HOS 2024: International Symposium on the Higher Order Structure of Protein Therapeutics

Schedule

Wednesday, 11 September, 2024

07:30-08:30 Foyer E - H

Registration for HOS 2024 and Mass Spec 2024

Registration will close at 17:00

08:00-08:30 Brookside A&B (Lower Level)

Breakfast Technical Seminar Presented by BioTools, Inc.

Enjoy an elevated breakfast while listening to a technical seminar presented by *Biotools, Inc.*

Breakthrough CD & FTIR Analysis for mAbs, ADCs and AAV's
Rina Dukor, *BioTools Inc*

08:30-08:45 Brookside A&B (Lower Level)

CASSS Welcome and HOS Introduction

Welcome back to HOS and thank you for joining us! See what CASSS is about, housekeeping rules, and prepare for an amazing Symposium.

08:45-09:45 Brookside A&B (Lower Level)

Keynote Presentation - The Evolution & Challenges of HOS Analysis in Biopharmaceutical Development: Past, Present & Future

Ivan Budyak
Plenary Session (Oral)

Steven Berkowitz, *Independent Consultant*

If one looks at the landscape of biopharmaceutical development over its more than four decade history, a key word that characterizes the progression of these drug products over this time period is "complexity". From peptides to small single-chain proteins (e.g., cytokines) to large multi-chain proteins (e.g., monoclonal antibodies) to large supra-macromolecular structures consisting of a large number of different protein subunits, serving as a drug delivery system (e.g., viral vectors), scientists have been tasked with the monitoring and characterization of the higher order structure (HOS) of these ever more complex drug products. How the information of HOS is gathered and utilized in successfully developing biopharmaceuticals touches many areas in the development process. Although methods have been available and continue to be developed to determine the atomic 3-D structure of these drugs, they present extensive challenges and are too time consuming to implement on a routine basis. As a result, although some of these methods can find use as important analytical tools in key critical files, e.g. INDs and BLAs, the day-to-day role of HOS analysis plays out in the utilization and interplay of an array of much simpler and easier to use analytical tools that collectively and indirectly report back information on the HOS called the "biophysical fingerprint", which is part of the integrated concept of "The Totality of the Evidence". In this talk we will take a look at some of the ways HOS information has been captured and utilized via the speaker's own personal experience working with others in developing biopharmaceuticals.

09:45-10:45 Salon E

Sip & See Networking Break: Exhibits and Posters

Take a quick stretch break, grab some coffee, meet our exhibitors, and engage with our poster presenters!

The exhibit hall is located on the lower level in Salon E.

10:45-12:20 Brookside A&B (Lower Level)

Session I - HOS Technologies: Novel and Current Best Practices

Thomas Cleveland IV, Mats Wikström

Session Chairs: Thomas Cleveland, *NIST* and Mats Wilkstroem, *Amgen Inc.*

Session Speakers:

IR Spectroscopy for Quantifying the Glycosatylation of Proteins in Water
Young Jong Lee, *National Institute of Standards and Technology (NIST)*

Applications Of NMR and Orthogonal Approaches to Monitor the Structural and Functional Impact of Met Oxidation of Monoclonal Antibody Samples
Igor Dikiy, *Regeneron Pharmaceuticals, Inc.*

Small-Angle Scattering to Characterize Biologics
Monica Castellanos, *AstraZeneca*

The nSoft Autonomous Formulation Laboratory: AI and Neutron Scattering for Bioformulation Optimization
Jonathan Seppala, *National Institute of Standards and Technology (NIST)*

On-Demand 3D Imaging of the Molecule in the Solution by Electron Density Topography: A Way for Understanding HOS Information from Small Proteins Up to Delivery Particles
Takashi Sato, *Rigaku Corporation*

12:20-13:25 Salon E

Eat & Greet: What's for Lunch?

13:25-15:00 Brookside A&B (Lower Level)

Session II - HOS in Cell & Gene Therapy

Balakrishnan Gurusamy, Nicholas Larson

Session Chairs: Gurusamy Balakrishnan, *Bristol-Myers Squibb Company* and Nicholas Larson, *Biogen*

Session Speakers:

Regulatory Perspectives on Structural Characterization of Gene Therapy Products
Andrew P. Byrnes, *CBER, FDA*

Characterizing Biologics using wNMR
Bruce Yu, *University of Maryland*

Mass Photometry Instruments for In Process Analytics of Viral and LNP Gene Therapy Vectors
Gael Nicolas, *Refeyn*

Analyzing RNA Structure Using Microfluidic Modulation Spectroscopy (MMS) and Measuring Structural Changes in Riboswitches
David Sloan, *RedShiftBio*

15:00-15:45 Salon E

Sip & See Networking Break: Exhibits and Posters

Take a quick stretch break, grab some coffee, meet our exhibitors, and engage with our poster presenters!

The exhibit hall is located on the lower level in Salon E.

15:45-17:25 Salon F - H

Session III - Joint HOS and Mass Spec Plenary Session: Comprehensive Toolboxes for Complex Problems

Mingyue Li, Frances Namuswe
Plenary Session (Oral)

Session Chair: Mingyue Li, *Pfizer, Inc.* and Frances Namusewe, *CDER, FDA*

Have a case study where mass spectrometry was used along with biophysical techniques or vice versa? Consider submitting your abstract to the joint CASSS MS and HOS session! For presentations at this session, the CASSS HOS and MS organizing committees are looking for examples of complimentary applications of various MS and HOS techniques to characterize complex systems and elucidate all types of structures. Bring your story of how HOS techniques and MS can solve challenging problems together!

Session Speakers:

Radical Protein Footprinting in Stabilized Whole Blood
Joshua Sharp, *University of Mississippi*

Characterization and Mechanistic Insights into the Formation of a mAb Hetero-Clipped Dimer
Joseph Valente, *Bristol-Myers Squibb Company*

Charge Detection Mass Spectrometry for Stoichiometry and Assembly
Martin Jarrold, *Indiana University*

Advancements in Subzero Temperature Chromatography for HDX-MS
Kyle Anderson, *NIST*

17:25-19:00

Mix & Mingle Welcome Reception for HOS and Mass Spec

Thursday, 12 September, 2024

07:30-08:30 Foyer E - H

Registration for HOS 2024 and Mass Spec 2024

Registration for HOS will close at 17:00

07:30-08:30 Salon E

Rise and Dine: Breakfast

Start the day off right with breakfast and coffee!

08:30-09:30 Salon F - H

Diverse Voices Session - Joint HOS and Mass Spec Breakfast Session

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.

Session Speakers:

Penny Peterson, *Tolmar, Inc.*
Cynthia Ziwawo, *Indiana University*
Geoffrey Hutchinson, *University of Washington*
Olubukola Abiona, *NIH-Oxford*

09:30-10:15 Salon E

Sip & See: Posters & Exhibits

Take a quick stretch break, grab some coffee, meet our exhibitors, and engage with our poster presenters!

The exhibit hall is located on the lower level in Salon E.

10:15-11:50 Brookside A&B (Lower Level)

Session IV - HOS in Antibody-based Therapeutics

Anne Kim, William Matousek

Session Chairs: Anne Kim, *Johnson & Johnson* and William Matousek, *Regeneron Pharmaceuticals Inc.*

Session Speakers:

Predict the Viscosity of Concentrated Antibody Solutions Using Integrative Experimental and Computational Screening
Pin-Kuang Lai, *Stevens Institute of Technology*

Excipient-Induced mAb Dynamics Unveiled by NMR: Fast-Tracking Biotherapeutic Formulations
Anupreet Kaur, *University of Maryland*

Studying Higher Order Structure of an Antibody-Drug Conjugate Through Chemical Screening and Computational Modeling
Sasha Ebrahimi, *GlaxoSmithKline* – Next Generation Investigator Award Winner

Propermab: An Integrative Framework for *in silico* Assessment of Antibody Developability Using Machine Learning
Bian Li, *Regeneron Pharmaceuticals, Inc.*

11:50-13:15

Lunch

13:15-14:15 Strathmore A&B

Roundtables - Session 1

Roundtable Topics:

1. Submission Data Packages: What is our common vision of IND and BLA today?
2. Toolboxes for Novel Modalities: What do we use and what are we missing?
3. Validation of Biophysical Methods Used in QC: How to apply and implement ICH
4. High Order Structure Comparability: Acceptance criteria, comparison, conclusions
5. Analytical/Biophysical Methods for Good Developability of Molecule(s) Selection

14:15-14:45

Sip & See Networking Break: Exhibits and Posters

Take a quick stretch break, grab some coffee, meet our exhibitors, and engage with our poster presenters!

The exhibit hall is located on the lower level in Salon E.

14:45-15:45 Strathmore A&B

Roundtables - Session 2

Roundtable Topics:

1. Submission Data Packages: What is our common vision of IND and BLA today?
2. Toolboxes for Novel Modalities: What do we use and what are we missing?
3. Validation of Biophysical Methods Used in QC: How to apply and implement ICH
4. High Order Structure Comparability: Acceptance criteria, comparison, conclusions
5. Analytical/Biophysical Methods for Good Developability of Molecule(s) Selection

15:45-16:45 Brookside A&B (Lower Level)

HOS Open Mic: Recall and Wrap Up

Plenary Session (Oral)

17:30-19:00

Exhibitor Reception