

Waters, Genovis focus on efficient workflows for biopharma characterization

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Firms Working to Co-Develop Automated Biotherapeutic Characterization Workflows, Combining Waters LC-MS Instrumentation and Genovis SmartEnzymes



Waters Corporation and Genovis AB are formally collaborating to develop and market complete routine biopharmaceutical characterization workflows based on the Waters™ BioAccord™ LC-MS System, Andrew+ pipetting robot and Genovis SmartEnzymes™.

The goal of the collaboration is to develop automated workflows for the rapid and consistent characterization of critical quality attributes (CQAs) of monoclonal antibodies (mAbs) and other protein-based drugs in bioprocess development, formulation, stability testing and quality control (QC).

The workflows in development are based on the pairing of the Waters BioAccord LC-MS System, Andrew+ pipetting robot and Genovis SmartEnzymes and will focus on addressing the application needs of GxP laboratories in the following areas:

- Product variant analysis [e.g. glycosylation, oxidation]
- · Bioprocess stability monitoring
- Biosimilar glycosylation analysis

"Biologics analysis is an area that is ripe for improvement. What takes analytical scientists several days to do, should take hours or minutes instead," said Jeff Mazzeo, Vice President, Global Marketing and Scientific Operations, Waters Corporation. "Today, up-front sample preparation is a major bottleneck to productivity, largely due to the number of manual steps involved and the outmoded technology by which samples are readied for analysis. By combining Genovis' SmartEnzymes with automation, liquid chromatography/time-of-flight mass spectrometry and application-specific software workflows from Waters, we intend to move biotherapeutic analysis forward in ways never thought possible."