Biotherapeutics Interest Group Workshop 65th ASMS Conference and Allied Topics, June 3 - June 8, 2017, Indianapolis, IN Charles Cheng, Ph.D. and Ashley Ruth, Ph.D.

The Biotherapeutics Interest Group (formerly the Protein Therapeutics Interest Group) workshop, entitled "Biotherapeutics: Hot Topics" was held from 5:45 PM to 7:00 PM on Tuesday, June 6, 2017. Approximately 150 people attended the workshop.

The primary goal of the workshop was to inspire and promote discussion on the use of mass spectrometry in the biopharmaceutical industry. We hoped an open free-form conversation would allow the audience to speak freely and learn from one another. A pre-conference survey was created using SurveyMonkey to provide potential discussion topics for conversation within the workshop (see survey below). The workshop started with a brief introduction from the co-chairs, and then a panel of four selected industrial professionals joined the stage (Hanliu (Leah) Wang, Pfizer; Iain Campuzano, Amgen; Chenjie Ji, Nova Bioassay; and Zhirui Lian, Eli Lilly & Co.). The panelists introduced themselves and the discussion began on the two main areas around which questions were focused in the survey to foster discussion during the workshop. A few slides from the survey results, included below, on various topics related to biotherapeutics characterization served as a starting point for our discussion.

The discussion began with a focus on "Native MS Strategies and Applications". After a brief introduction of the topic by Charles Cheng, the panelists shared their experience and unique advantages of using native MS in their own laboratories. Workshop attendees from several different companies and government agencies also shared their perspective on the use of native MS. Applications ranged from monoclonal antibodies to ADCs to nanodiscs and more. Lively exchanges on the proper control on the native ESI and cautions on over-interpretation of the date were also carried out among audience members and panelists/chairs. Active discussion occurred without the need to provide prompts from 'backup' questions prepared to encourage discussion.

Our conversation then moved on to discuss 'Mass Spectrometry Software for Biotherapeutics: Challenges and Strategies." Attendees and survey respondents used a mixture of software available from a variety of vendors, including but not limited to instrument vendors. Many were also using vendor-independent software packages. A desire for deconvolution software to improve for not only monoclonal antibodies, but also ADCs, was also discussed. Positive feedback regarding the GeneData product that accounts for two harmonics for deconvolution of spectra was mentioned, but a limited number of workshop attendees had experience with the product.

Overall, the audience was very engaged and there was a lot of informative discussion. The workshop was adjourned around 7pm. Next year, Charles Cheng will tentatively be joined by Olga Friese from Pfizer as the Biotherapeutics Interest Group workshop organizers.

Slides presented to the audience at the Biotherapeutics Workshop.

Biotherapeutics Interest Group 2017

Tuesday, June 6th, 2017 Room 231 – 234 5:45 PM – 7:00 PM

Co-chairs: Charles Cheng (Amgen) and Ashley Ruth (BioTechLogic)

Panelists

- Olga Friese & Hanliu (Leah) Wang, Pfizer
- Iain Campuzano, Amgen
- Chenjie Ji, Nova Bioassay
- Zhirui Lian, Eli Lilly

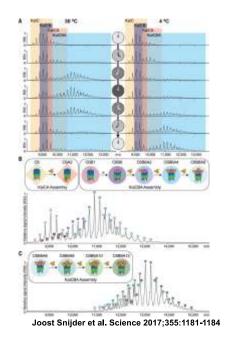
Workshop Goals

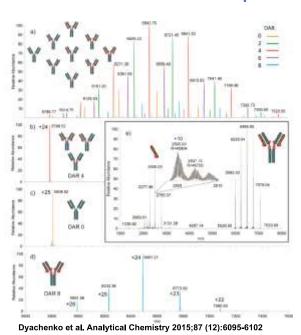
- Provide an additional venue for discussion of hot topics in the field of biotherapeutics beyond the poster and oral sessions
- Foster interactive discussions among scientists with varied backgrounds with a common interest in biotherapeutics
- Identify other areas where additional future discussion would be useful in advancing biotherapeutics

Workshop Agenda

- Discussion of Survey Results
- Introduction of Panelists
- Native MS Strategies and Applications for Biotherapeutics
- MS Software: Challenges and Strategies
- Open Q&A

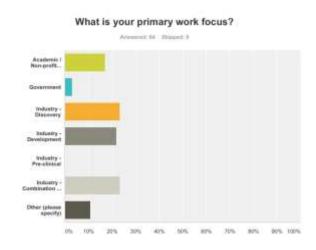
Native MS Strategies and Applications for Biotherapeutics



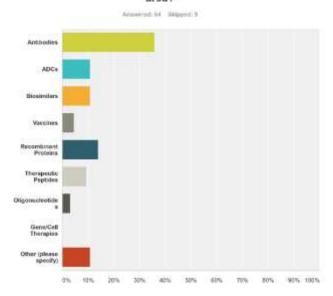


Biotherapeutics workshop survey and results

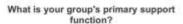
Survey Results

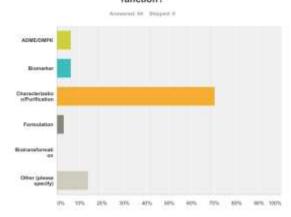


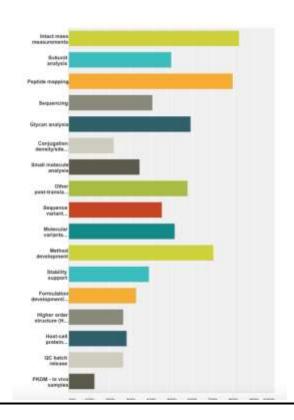
What is your specific biotherapeutic focus area?



Survey Results







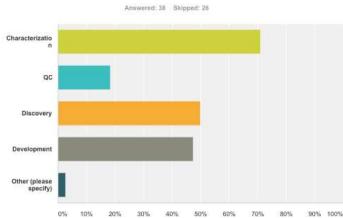
Survey Results

Are Native-ESI/protein complex workflows being used in your laboratory?

Answered: 64 Skipped: 0

- Ion mobility mass spectrometry
- Cysteine Conjugated ADCs, ADC Analysis
- Native Protein Interactions

Where is native ESI and/or protein complex analysis being used in your laboratory?



- HMMS
- **Trisulfide Characterization**
- Structural Evolution in Gas Phase

Survey Results

What types of MS software tools are used in your laboratory? (choose all that apply)

