BioSpectrum
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ASIA EDITION

Waters BioAccord system boosts biosimilar drug development and commercialization

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End-to-End compliant-ready workflow helps biotherapeutic protein manufacturers meet regulatory and attribute-based product analysis requirements for drug identity, purity, and quality

Waters Corporation introduced a new peptide multi-attribute method (MAM) workflow for the Waters™ BioAccord™ LC-MS System, enabling drug development, manufacturing, and QC scientists to monitor efficacy and safety through the analysis of critical quality attributes (CQAs) of monoclonal antibodies (mAbs) and other protein-based drugs.

New Peptide MAM (multi-attribute method) workflow for the BioAccord LC-MS System monitors product quality attributes that can affect efficacy and safety of innovator drugs and biosimilars. Now, scientists can have a single, sensitive multiplexed method to accurately assess the most important attributes of protein-based drugs that enable rapid decision-making for product development, manufacturing, and release.

The peptide MAM workflow for the BioAccord System monitors for:

- Product variants
- Product degradation and impurities
- Process stability-indicating modifications

“Waters BioAccord System meet the needs for robust and reproducible results with full traceability and data integrity from injection to reporting. Automated workflows for intact mass, peptide mapping and monitoring as well as for released N-glycans analysis provide us with reliable results quickly” says Dr. Arnaud Delobel, R&D Director, Quality Assistance, CRO, Belgium. Quality Assistance uses the Waters BioAccord System as part of a comprehensive portfolio of mass spectrometry services it provides to the pharmaceutical industry.

The BioAccord System pairs the ACQUITY™ UPLC™ I-Class Plus with the ACQUITY RDa™ Mass Detector featuring SmartMS™ enabled usability features. The system offers a wide range of users with varying MS experience, industry-leading automated setup and self-diagnosis capability delivered through modern instrument control software and an intuitive user interface, all within a small footprint. In addition to peptide MAM, the BioAccord System also features workflows for other routine analyses of biotherapeutics: peptide mapping, intact/subunit mass analysis, released glycan profiling and oligonucleotide mass confirmation.

waters_connect™: A Single, Platform for LC and LC-MS Applications

waters_connect is a compliant-ready informatics platform enabling scientists to manage functionality of BioAccord System in workstation or laboratory networked deployments. It’s a growing platform of streamlined purpose-built applications that enhances the value that the BioAccord System brings to everyday sample analysis. Providing a complete audit trail for acquisition, processing and reporting of data, waters_connect meets and exceeds expectations for regulatory compliance, while maintaining the highest standards of data integrity.