

Waters Peptide Multi-Attribute Method for BioAccord System Boosts Innovator and Biosimilar Drug Development and Commercialization

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New End-to-End Compliant-Ready Workflow Helps Biotherapeutic Protein Manufacturers Meet Regulatory and Attribute-Based Product Analysis Requirements for Drug Identity, Purity, and Quality

NEWS SUMMARY:

- 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.
- End-to-end streamlined LC-MS workflow for analyzing monoclonal antibodies and other protein and peptide-based drugs.
- Workflow on waters_connect compliant-ready informatics platform easily facilitates creating Peptide MAM and delivering results.
- Alerts user whenever a measured attribute falls outside specifications
- New Peak Detection feature flags unexpected peaks and minimizes false positives.

MILFORD, Mass.--(BUSINESS WIRE)-- Waters Corporation (NYSE:WAT) today 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.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210318005518/en/>

New Peptide MAM (multi-attribute method) workflow for the BioAccord LC-MS System monitors product quality attributes that can affect efficacy and

“The BioAccord System moves attribute-based monitoring out of centralized MS labs and into

safety of innovator drugs and biosimilars. (Photo: Business Wire)

the hands of more scientists in regulated and quality control laboratories who may not have extensive experience operating mass spectrometers,” said Jeff Mazzeo, Ph.D., Vice President – Global Marketing and Scientific Operations, Waters Corporation. “With this new method for the BioAccord System on the waters_connect platform, scientists 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

Quality Assistance, a leading contract research organization based in Belgium, uses the Waters BioAccord System as part of [a comprehensive portfolio of mass spectrometry services](#) it provides to the pharmaceutical industry.

“Investing in state-of-the-art equipment is essential for remaining at the forefront of analytical sciences,” says Dr. Arnaud Delobel, R&D Director, Quality Assistance. “Our Waters BioAccord System strengthens our ability to meet the needs of customers 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.”

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.

Additional Resources

- Download the applications note: [A Streamlined Compliant-Ready Workflow for Peptide-Based Multi-Attribute Method \(MAM\)](#)
- Visit our web site: [BioAccord LC-MS System for Biopharmaceuticals](#)
- Watch the video: [Multi-Attribute Method Overview](#)
- Learn about waters_connect: [waters_connect: All Your Applications in One Interface](#)
- Read our blog post: [Biopharma's Future: Next-Generation LC-MS Workflows for Peptide MAM](#)
- Connect with Waters via [LinkedIn](#), [Twitter](#), and [Facebook](#)

About Waters Corporation (www.waters.com)

Waters Corporation (NYSE:WAT), the world's leading specialty measurement company, has pioneered chromatography, mass spectrometry, and thermal analysis innovations serving the life, materials, food and environmental sciences for more than 60 years. With more than 7,400 employees worldwide, Waters operates directly in 35 countries, including 14 manufacturing facilities, and with products available in more than 100 countries.

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