ASMS Biotherapeutics Interest Group Workshop

71st ASMS Conference on Mass Spectrometry and Allied Topics, June 4 -8, 2023, Houston, TX

Presiding: Da Ren, BioTherapeutics Solutions; Andrew Mahan, Janssen

The Biotherapeutics Interest Group workshop, entitled "New Aspects in the Development and Implementation of MAM", was held from 5:45 PM to 7:00 PM on Monday, June 5, 2023. The primary goal of the workshop was to inspire and promote discussion on the latest development and applications of Multi-Attribute Method (MAM) in the biopharmaceutical industry.

The workshop started with a welcome note from the co-chairs, and then a general introduction of co-chairs and five selected panelists including Sarah Rogstad from FDA, Li Jing from US Pharmacopeia (USP), Andrew Dawdy from Pfizer, Silvia Millan Martin from The National Institute for Bioprocessing Research and Training (NIBRT) in Ireland, and Ken Cook from Thermo Fisher Scientific.

After the panel introduction, three polling questions were presented to the workshop attendees:

1. Are you using MAM?
2. Where are you using MAM? (Characterization or QC?)
3. Do you use new peak detection?

Most of the attendees are using MAM with around 10% using MAM in QC. About half of the attendees are using the new peak detection function. The discussion started immediately after the polling questions. The first question from the audience was "What is MAM?". The question was to seek the formal definition of MAM, and the clarification on the scope of MAM. Li from USP and workshop co-chairs provided the definition of MAM quoting the upcoming USP MAM chapter <1060>, which defines MAM as the LC-MS peptide mapping method with proper controls, and MAM has two stages: Characterization stage and Monitoring (QC) stage. The consensus from the audience is that the major hurdle they encountered during the implementation of MAM is not the technical aspect, but rather the unwillingness to change from the routine use of conventional assays. Sarah from FDA got many questions on regulatory filings using MAM. In general, Sarah encouraged the sponsors to contact the FDA Emerging Technology Team (ETT) before submitting the regulatory filings, and it's a case-by-case decision depending on the nature of the use of MAM in the filings. Andrew from Pfizer, Silvia from NIBRT, and Ken from Thermo provided some examples and comments on MAM implementation from pharmaceutical companies and vendors' point of view.

The workshop was adjourned around 7pm. Da Ren will be rotating off as the workshop co-chair after this year. Sarah Rogstad from FDA (Sarah.Rogstad@fda.hhs.gov) will take the co-chair role together will Andy Mahan in the 2024 workshop.