

Title and Date: New aspects in the development of Multi-Attribute Method (MAM), June 3rd, 2020

Description: The advances of new indication and therapeutic modalities in the pharmaceutical industry drives the development of new analytical methods that provide enhanced content in a more efficient manner. In the past of decade, liquid chromatography (LC)-mass spectrometry (MS)-based Multi-Attribute Method (MAM) has successfully demonstrated its capability in replacing traditional chromatographic and electrophoretic testing methods for monitoring both product and process quality attributes (Rogers et al., AAPS J, 2017). As we enter a new decade of technology and method development, MAM and its original initiation of MS in QC are facing many new aspects. Recent advances in mass spectrometry instrumentation have provided novel opportunities in reforming the original MAM. The industry-wide MAM Consortium inspires method development and diversity for new MAM approaches that are fitting into different applications in biopharma R&D schemes. New/multiple enzyme digestion approaches, subunit analysis-based MAM, fully automatic sample preparation, compact MS for MAM in QC and new data acquiring approaches like PRM have been presented recently. The biotherapeutic interest group workshop offered a forum for members to share and discuss those new aspects in the development of MAM. Each panelist provided a short introduction to how they were leveraging MAM followed by a discussion on the current state of the technology and future directions for MS-based MAM.

Organizers: Rich Rogers (Juno Therapeutics), Da Ren (Amgen), and Hao Zhang (Amgen)

Panelists: Yuko Ogata (Just-Evotech Biologics), Carly Daniels (Pfizer), Shawn Li (Merck), Chris Yu (Genentech), Trina Mouchahoir (NIST/IBBR), Ting Song (Amgen)