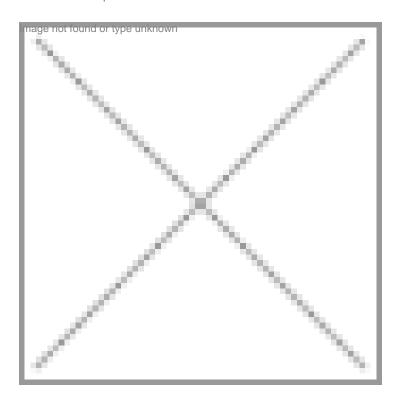


Mass Spectrometry in Characterization of Biotherapeutics

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-Dr. John C Gebler, director, Biopharmaceutical Sciences, Waters Corporation

Mass spectrometry (MS) has been a useful tool for chemists and scientists for almost 100 years. The technology hasevolved it a rapid pace. It took over 70 years to develop technology that would allow the mass analysis of biopolymers. In the late 980's electrospray ionization (ESI) methods were demonstrated to obtain good mass analysis of intact proteins. This nethod quickly became commercial instrumentation in the early 1090's. Since ESI-MS acted upon aqueous samples, the nterfacing of liquid chromatography (LC) soon became a standard method.

n 1997, Waters Corporation acquired MicroMass. This marriage brought together a premier MS manufacture with a premier LC company. At that time, proteomics was at its genius and evolving rapidly. This positioned Waters as a major supplier of LC and quadrupole time of flight (QTof) MS systems of complex peptide mixtures from biological samples.

More recently, Waters has become a global player in providing system solutions for the characterization of biopolymers. A system solution is defined as the combination of sample prep, LC, column chemistry, MS system, and informatics. Each element has been optimized to provide extraordinary performance, robustness, and engineered simplicity. Today, mass characterization of intact monoclonal antibodies with high mass accuracy is routine and can be completed in four minutes. Peptide maps benefit from UPLC systems resulting in high resolution separations and reproducibility. Today, informatics tools the BiopharmaLynx have greatly reduced the burden of data analysis. Currently there are solutions for intact proteins,

peptide maps, synthetic oligonucleotides and peptides, glycans, amino acid analysis, and media analysis.