attributes

Chris Sauer, Janssen Pharmaceuticals

Ion Mobility-Mass Spectrometry and Collison Induced Unfolding Workflows for the Structural Characterization of Protein Therapeutics

Rosendo Villafuerte-Vega, University of Michigan

4:20-4:30pm Grand Ballrooms 1-3 (Floor 2)

Mini-Break - Head to Roundtables

Grab a bottled water and head to the Roundtable Session.

4:30-5:30pm Explore Room (Floor 2)

Roundtable Session

Roundtable Topics:

- 1. New Mass Spec Methods to Tackle New Biotherapeutic Challenges
- 2. End-to-End Automation: Sample Prep to Data Analysis for MS Workflows
- 3. Multi-Attribute Method (MAM) in Development vs. MAM in QC
- 4. MS of RNA and Oligonucleotides: Characterization and Quantitation of PQAs
- 5. Best practices for sequence variant analysis
- 6. Qualification and Validation of MS Methods
- 7. Timing and Frequency of Forced Degradation and Variant Characterization Studies
- 8. Best Practices for Predicting, Elucidating and Monitoring Hotspots by MS
- 9. Structural MS New Developments in Limited Digestion, HDX, FPOP, Charge Detection, and Ion Mobility
- 10. Shifting from D&I to DEI & Belonging

5:30-7:00pm Grand Ballrooms 1-3 (Floor 2)

Exhibitor & Poster Reception

Join our vendor partners for an evening of delicious hors d'oeuvres, small plates and libations. Exhibitors will take a few minutes to discuss their company, what they do and how their product or service can help you perform your job or routine tasks even better! Dinner will not be necessary after this reception!

Friday, 8 September, 2023

7:30-8:30am Burnham Office (Floor 2)

Registration for Mass Spec

Registration will close at 3:00 PM CDT.

7:45-8:45am Explore Room (Floor 2)

Rise & Dine: Breakfast

Start the day off right with breakfast and coffee. You may also view e-posters from your device and visit the Exhibit Hall before the sessions start!

Today is the last day of Mass Spec 2023. Are you ready?

8:45-8:50am Grand Ballrooms 4-6 (Floor 2)

Welcome & Introductory Comments

Presented by: Chris Chumsae, Bristol-Myers Squibb Company

8:50-9:50am Grand Ballrooms 4-6 (Floor 2)

Keynote Session IV: Perspective on MAM

Co-Chairs: Chris Chumsae

Session Speaker:

Perspective on MAM

Tura Camilli, Genentech, a Member of the Roche Group

9:50-10:20am Grand Ballrooms 1-3 (Floor 2)

Sip & See: Poster Session V & Exhibits

Please take this opportunity to visit the posters and exhibitors. You may also view any e-poster submissions using your electronic device. E-posters are available for online viewing for the duration of the symposium.

10:20-11:55am Grand Ballrooms 4-6 (Floor 2)

Session V: New Technologies, Approaches and Methods

Co-Chairs: Frances Namuswe, Richard Rogers

Session Speakers:

Oligonucleotide Mapping via LC-UV-MS/MS to Enable Comprehensive Primary Structure Characterization of mRNA

Andrew Dawdy, Pfizer, Inc.

High-Throughput Characterization of Antibodies via Automated Microdroplet Reactions

Harsha Gunawardena, Janssen Research & Development, LLC

Exposing the Molecular Heterogeneity of Glycosylated Therapeutics

Rafael Melani, Thermo Fisher Scientific

11:55am-12:55pm Grand Ballrooms 4-6 (Floor 2)

Lunch

Mass Spec attendees should grab their lunch and beverages and return to the general session room if they plan on attending the lunch and learns.

12:55-1:25pm

Sip & See Session VI: Posters & Exhibits (**Subject to change)

Last poster session. Subject to change...depending on if you all wish to end a little earlier!

1:25-3:00pm Grand Ballrooms 4-6 (Floor 2)

<u>Session VI: Multispecifics: Characterization and Development Changes: ADCs and Antibody</u> Oligonucleotide Conjugates

Co-Chairs: Chris Chumsae, Hillary Amber Schuessler

Session Speakers:

Forced Degradation and MS Workflows in Lead Optimization/Early Development Alayna George Thompson, *AbbVie*

High-Throughput Antibody Screening Using an Online Fluidic Device Couple with High Resolution Mass Spectrometer for Early-Stage Cell Line Development

Rachel Liu, Genentech, a Member of the Roche Group

MS-based Characterization of the Chain Pairing and N-linked Glycosylation of a Two-mAb Cocktail Co-expressed in-vivo Using Gene Therapy Approaches

Yuetian Yan, Regeneron Pharmaceuticals, Inc.

3:00-3:10pm

Home Stretch Break

One last stretch before the final session of Mass Spec 2023!

3:10-4:45pm Grand Ballrooms 4-6 (Floor 2)

Session VII: Product and Process Characterization

Co-Chairs: Andrew Mahan, Da Ren

Session Speakers:

Assay Replacement Strategies using MAM

Adam Evans, Janssen Research and Development, LLC

Intact-level Multi-Attribute Monitoring of Complex Biologics Using Imaged Capillary Isoelectric Focusing with UV/MS (icIEF-UV/MS)

Anita Liu, Merck & Co., Inc.

Comprehensive Characterization of Adeno Associated Virus Therapeutics using Mass Spectrometry Methods

Shannon Raab, Eli Lilly and Company

4:45-5:00pm Grand Ballrooms 4-6 (Floor 2)

Closing Remarks and Invitation to Mass Spec 2024

Co-Chairs: Frances Namuswe