- **Title of workshop**
    - MS-Based Process Analytical Technology (PAT): Monitoring Everything from Large Molecules to Cell Therapies

- **Date of workshop**
    - June 4, 2020

- **Organizers/Presiders list**
    - Richard Rogers – BMS (Richard.rogers@junotherapeutics.com)
    - Glenn Harris – 908 Devices Inc. (gaharris@908devices.com)

- **Description or goals of workshop**
    - The biotherapeutic landscape is continuously changing. The modalities used to treat patients include large molecules, small molecules, and cell and gene therapies. A significant goal of biotherapeutic process development (PD) is to produce the same high-quality product in every experiment regardless of scale. To achieve this goal, PD scientists need to employ process analytical technologies (PAT) that can provide data on the upstream process (e.g., temperature, pH, glucose, amino acids, cell viability, and metabolites), downstream process (e.g., process-related impurities and host-cell impurities) and product quality attributes of the final product (e.g., charge isoforms, aggregates, glycoforms, cell viability, and CAR frequency). Mass spectrometry (MS) is a precious tool for characterizing drug substance and drug product for every type of modality. MS is used to identify critical quality attributes that affect the safety and efficacy of the drug product. However, MS-based PAT may also be used to characterize in-process molecules and study other upstream and downstream parameters that dictate the attributes of the final drug product. This workshop will be an interactive discussion amongst a panel of experts and the workshop attendees on the current state of mass spectrometry-based PATs and how they are improving PD. Topics may include application of MS for real-time (on-line / at-line) analysis of in-process materials, automated sample handling/preparation, automated data processing, charge isoform characterization, and characterization and monitoring of cell therapy products and intermediates. Please join us to ask questions, share your knowledge and experience, and discuss the future of MS-based PAT.

- **Titles and summaries of presentations**
    - There were four presentation in total
        1. Richard Rogers gave a general outlook and general use of PAT MS methods used at his organization
        2. Glenn Harris showed slides outlining the typical problems associated with at-line spent media analysis for bioprocesses and his organization's new analyzer, the Rebel, that address many of those issues.
        3. Cédric Mesmin (Merck KGaA) presented a thorough case study on his team's use of PAT MS to monitor a variety of process parameters and critical quality attributes of fermentation processes.

4. Zachary Dunn (Merck) reviewed the latest developments with their end-to-end semi-autonomous PAT suite monitoring samples straight from a benchtop bioreactor.