

The Four M's of Protein Analytical Chemistry; Minimalist, Miniaturization, Multiplexing, and Managing the Analytical Technology for the Characterization of Proteins

Chuck Demarest¹, Rob Dufield¹, Nathan Lacher¹, Jeff Schneiderheinze¹,
Yining Zhao² and Gary Bild¹

¹Analytical R&D, Pfizer Global R&D
Chesterfield Parkway, Chesterfield, MO 63017

²Analytical R&D, Pfizer Global R&D
Eastern Point Road, Groton, CT 06340

Various strategies have been developed for integrating the development and qualification of analytical technology for the characterization of a protein, specifically monoclonal antibodies (mAb). Although monoclonal antibodies are regarded as having a high level of structural complexity and product heterogeneity, a **Minimalist** analytical approach has been developed for the analysis of these molecules. The minimalist analytical approach includes the development, qualification, and utilization of "Platform" analytical methods for the release and stability testing of the drug substance and the drug product. The Platform analytical methods were developed such that they can be utilized within a R&D and Commercial environment, as well as by Contract Research Organizations (CRO's). The enhancement of micro-fabrication technology can be utilized for the analysis of protein proteolytic maps. Thus, **Miniaturization** via chip technology can be utilized for the analysis of proteolytic methods required for the characterization of a protein. As the workload increases within the laboratory and higher throughput is required, the need arises to **Multiplex** the analytical technology. For a protein analysis the multiplex concept involves performing an on-chip proteolysis using immobilized enzyme in one channel followed by the on-chip separation in a second channel. The term multiplex can also be defined as performing parallel analyses on the same chip. As a result of increasing the sample throughput the need arises to **Manage** the information that is being generated. In order to improve the throughput of the lab in the future, parallel analytical technology as well as an integrated informatics system will need to be developed. This presentation will discuss the challenge of developing enabling analytical technology for protein characterization as it relates to how the four **M's** are being utilized in today's environment, as well as in the future.