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Waters and Sartorius Partner to Help Bioprocess Scientists Accelerate Clone Selection and Process Development

- Collaboration to combine the Waters™ BioAccord™ LC-MS System as a bioprocess analyzer with the Sartorius Ambr® bioreactor system gives bioprocess scientists both faster and direct access to advanced quality characterization information.
- Combination to accelerate turnaround time for robust data about critical quality and cell culture media attributes by several weeks, aiding bioprocess scientists in clone selection and process development.
- Companies to collaborate on opportunities for adapting analytical mass spectrometry methods to new modalities and incorporating its use in bioprocess monitoring, process control and Critical Quality Attribute (CQA) measurement.

Waters Corporation (NYSE: WAT) and Sartorius (DAX: SRT:GR) announced today they will partner to provide bioprocess experts with direct access to high-quality mass spectrometry (MS) data to accelerate the speed and improve the accuracy of biopharmaceutical process development. Sartorius and Waters will partner to implement the BioAccord™ LC-MS System from Waters as a new bioprocess analyzer with data connectivity to Sartorius' Ambr® multi-parallel bioreactor systems to deliver mass spectral information on drug substances, related analytes and cell culture media. This combination will greatly accelerate and improve the accuracy and speed of tasks from clone selection to bioprocess optimization.

At a ~10% CAGR from 2020 to 2025, biopharmaceuticals is the fastest-growing segment of the overall pharmaceutical market, according to a report by Evaluate Pharma. Fueling this growth is the unprecedented rate at which highly complex new biologics are coming to market. As a consequence, biopharmaceutical manufacturers are requiring more upstream analytical data than ever about drug product attributes and bioprocessing efficiency to enable the development of new, better, and more affordable medicines.

"Waters and Sartorius share a commitment to biopharmaceutical customers to solve their problems with the very best process and analytical tools," said Davy Petit, Senior Director of Global Pharmaceutical and Biomedical Research Business, Waters Corporation. "Clone selection and process development can benefit significantly from at-line versatile mass spectrometry data which can help bioprocess engineers

accelerate workflows and increase confidence in making critical decisions. The combination of our technology in the hands of bioprocess scientists, alongside the well-established Sartorius Ambr bioreactor systems installed-base, can significantly reduce the development timeline for delivery of medicines and vaccines.”

“The combination of Ambr and the easy-to-use at-line Waters BioAccord LC-MS System will save bioprocess scientists substantial time and accelerate clone selection and upstream process development,” said Mario Becker, Head of Product Management Cell Culture Technologies at Sartorius. “The closer we can bring fundamentally important MS data to the point where it is needed, and the more Ambr samples that can be tested for quality attributes, the better we can provide bioprocess scientists a more complete picture of drug product quality at any point during cell-line, media, and process development. Eventually, we can envisage such process control, monitoring and product quality testing being fully integrated into the manufacturing environment.”

Fast Access to Mass Spectrometry Data for Those Who Are Not Mass Spec Experts

Biological drugs are made by living cells in bioreactors like the Sartorius Ambr high throughput bioreactor system. At the conclusion of the cell culture process, the proteins are separated from the cell residue and samples are sent to a central laboratory to await testing by analytical scientists using specialist liquid chromatography-mass spectrometry (LC-MS) instruments. It’s not uncommon for the process to stretch across 2-4 weeks or more depending on the workload, equipment availability, priorities, and staffing levels of the central analytical laboratory.

The combined offering from Sartorius and Waters aims to shorten the process from what can take over a month to two days or less, while giving more control to bioprocess scientists to obtain robust mass spectrometry data for drug substance and cell culture media samples. The industry-leading range of Sartorius Ambr multi-parallel bioreactors has been developed to take scientists through the early steps of their upstream process from cell selection, through to process optimization. The Waters BioAccord System is a small footprint LC-MS instrument designed as an easy-to-operate, at-line benchtop bioprocess analyzer. Its pre-defined analytical methods, guided workflows, auto-calibration, and auto-tuning features allow those without any mass spectrometry experience to obtain high-quality mass spectral data within minutes.

Availability

Interested customers can contact both Waters and Sartorius:

- Waters Corporation contact: John_Gebler@waters.com
- Sartorius contact: Ian.Ransome@Sartorius.com

Additional Resources

- Learn more about the Sartorius-Waters collaboration
- Learn more about the Waters BioAccord System with ACQUITY Premier
- Learn more about Sartorius Ambr multi-parallel bioreactor systems

A profile of Sartorius

The Sartorius Group is a leading international partner of life science research and the biopharmaceutical industry. With innovative laboratory instruments and consumables, the Group's Lab Products & Services Division concentrates on serving the needs of laboratories performing research and quality control at pharma and biopharma companies and those of academic research institutes. The Bioprocess Solutions Division with its broad product portfolio focusing on single-use solutions helps customers to manufacture biotech medications and vaccines safely and efficiently. The Group has been annually growing by double digits on average and has been regularly expanding its portfolio by acquisitions of complementary technologies. In fiscal 2020, the company earned sales revenue of some 2.34 billion euros. At the end of 2020, nearly 11,000 people were employed at the Group's approximately 60 manufacturing and sales sites, serving customers around the globe.

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, and food 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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