Biotherapeutics Interest Group Workshop
67th ASMS Conference and Allied Topics, June 2 - June 6, 2019, Atlanta, GA

Andrew Dawdy Ph.D. and Hao Zhang, Ph.D.

The Biotherapeutics Interest Group (formerly the Protein Therapeutics Interest Group) workshop, entitled "MS-Based Multi-Attribute Method (MAM): The Future of Biotherapeutic Development Analytics", was held from 5:45 PM to 7:00 PM on Monday, Jun. 3, 2019. Approximately 200 people attended the workshop.

The primary goal of the workshop was to inspire and promote discussion on application of Multi-Attribute Method (MAM), an emerging mass spectrometry-based methodology with the potential to significantly transform standard analytical practice for biotherapeutic development across the biopharma industry. MAM's popularity has exploded as evidenced by the formation of an industry-wide MAM Consortium, assessment of its suitability by the FDA, and the rapid growth in MAM-centric products from numerous vendors. We hoped an open a free-form conversation would allow the audience to speak freely and share MAM information and knowledge across biotherapeutic industry.

The workshop started with a welcome note from the co-chairs, and then a general introduction of co-chairs and a panel of six selected industrial professionals (Richard Rogers from Just Biotherapeutics, Da Ren from Amgen, Douglas Richardson from Merck, Fateme Tousi from Sanofi, Sergei Saveliev from Promega, Leah Wang from Pfizer). The first section was the brief introduction of Multi-Attribute Method (MAM) by Andrew. His introduction covered the basics and history of MAM, example MAM workflow et al. The introduction closed with a list of proposed topics for following discussion: 1) Characterization/PQA library Generation; 2) Routine Monitoring and New Peak Detection; 3) MAM in non-GMP vs GMP environments. Those three major topics can be detailed into many aspects of MAM like sample preparation, instrumentation, system suitability, software and user experience.

Each panel member provided individual summary about the topic they wanted to prompt discussion around. The discussion began with a focus on "MAM in hotspot characterization". Fateme gave a short presentation about how to use MAM to support hotspot characterization work. Most discussion revolved around what is the MAM capability to replace numerous routine chromatographic and electrophoretic assays used in batch release for characterization and monitoring the PQAs that contribute to product-related heterogeneity such as N-glycosylation, charge isoforms, oxidation, fragmentation, and aggregation. One detailed discussion was about using trypsin only MAM data for many challenge attributes like fragmentation.

The discussion was moved to the MAM initiation effort from worldwide industry, especially the MAM consortium. Richard and Da provided an update about the progress of this effort. Further discussion point centered around using a MAM readout to replace traditional assay readout in market application to regulatory agencies. The consortium discussion was followed by another popular topic, MAM in non-GMP vs GMP environments. This is an area that is actively being discussed from both pharmaceutical companies, as well as instrument vendors. Many detailed topics related to GMP testing

were brought up by the panel members and audience. Towards the end of the workshop, discussion moved briefly to the topic of available software support for MAM.

Overall, the topic of PQA monitoring by MAM was very popular and the discussion was very active. The attendance of the workshop was high, a reflection of interest from broad attendees of ASMS. The workshop was adjourned around 7pm. Andrew Dawdy will be rotating off after this year. Yuping Zhou from Eli Lilly, as well as Richard Rogers from Just Biotherapeutics volunteered to help with the workshop next year. It should be note that Richard was one of the panelist this year, and we propose to have Richard Rogers (Richard.rogers@gmail.com) to join Hao Zhang of Amgen as the Biotherapeutics Interest Group workshop organizers.