Multi-Attribute Method (MAM): New Aspects in Development

(Interest Group: Biotherapeutics)
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The primary goal of the workshop was to provide education and advice regarding the implementation and use of a mass spectrometry based muti-attribute method for biotherapeutic characterization and release from the quality lab. This was mediated through questions and answers with an expert panel consisting of Yuko Ogata (Just-Evotec), Feng Yang (Genentech), Sara Carillo (NIBRT), Brent Kochert (Merck) and Rich Rogers (Umoja Biopharma).

The workshop began with a welcome and a general introduction of the panelists. Each panelist was then invited to give a ~5 minute rapid-fire presentation on their offering or experience with MS-based MAM. The floor was then opened for comments and questions. Topics included application of MS based MAM in the development lab and quality control (QC) lab, software used for MAM, and specifically how to apply new peak detection for MAM analysis.

New peak detection (NPD) (differential analysis) is the cornerstone of MS-based MAM. The goal of MS-based MAM is to reduce the QC footprint and replace conventional assays used to release biotherapeutics. NPD is essential to replace current purity methods like charge variant analysis or reduced capillary electrophoresis. NPD compares a reference data file to a test data file. The workshop focused on how to successfully apply NPD in the development lab with the goal of transferring MAM to the QC lab. Each panelist gave their perspective on how to successfully utilize NPD. The panelists and audience were at different stages of MAM implementation which provided a rich discussion on how mass spectrometry is currently used by biopharma.