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Waters and Sartorius Expand Collaboration to Deliver Comprehensive Bioanalytics for Downstream Biomanufacturing

- Integration of Sartorius' process scale multi-column chromatography with Waters' process analytical technology to provide robust analytical data for downstream biomanufacturing of mAbs, recombinant proteins, vaccines, and other biologics.
- Integrated solution to deliver vital analytical data in days, not weeks and to reduce waste and help lower drug production costs.
- Bioprocess scientists will be able to do product quality checks closer to the process, saving weeks
 of production time.ⁱ

Waters Corporation (NYSE:WAT) and Sartorius announced a new collaboration to develop integrated analytical solutions for downstream biomanufacturing, expanding their joint agreement that began with upstream bioprocessing analytics. Software and hardware integrations between the Waters[™] <u>PATROL[™]</u> <u>UltraPerformance Liquid Chromatography (UPLC[™]) Process Analysis System and the Sartorius[™] Resolute^{*}</u> <u>BioSMB[™] multi-column chromatography platform</u> will give bioprocess engineers access to more comprehensive analytical data for downstream batch and continuous manufacturing, improving yields while reducing waste and driving down biomanufacturing costs.

"From the beginning of our collaboration with Sartorius, we've strived to give bioprocess engineers faster and more direct access to critical quality attribute information about their drug products in the name of improving production yields and getting drugs to patients faster," said Jon Pratt, Senior Vice President, Waters Division. "Based on the positive response of customers to our collaborative efforts with upstream bioprocessing analytics, we see tremendous benefit to combining the PATROL Process Analysis System and the Sartorius BioSMB to bring timely point-of-decision analytics to downstream biomanufacturing for monoclonal antibodies, recombinant proteins, vaccines and AAV gene therapies."

"Now that intensified, continuous manufacturing of biologics is becoming a reality, there is a greater need for real-time analytical measurement," said René Fáber, Head of Bioprocess Solutions Division, Sartorius. "The value of combining technologies from Sartorius and Waters lies in bringing fundamentally important analytics to the point where it is needed and giving bioprocess engineers a more complete understanding of their downstream manufacturing processing and its effects on drug product quality. We believe this can have significant impacts on drug production costs by helping to increase yields and reduce waste."

In-process sampling and the analysis of biological drugs sent to a central laboratory can take weeks before the results of necessary quality checks are in. Waters and Sartorius have shown how bioprocess scientists

can streamline these analytics, so that product quality tests for protein A, aggregation and charge variants occur closer to the process, potentially saving weeks of production time. This has a positive impact on total process yield and product quality because the individual downstream unit operation can be further optimized much more easily, and corrective actions can be taken much faster.

Additional Resources

- Learn more about the <u>Sartorius Resolute BioSMB system</u>.
- Learn more about the <u>Waters PATROL UPLC Process Analysis System</u>.
- Follow and connect with Waters via <u>LinkedIn</u>, <u>Twitter</u>, and <u>Facebook</u>
- Follow Sartorius on <u>LinkedIn</u>, <u>Twitter</u>, and <u>Facebook</u>

A profile of Sartorius

The Sartorius Group is a leading international partner of life sciences research and the biopharmaceutical industry. With innovative laboratory instruments and consumables, the Group's Lab Products & Services division focuses on laboratories performing research and quality control at pharmaceutical and biopharmaceutical companies as well as academic research institutes. The Bioprocess Solutions division, with its broad product portfolio focusing on single-use solutions, helps customers manufacture biotech medications and vaccines safely, rapidly and economically. The company based in Goettingen, Germany, has a strong global reach with around 60 production and sales sites worldwide. Sartorius delivers significant organic growth and regularly expands its portfolio through the acquisition of complementary technologies. In fiscal 2022, the company generated sales revenue of around 4.2 billion euros. At the end of 2022, around 16,000 employees were working for customers around the globe.

About Waters Corporation

<u>Waters Corporation (NYSE: WAT)</u>, a global leader in analytical instruments and software, has pioneered chromatography, mass spectrometry, and thermal analysis innovations serving the life, materials, and food sciences for over 60 years. With more than 8,200 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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ⁱ Evolving Analytics in the Upstream Lab by Using the Power of LC-MS, a Waters/Sartorius webinar