Table 4: Peak ID

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Scope:

Capillary electrophoresis (CE) is an effective tool for the analysis of charge and size variants of protein, nucleotide, and small molecule pharmaceuticals. As such, CE is routinely included in characterization and control system toolkits to ensure product purity, structure, and stability during development and manufacturing. While CE provides exquisite separations of product variants, direct peak identification can be challenging due to limited mass throughput, complexity of buffer components, and/or challenges related to direct coupling to mass spectrometers. This roundtable aims to discuss the technical strategies, challenges, and solutions offered by currently available tools for CE peak identification as well as identify new opportunities for development in this space.

Questions for Discussion:

1. At what stage in development do you determine the identity of peaks? Once the identity is determined, how is this information used? How is the impact of the peak identity determined?
2. What methods and technologies do you use to identify peaks? Are these methods "platform" or is molecule specific development required? Is identification performed at the peak region level or are individual peaks identified? If both, under what circumstances is individual peak ID necessary?
3. What challenges do you face in identifying peaks in CE methods? How can we overcome these challenges? Is there a need for new technologies to be developed?