

Characterization of Protein Therapeutics

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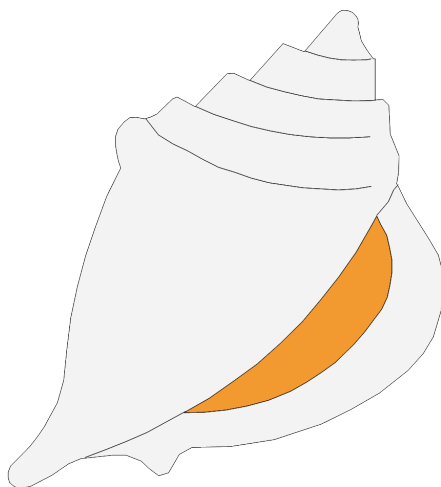
Guodong Chen

Bristol-Myers Squibb

&

Justin Sperry

Pfizer



28th ASMS Sanibel Conference on Mass Spectrometry
January 21 - 24, 2016
Clearwater Beach, FL

Sanibel Conference Committee

Erin Baker
PNNL

Patrick Griffin
Scripps Research Inst.

Fanyu Meng
Merck & Co., Inc.

Victor Ryzhov
Northern Illinois University

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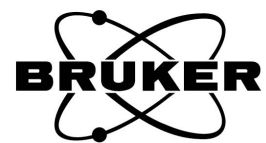
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Guodong Chen
Bristol-Myers Squibb

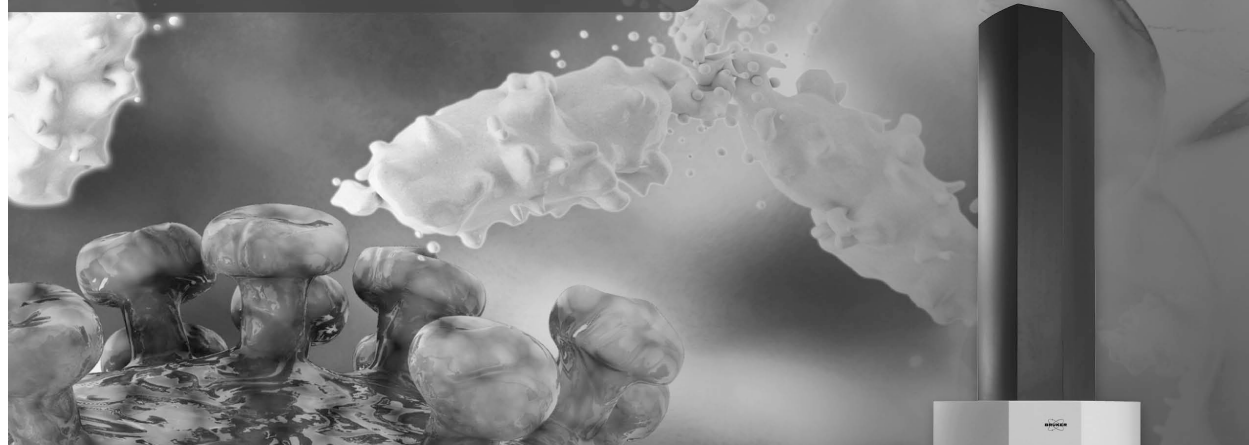


Justin Sperry
Pfizer



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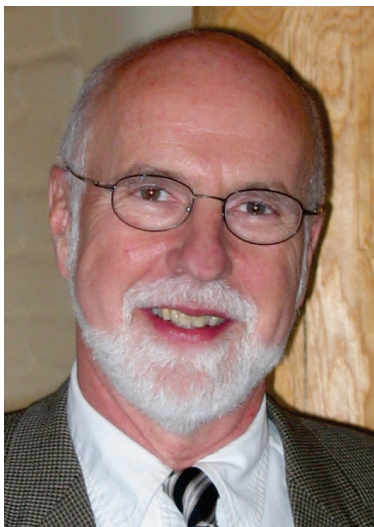
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Speakers – please arrive ½ hour before your session begins to load your presentation

THURSDAY, JANUARY 21

4:00 - 7:00 pm Setup Session I Posters, *Salon ABC, Citrus & Mangrove*

7:00 – 8:00 pm Opening Plenary



Mass Spectrometry-Based Biophysics Enables Methods for Protein Therapeutics

Michael Gross, *Washington University, St. Louis*

Salon D&E

8:00 – 10:00 pm

Reception

Salon ABC, Citrus & Mangrove

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FRIDAY, JANUARY 22

8:30 – 11:45 am Sequence Analysis and Protein Stability Session Chair: Guodong Chen, <i>Bristol-Myers Squibb</i> <i>Salon D&E</i>	
8:30-9:00 am	Scott McLuckey , Purdue University, “ <i>Novel Applications of Ion/Ion Reactions in Protein Therapeutics</i> ”
9:00-9:30 am	Don Hunt , University of Virginia, “ <i>Instrumentation and Methods for the Identification of Intact Proteins in Mixtures and for Sequence Analysis of Antibodies and Post-translationally Modified, Intact Proteins on A Chromatographic Time-Scale</i> ”
9:30-10:00 am	Jennifer Brodbelt , University of Texas, Austin, “ <i>UV Photodissociation for Analysis of Antibodies</i> ”
10:00-10:15 am	Coffee Break
10:15-10:45 am	Igor Kaltashov , University of Massachusetts, Amherst, “ <i>New Methods to Monitor Protein Aggregation and Association based on Native ESI-MS and Non-denaturing Chromatography</i> ”
10:45-11:15 am	Dingyi Wen , Biogen, “ <i>Disulfide Structure Determination by Mass Spectrometry</i> ”
11:15-11:45 am	Taylor Zhang , Genentech, “ <i>Antibody Fc Deamidation, the Well-known and the Less Well-known</i> ”
11:45-1:00 pm	Group Lunch

FRIDAY, JANUARY 22

1:00 – 3:00 pm Product/Process Related Characterization Session Chair: Lisa Marzilli, <i>Pfizer</i> <i>Salon D&E</i>	
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1:00-1:30 pm	Li Tao , Bristol-Myers Squibb, “ <i>Characterization of Molecular Variants in Protein Therapeutics</i> ”
1:30-2:00 pm	Carlito Lebrilla , University of California, Davis, “ <i>The Characterization of Protein Glycosylation in Biotherapeutic Drugs</i> ”
2:00-2:30 pm	Melissa Alvarez , Genentech, “ <i>Taking SVA to the Next Level: Towards Faster and More Reliable Detection of Sequence Variants</i> ”
2:30-3:00 pm	Justin Sperry , Pfizer, “ <i>Current MS Approaches for the Characterization of HCPs in Biotherapeutics</i> ”
3:00-7:00 pm	Free Time

7:00 pm – 8:00 pm Late Breaking Session I Session Chair: Michael Boyne, <i>BioTechLogic</i> <i>Salon D&E</i>	
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7:00-7:20 pm	Sunny Zhou , Northeastern University, “ <i>Meet the Challenge of Discovering Unknowns: Protein Modifications in Biotherapeutics</i> ”
7:20-7:40 pm	Joomi Ahn , MedImmune, “ <i>Investigation of IgG4 Monoclonal Antibody Aggregation by HDX MS and Other Biophysical Tools</i> ”
7:40-8:00 pm	Tawnya Flick , Amgen, “ <i>Applications of Mass Spectrometry in Process Development of Antibody Drug Conjugates and Novel Bioconjugates</i> ”

8:00 – 10:00 pm Poster Session I <i>Salon ABC, Citrus & Mangrove</i> remove poster session I posters at 10:00 pm Poster Session II setup posters by 8:30 am	
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SATURDAY, JANUARY 23

8:00 - 8:30 am
Poster Session II
set up your posters

8:30 – 11:30 am
Higher Order Structure Analysis
Session Chair: Igor Kaltashov, *University of Massachusetts, Amherst*
Salon D&E

- 8:30-9:00 am **Alessandra Luchini**, George Mason University, “*Protein Painting: Mass Spectrometry and Dyes to Identify Native Protein-Protein Hotspot on Therapeutic Targets*”
- 9:00-9:30 am **Guodong Chen**, Bristol-Myers Squibb, “*Epitope Mapping in Biotherapeutics Discovery: Strategy and Case Study*”
- 9:30-10:00 am **Jeffrey Hudgens**, National Institute of Standards and Technology, “*Progress toward Harmonization of HDX-MS Measurements of mAbs*”
- 10:00-10:30 am **Coffee Break**
- 10:30-11:00 am **David Weis**, University of Kansas, “*HDX-MS Provides New Insights into Development Challenges in Formulation and Aggregation*”
- 11:00-11:30 am **George Bou-Assaf**, Biogen, “*The Utility of Hydrogen/Deuterium Exchange Mass Spectrometry in Biopharmaceutical Comparability Studies*”
- 11:30-1:00 pm **Lunch**, on your own

1:00 - 3:00 pm
Antibody-Drug Conjugates and In Vivo Quantitation
Session Chair: Melissa Alvarez, *Genentech*
Salon D&E

- 1:00-1:30 pm **Lisa Marzilli**, Pfizer, “*Using Mass Spectrometry to Overcome the Challenges of Antibody-Drug Conjugate Characterization*”
- 1:30-2:00 pm **Tim Olah**, Bristol-Myers Squibb, “*Bioanalytical Strategies for the In Vivo Quantitation of Novel Forms and Components of ADC Modalities*”
- 2:00-2:30 pm **Surinder Kaur**, Genentech, “*Understanding the Fate of Antibody-Drug Conjugates In Vivo during Nonclinical and Clinical Drug Development*”
- 2:30-3:00 pm **Paula Ladwig**, Mayo Clinic, “*Quantification of the IgG2/4 Kappa Monoclonal Therapeutic Eculizumab from Serum using Microflow LC-ESI-Q-TOF Mass Spectrometry*”
- 3:00-7:00 pm **Free Time**

SATURDAY, JANUARY 23

7:00 – 8:00 pm

Late Breaking Session II

Session Chair: Brandon Ruotolo, University of Michigan

- | | |
|--------------|---|
| 7:00-7:20 pm | Richard Vachet , University of Massachusetts, Amherst, <i>“Investigating Protein Therapeutic Structure with Covalent Labeling and Mass Spectrometry”</i> |
| 7:20-7:40 pm | Jason Tang , Eli Lilly, <i>“High Order Structure Characterization of Engineered Bispecific Antibodies by LC-MS based Methods”</i> |
| 7:40-8:00 pm | Sarah Rogstad , FDA, <i>“The Use of Mass Spectrometry in FDA Applications for Biotherapeutics: A Retrospective Review”</i> |

8:00 – 10:00 pm

Poster Session II

Salon ABC, Citrus & Mangrove

SUNDAY, JANUARY 24

8:30 – 11:35 am Biosimilars and New Directions Session Chair: Justin Sperry, Pfizer <i>Salon D&E</i>	
8:30-9:00 am	Michael Boyne , BioTechLogic, <i>“The Evolving Role of Mass Spectrometry in the Regulatory Setting”</i>
9:00-9:30 am	Alain Beck , Centre d'Immunologie Pierre Fabre, <i>“Cutting-edge Mass Spectrometry Characterization of Originator, Biosimilar and Next Generation Antibody Related Products”</i>
9:30-10:00 am	Albert Heck , Utrecht University, <i>“A Detailed Look at Antibodies, Plasma Proteins and Their Interactions by High-Resolution Mass Spectrometry”</i>
10:00-10:30 am	Coffee Break
10:30-11:00 am	Joseph Loo , University of California, Los Angeles, <i>“Location, Location, Location: Tandem Mass Spectrometry to Derive Site-Specific Information for Non-covalent Protein Complexes”</i>
11:00-11:30 am	Brandon Ruotolo , University of Michigan, <i>“Collision Induced Unfolding of Intact Antibodies: Rapid Characterization of Disulfide Bonding Patterns, Glycosylation, and Structures”</i>
11:30-11:35 am	Closing Remarks (Justin Sperry, Pfizer)

Poster Session I, Friday 8:00 - 10:00 pm

- 1 *Investigation of IgG4 Monoclonal Antibody Aggregation by HDX MS and Other Biophysical Tools; Joomi Ahn; MedImmune*
- 2 *Antibody Subunit Characterization by LC separation and CID/ETD Fragmentation with an Ultrahigh Resolution QTOF; Christian Albers; Bruker Daltonik GmbH*
- 3 *Automated Method for Structural Characterization of Membrane Proteins in Bicelles Using HDX-MS.; Kyle Anderson; National Institute of Standards and Technology*
- 4 *Analysis of a Monoclonal Antibody by Top-Down LC-MS/MS Using a 21 Tesla FT-ICR Mass Spectrometer; Lissa Anderson; National High Magnetic Field Laboratory*
- 5 *Hydrogen Exchange Mass Spectrometry Reveals Protein Interfaces and Distant Dynamic Coupling Effects during the Reversible Self-Association of an IgG1 Monoclonal Antibody; Jayant Arora; University of Kansas*
- 6 *The Separation and Quantitation of Peptides with and without Oxidation of Methionine and Deamidation of Asparagine; Majors Badgett; University of Georgia*
- 7 *De novo Sequencing Using MELD Proteolysis Coupled to a "Sequence Assembly" Algorithm; Dominique Baiwir; University of Liege*
- 8 *Norleucine Content in Brolucizumab (RTH258) by LC/MS Peptide Mapping; Rodney Bannwart; Alcon Labs, a Novartis Co.*
- 9 *Improved Sensitivity for the Qualitative and Quantitative Analysis of Active Ricin by MALDI-TOF Mass Spectrometry; Jakub Baudys; Centers for Disease Control and Prevention*
- 10 *Deconvolution of SWATH MS/MS Data for Comprehensive Peptide Mapping; Lyle Burton; Sciex*
- 11 *Two-Dimensional Time-Resolved LC-MS Deconvolution to Achieve Deep Understanding and Accurate Quantification of Biological Drugs; David Bush; Genedata Inc*
- 12 *IM-MS Characterisation of Protein Therapeutics; Sneha Chatterjee; University of Antwerp*
- 13 *Profiling, Localizing and Quantifying Conjugation Sites of Lysine-conjugated ADCs; Liuxi Chen; Waters Corporation*
- 14 *Identification of Recombinant Monoclonal Antibody Charge Variants Using OFFgel Fractionator and Mass Spectrometry; Guilong Charles Cheng; Alexion Pharmaceutical, Inc.*
- 15 *Assessment on Monoclonal Antibody Aggregation Using Multiple Reaction Monitoring-Mass Spectrometry.; Sao Fong Cheung; University of Maryland*
- 16 *Native Ion Mobility Mass Spectrometry for the Characterization of Proteins; Caroline S. Chu; Agilent Technologies, Inc.*
- 17 *Structural Characterization of a Monoclonal Antibody (mAb) - Maytansinoid Immunoconjugate; Hyo (Helen) Chung; Amgen Inc.*
- 18 *Building Recurrent Glycan Spectral Libraries for the NISTmAb Reference Material; Lorna De Leo; National Institute of Standards and Technology*
- 19 *Characterizing the Higher Order Structure and Self-Association of Therapeutic Monoclonal Antibodies; Paul Devine; University of Leeds*

Posters are located in the Salon ABC, Citrus & Mangrove
 Poster Session I Posters: Setup up by 6:30 pm on Thursday
 Remove at 10:00 pm on Friday
 Poster Session II Posters: Setup by 8:30 am on Saturday
 Remove at 11:35 am on Sunday

Poster Session I, Friday 8:00 - 10:00 pm

- 20 *Intact and Bottom Up Analysis of mAb Based Pharmaceuticals; **Renee Easter**; US Food and Drug Administration*
- 21 *Applications of Mass Spectrometry in Process Development of Antibody Drug Conjugates and Novel Bioconjugates; **Tawnya Flick**; Amgen, Inc.*
- 22 *Folding Pathways of the DNA Binding Protein HMGA2: AT-Hooked Peptide-DNA Complexes; **Alyssa Garabedian**; Florida International University*
- 23 *Hydrogen Exchange Mass Spectrometry can Reliably Detect Small Fractions of Destabilized Protein in Comparability Studies; **Tyler Hageman**; University of Kansas*
- 24 *Title Bottom-Up Quantitative Measurement of an Antibody Therapeutic in Human Plasma by LC-MS/MS Using Formic Acid Digestion: A Comparison with Ligand Binding Results; **Jack Henion**; Q2 Solutions BioSciences*
- 25 *Determination of Authentic Deamidation Sites in Adalimumab Using a Peptide Mapping Protocol Performed at Low pH.; **Chris Hosfield**; Promega Corporation*
- 26 *Sub-Unit and Middle-Down Analyses of Monoclonal Antibody on a Fusion Lumos Orbitrap Mass Spectrometer.; **Stephane Houel**; Thermo Fisher Scientific*
- 27 *New Integrated Informatics Solution for Protein Biotherapeutics Characterization.; **Stephane Houel**; Thermo Fisher Scientific*
- 28 *MS-Based Epitope Mapping of Plasmodium Vivax Vaccine Candidate Duffy Binding Protein; **Yining Huang**; Washington University, St. Louis*
- 29 *Mass Spectrometric Characterization of the N-Glycan Found in the CDR Region of a Rat Antibody Light Chain; **John O. Hui**; Amgen*
- 30 *Characterization of Stable Isotope Labeled Chinese Hamster Ovary Proteins (SIL-CHOP) and Use as an Internal Standard for Quantification of HCPs by Mass Spectrometry; **Pegah Jalili**; MilliporeSigma*
- 31 *A Sequence Variant Database Searching Strategy Using Wild Type Peptides as Decoys; **Tao Jiang**; University of Michigan*
- 32 *Deconvolution of Intact Mass Spectra as a Tool to Measure Payloads of Cytotoxic Drugs Linked to Monoclonal Antibodies; **Shambaugh Joe**; Genedata Inc*
- 33 *The Optimization of Host-Cell Protein Detection Using Data-Independent SWATH-MS; **Melanie Juba**; Sciex*
- 34 *Hydrogen Deuterium Exchange Mass Spectrometry (HDX-MS) as a Tool to Map FCγRs Interactions with Specific mAb-Glycoforms; **Ioannis Karageorgos**; National Institute of Standards and Technology*
- 35 *Use of Fast Photochemical Oxidation Coupled with Mass Spectrometry to Study Protein Interfaces in HER2 Higher Order Complexes; **Theodore Keppel**; Washington University, St. Louis*
- 36 *Interrogating the Co-Purification Mechanism of Glutathione S-Transferase A, a Biotherapeutic Contaminant; **Michael Tae-Jong Kim**; Genentech*
- 37 *Characterization of Higher Order Structure of Monoclonal Antibodies Using Covalent Labeling Techniques; **Janna Kiselar**; Case Western Reserve University*

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 Remove at 11:35 am on Sunday

- 38 *Comprehensively Characterizing the N and O-Linked Glycosylation of a Recombinant Human EPO Using HILIC-MS; **Matthew Lauber**; Waters Corporation*
- 39 *A New pI Fractionator for Analysis of Blood Samples from AD-Patients; **Thorleif Lavold**; Biomotif AB*
- 40 *Automation and Tandem Mass Spectrometry Approaches for the Structural Characterization of Protein Pharmaceuticals by Hydroxyl Radical Protein Footprinting; **Franklin Leach III**; Photochem Technologies*
- 41 *Intact Protein Characterization of an Acidic Histone Chaperone Protein, Nucleoplasmin, Using Front-End Electron Transfer Dissociation Technology; **Stephanie Lehman**; University of Virginia*

Poster Session II, Saturday 8:00 - 10:00 pm

- 1 *Quantification of the IgG2/4 Kappa Monoclonal Therapeutic Eculizumab from Serum Using Microflow LC-ESI-Q-TOF Mass Spectrometry; **Paula Ladwig**; Mayo Clinic*
- 2 *Mapping of the Interleukin-23/Antibody Epitope by Fast Photochemical Oxidation of Proteins (FPOP) and Mass Spectrometry; **Jing Li**; Washington University, St. Louis*
- 3 *Fast Photochemical Oxidation of Proteins (FPOP) and Mass Spectrometry Map the Epitope for binding of Interleukin-6 Receptor Subunit Alpha with Adnectins; **Ke (Sherry) Li**; Washington University, St. Louis*
- 4 *Evolving High Throughput Glycan Analysis in Clone Selection Process for a Therapeutic Protein; **Melanie Lin**; Shire Pharmaceuticals*
- 5 *Accurate Quantitation of mAb C-Terminal Lysine Levels Using an O18-Labeling Assisted LC-MS Method; **Anita Liu**; Regeneron Pharmaceuticals*
- 6 *Characterization of IgG2 Disulfide Bonds with LC/MS/MS and Post-column Online Reduction; **Hongji Liu**; Medimmune*
- 7 *A New Workflow for Disulfide Bond Mapping of Protein Digests; **Steve Madden**; Agilent Technologies*
- 8 *A Unique Method to Identify Mutations of Bulk Recombinant Proteins by Using N-Terminal Labeling Combined with the MELD Method; **Gabriel Mazzucchelli**; University of Liege*
- 9 *FPOP, with a Pulsed-Laser Beam, Photolyzes H₂O₂, to Yield •OH for MS-Based Protein Footprinting on the Microsecond Timescale; **Ben Niu**; Washington University, St. Louis*
- 10 *The use of Isotopically Labeled Glycoproteins as Internal Standards for the Quantitation of N-linked Glycans; **Ron Orlando**; CCRC/UGA and Glycoscientific*
- 11 *Molecular Insights to the Thermal Stability of mAbs with Variable Temperature Ion Mobility Mass Spectrometry; **Kamila Pacholarz**; University of Manchester*
- 12 *Pepsin-Containing Membranes for Controlled Monoclonal Antibody Digestion Prior to Mass Spectrometry Analysis; **Younge Pang**; Michigan State University*
- 13 *Evaluation of an Fc Fusion Protein Using 2D-HPLC-MS to Support Transfer of Drug Product Manufacturing Process; **Ryan Pettitt**; Amgen, Inc.*

Poster Session II, Saturday 8:00 - 10:00 pm

- 14 *The Use of Mass Spectrometry in FDA Applications for Biotherapeutics: A Retrospective Review;* **Sarah Rogstad**; US Food and Drug Administration
- 15 *Characterization of Glycans from Zambian Clone Virus by Mass Spectrometry;* **Teerapat Rojsajakul**; Harvard Medical School
- 16 *High Sensitivity Intact Antibody Drug Conjugate Analysis Using an Integrated Microfluidic Device Coupled to High Resolution Mass Spectrometry;* **Gregory Roman**; Waters Corporation
- 17 *Inductive Electric Fields Applied to ESI & MALDI for Protein Therapeutic Analysis and QC.;* **Drew Sauter**; nanoLiter LLC
- 18 *Characterization by Mass Spectrometry of Sialylated Glycoforms in Antibodies.;* **Patrick Schlinder**; Novartis
- 19 *De Novo Sequencing in Biopharmaceutical Discovery;* **K. Ilker Sen**; Janssen BioTherapeutics, Johnson&Johnson
- 20 *Mass Spectrometric Studies of a New Antibody Specific Proteases – IdeZ;* **Stephen Shi**; New England Biolabs
- 21 *Systematic Reveals Surprising – Previously Unreported Glycosylations on HLA Peptides;* **St. John Skilton**; Dir. Protein Metrics International
- 22 *Mapping of Fab-1: VEGF Interface Using Carboxyl Group Footprinting Mass Spectrometry with Advanced Software Data Processing;* **St. John Skilton**; Dir. Protein Metrics International
- 23 *Using Hydrophilic Interaction Chromatography – Mass Spectrometry for Heightened Product Characterization to Overcome Challenges with Hydrophobic Antibody Drug Conjugates and Monoclonal Antibodies;* **Jacquelynn Smith**; Pfizer Inc.
- 24 *Rapid Antibody Digestion Enabled by Automated Reversed-Phase Cleanup.;* **Ning Tang**; Agilent Technologies
- 25 *Determination of Drug-to-Antibody Ratio of Antibody-Drug Conjugates Using Automated Sample Preparation and a Novel DAR Calculator.;* **Ning Tang**; Agilent Technologies
- 26 *LCMS Analysis of Antibody Drug Conjugates and Calculation of Drug to Antibody Ratio (DAR);* **Ning Tang**; Agilent Technologies
- 27 *Collision Induced Unfolding of Antibody Ions: IM-MS Assesses the Similarity of Therapeutic Antibody and its Biosimilar;* **Yuwei Tian**; University of Michigan
- 28 *gMODs: An Open Source Data Analysis Tool for Quantifying the Differential Site Occupancy of Therapeutic Protein Modifications;* **Tsung-Heng Tsai**; Northeastern University
- 29 *Investigating Protein Therapeutic Structure with Covalent Labeling and Mass Spectrometry;* **Richard W. Vachet**; University of Massachusetts, Amherst
- 30 *Purity Assessment of Bispecific Antibodies by Chromatography and Mass Spectrometry Techniques;* **Chunling Wa**; Boehringer Ingelheim Pharmaceuticals, Inc.
- 31 *MS-Based Characterization of Engineered IgG Hexamers and their Role in Complement Activation;* **Guanbo Wang**; Utrecht University

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Remove at 11:35 am on Sunday

Poster Session II, Saturday 8:00 - 10:00 pm

- 32 *Enterprise Mass Spectrometry Software Solution Enabling Characterization of Biotherapeutics from Discovery and Development to Production and Quality Control; **Cassandra Wigmore**; Genedata AG*
- 33 *Elimination of Allosteric Artifacts in Epitope Mapping Experiments using Time-Resolved ElectroSpray Ionization Hydrogen Deuterium EXchange (TRESI-HDX); **Derek Wilson**; York University*
- 34 *Characterization of Monoclonal Antibody and its Derivatives by Ion Mobility Quadrupole Time-of-Flight (IM Q-TOF) Mass Spectrometry; **David Wong**; Agilent Technologies*
- 35 *De Novo Identification and Profiling of Disulfide Bonds in Biopharmaceuticals Including Analysis of DSB Scrambling; **Jason Wood**; Bruker Daltonics*
- 36 *Evaluatyon of Hemoglobin-Haptoglobin Complex as a Carrier of Anti-HIV Drug (Adefovir) in Macrophage-Targeting Drug Delivery System; **Shengsheng Xu**; University of Massachusetts, Amherst*
- 37 *Characterization and Modeling of Asn Deamidation in the Light Chain CDR Region of a Monoclonal Antibody in vitro and in vivo; **Xiaobin Xu**; Regeneron Pharmaceuticals, Inc.*
- 38 *Innovator and Biosimilar Infliximab: Comparability Assessment of the Host Cell Proteins and Protein Higher Order Structure; **Ying Qing Yu**; Waters Corporation*
- 39 *Improving Accuracy and Precision Using Multiple Transitions; **Adam Zabell**; Indigo BioAutomation*
- 40 *The Quantification of Intact Antibody Drug Conjugate by Affinity Capture HR/AM LC-MS; **Dongliang Zhan Zhan**; PPD, Inc.*
- 41 *HDX-MS Studies on Antibody Drug Conjugate; **Jie Zheng**; The Scripps Research Institute*
- 42 *Meet the Challenge of Discovering Unknowns: Protein Modifications in Biotherapeutics; **Zhaohui Sunny Zhou**; Northeastern University*
- 42 *Characterization and Quantification of Intact Glycopeptides from Imiglucerase and Velaglucerase Alfa Using Electron Transfer Dissociation and Tandem Mass Tags; **Hongbin Zhu**; US Food and Drug Administration*