Biotherapeutics Interest Group Workshop
66th ASMS Conference and Allied Topics, June 3 - June 7, 2017, San Diego, CA

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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 Monday, Jun. 4, 2018. 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 a 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 (Hao Zhang and Pavel Bondarenko, Amgen; Paul Brown, Pfizer; Igor Kaltashov, University of Massachusetts and Lin Liu, Sanofi). 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 "Novel Modalities beyond mAbs". Most discussion revolved around characterization of bispecific antibodies, with questions from Amgen and Pfizer on characterization of mispairing. Based on the survey, 5-15% of survey respondents reported that they work on vaccines, oligonucleotides, gene therapies, cell therapies, and/or nanoparticles. However, the general impression during the discussion was that the experience in these areas were still limited, and discussions have not been very active.

Our conversation then moved on to discuss "Novel Separation in Conjunction with Mass Spectrometry". Based on pre-meeting survey, a range of separation techniques are being used, including ~100% use RP, ~50% HILIC, and SEC, ~25% use IEX, CE, Normal phase. A majority of the survey respondents see utility of directly coupling SEC, CE, and IEX to MS. Discussions during the workshop echo the survey results, with particularly IEX being brought to central stage. This is an area that new approaches and methods are actively being developed, from both pharmaceutical companies, as well as instrument vendors.

In addition, a topic of size exclusion chromatography and challenges in quantitation of aggregate was discussed for roughly 10-15 min. The discussion brought to light bio-relevance of higher oligomer vs. dimer based on SEC, as well as issues of response factor in UV vs. MS response.

Towards the end of the workshop, discussion moved briefly to the topic of forced degradation and stability studies and their relation to understanding biotherapeutic structure-function. Bio-relevant methods for force degradation, techniques to characterize degradation, and relevant product/critical quality attributes may be a topic of interest for next year's workshop.

Overall, the topic of novel modalities, particularly gene therapy turned out to be a topic that is too new to the audience, and the discussion was not very active. This is something the future workshop organizers should keep as a lesson. The attendance of the workshop was high, a reflection of interest from broad attendees of ASMS. The workshop was adjourned around 7pm. Charles Cheng will be rotating off after this year. Hao Zhang (hzhang01@amgen.com) from Amgen, as well as Jon Reed (Jon.reed@boehringer-ingelheim.com) from Boehringer Ingelheim volunteered to help with the workshop next year. It should be note that Hao was one of the panelist this year, and we propose to have Hao Zhang of Amgen to join Andrew Dawdy of Pfizer as the Biotherapeutics Interest Group workshop organizers.