NEW SOFTWARE FOR BIOPHARMACEUTICAL CHARACTERIZATION

Improves productivity and usability of data in development process

The pharmaceutical industry’s development pipeline is embracing a higher percentage of biopharmaceutical investigation, including proteins, antibodies, vaccines, peptides, and nucleic acids. Due to the inherent heterogeneity of biopharmaceuticals, detailed characterization results must be provided as part of a regulatory submission. Mass spectrometry plays a critical role in characterizing protein pharmaceuticals.

Waters’ accurate mass instruments combine with market-leading UPLC® technology for powerful analysis of the mass and heterogeneity of intact proteins, and for confirming the expected primary sequence. Waters systems also excel at determining modifications to the expected sequence, such as glycosylation, oxidation, and deamidation.

Waters software meets the similar needs to improve researchers’ ability to analyze and report biopharmaceutical characterization data, converting a primarily manual process and bottleneck in labs to a seamlessly efficient step in the development process. The BiopharmaLynx™ Application Manager for MassLynx™ software, developed in collaboration with leading characterization scientists at major biopharmaceutical firms, automates the process of data analysis and reporting of mass spectrometry characterization information for protein therapeutics.

With BiopharmaLynx, data analysis and reporting that had taken up to several days per sample can now be achieved in a matter of hours. The software greatly improves the productivity of both peptide mapping and intact mass LC/MS characterization studies.

**BiopharmaLynx features:**

- Automatically processes time-of-flight MS data, including peptide map results and intact mass measurements
- Automatically analyzes and assigns results, defining the sequence/features of known proteins, and determining the ID of modified forms
- Automatically generates biopharmaceutical-specific reports
- Allows users to edit assignments, annotate new peaks, and compare experimental samples to a reference by using tabular and graphical visualization tools
BiopharmaLynx for peptide mapping

- Identifies and quantifies ions in a peptide map, including intra- and inter-sample relative quantitation

- Assigns ions to expected and modified peptides from a defined protein sequence, determining sequence coverage and ID-modified peptides

BiopharmaLynx for analysis of intact proteins

- Deconvolution settings can be defined for known proteins, and as generic for unknown proteins

- Annotates deconvoluted mass data with protein identities and their modifications

- Automatically calculates percentage of each protein variant

By combining BiopharmaLynx with ACQUITY UPLC® and exact mass instruments, including the Synapt™ HDMS™ system, Waters delivers total system solutions for biopharmaceutical labs that enable them to get new therapies to market faster.