Proposal for the 2016 Sanibel Conference

Title: Characterization of Protein Therapeutics by Mass Spectrometry: Recent Developments and Future Trends

Summary statement on program focus, timeliness, potential audience

Since the introduction of the first recombinant DNA-derived protein insulin in the 1980s and the launch of Interferons and Interleukins in the 1990s, the protein therapeutics market has shown tremendous growth. This is largely due to advances in recombinant DNA technology that have provided the means to produce protein therapeutics. Mass spectrometry (MS), due to its analytical sensitivity and specificity, is uniquely positioned to cope with the additional challenges required for protein therapeutic characterization and quantitation.

The conference will bring together experts in the field of protein therapeutics characterization from industry and academia. Molecules such as monoclonal antibodies (mAbs), fusion proteins, PEGylated proteins, and antibody-drug conjugates (ADCs) are topics of interest to the large audience focused on protein therapeutics. Discussions will be given on current status and trends in MS characterization of protein therapeutics with the focus on qualitative and quantitative analysis.

A focused Sanibel Conference on protein therapeutics would be timely as R & D of protein-based drugs is being emphasized throughout the pharmaceutical industry. This new landscape has and will impact the careers of a significant number of current and future ASMS members. The conference will be of great value to attendees from both industry and academic institutes.

Organizers: **Guodong Chen (Bristol-Myers Squibb)**
Justin Sperry (Pfizer)

Plenary: an introductory speaker with broad appeal: John Stults (Genentech)

Session 1 – Ion Activation for Sequence Analysis

Topic 1: Ion/Ion reaction	Scott McLuckey (Purdue)
Topic 2: ETD/antiboy sequencing	Don Hunt (University of Virginia)
Topic 3: Photodissociation	Jennifer Brodbelt (University of Texas)

Session 2 - Protein stability

Topic 1: Protein degradation	David Hambly (Amgen)
Topic 2: Protein aggregation	Igor Kaltashov (Univ. of Massachusetts Amherst)
Topic 3: disulfide-bond mapping	Sheng Gu (Biogen)

Session 3 - Product-Related Characterization

Topic 1: Protein modifications	Li Tao (BMS)

Topic 2: Glycosylation	Carlito Lebrilla (University of California Davis)
Topic 3: Sequence variant analysis	Melissa Alvarez (Genentech)

Session 4 - Process-Related Characterization

Topic 1: Host cell protein analysis	Jenny Thompson (MedImmune)
Topic 2: Multiattribute testing	Rich Rodgers (Amgen)
Topic 3: Bioreactor monitoring	Mike Reily (BMS)

Session 5 – Higher Order Structure Analysis - Footprinting

Topic 1: FPOP	Mike Gross (Washington University)
Topic 2: Protein painting	Alessandra Luchini (George Mason University)
Topic 3: Cross-linking	James Bruce (University of Washington)

Session 6 – Higher Order Structure Analysis – HDX-MS Applications

Topic 1: Epitope Mapping	Richard Huang (BMS)
Topic 2: Comparability	Damian Houde (Biogen)
Topic 3: Formulation/development	Zhonqi Zhang (Amgen)

Session 7 – Native MS

Topic 1: Ion mobility MS	Brandon Ruotolo (University of Michigan)
Topic 2: Non-covalent complex	Joseph Loo (UCLA)
Topic 3: Therapeutic antibodies	Albert Heck (Utrecht University)

Session 8- Antibody-Drug Conjugates

Topic 1: ADC discovery	Christoph Rader (The Scripps Research Institute)
Topic 2: ADC characterization	Melissa Ly (Pfizer)
Topic 3: HOS of ADC	Lucy Pan (Seattle Genetics)

Session 9 - In vivo Quantification

Topic 1: Pegylated proteins/mAbs	Tim Olah (BMS)
Topic 2: ADCs in vivo	Surinder Kaur (Genentech)
Topic 3: Target protein	Hendrik Neubert (Pfizer)

Session 10 - Biosimilars

Topic 1: Regulatory perspective	Michael Boyne (FDA)
Topic 2: Reference mAb	Jeffrey Hudgens (NIST)
Topic 3: MS characterization	Andreas Seidl (Sandoz)