

Pharmaceutical Interest Group Workshop
Mass Spectrometry-Based Process Analytical Technology (PAT)
67th ASMS Conference and Allied Topics, June 2 - June 6, 2019, Atlanta, GA
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The Pharmaceuticals Interest Group workshop, entitled “Mass Spectrometry-Based Process Analytical Technology (PAT)”, was held from 5:45 PM to 7:00 PM on Wednesday, Jun. 6, 2019. Approximately 100 people attended the workshop.

The primary goal of the workshop was to provide education and advice regarding what is available and practiced in the world of mass spectrometry-based PAT. This was mediated through questions and answers with an expert panel consisting of three vendors offering various forms of MS-based PAT technology (Sean McCarthy-Sciex, John Gebler-Waters, and Glenn Harris-908 Devices), and two biopharmaceutical scientists currently implementing PAT in their organizations (Jonathan Bones-NIBRT and Da Ren Amgen). We hoped an open a free-form conversation would allow the audience to speak freely about their concerns, hopes, and experience with MS-based PAT.

The workshop began with a welcome from the co-chairs and a general introduction of the panelists. Each panelist was then invited to give a ~5 minute rapidfire presentation on their offering or experience with MS-based PAT. The co-chairs proceeded to open the floor for comments and questions. Topics included application of MS for real-time (on-line / at-line) analysis of in-process materials, quality by design (QbD), continuous biomanufacturing, automated sample handling / preparation, automated data processing (e.g. intact deconvolution), novel technologies for MS-based charge isoform characterization, application of proteomics or metabolomics to support process development, and others.

The audience was very engaged and discussion continued without breaks during the entire workshop. There appeared to be a sound agreement in the value of MS-based PAT in the development space, though a minority of the workshop attendees were yet employing MS-based PAT in their work. This appears to be due to the lack of out-of-the-box solutions that are friendly to a wide audience, but it was evident that vendors are working to remedy this. Some examples of MS-based PAT in practice were very compelling, such as Jonathon Bones’ LC/MS workflow driven by a MAST system that allows for online titer determination by ProA, aggregation analysis by SEC-MS, charge variant analysis by IEX-MS, and subunit/glycoform monitoring by RP-MS.

While great value in MS-PAT was seen in the development space, fewer saw the driver of MS-based PAT being its use in continual monitoring of CQAs during GMP and commercial manufacturing. The majority thought was that it is best to gain strong knowledge of attributes and their relationship to the process such that we do not need to directly monitor attributes during manufacturing processes. Still, there was brief discussion around the idea of using MS-based PAT to provide automatic feedback during a manufacturing process, indicating that this idea has at least been considered though nobody claimed to be implementing this.

Overall, the topic of MS-based PAT was popular and the discussion was very active. The attendance of the workshop was high, a reflection of interest from a broad attendees of ASMS. The workshop was adjourned around 7pm. Andrew Dawdy will be rotating off after this year. and Richard Rogers will be selecting a new co-chair as replacement.