

Sartorius Stedim Biotech Launches Chemistry Testing Services

Goettingen, GER | Glasgow, UK – May 4, 2017: Sartorius Stedim Biotech (SSB), a leading international supplier for the biopharmaceutical industry, announced the launch of a full range of chemistry testing services. Offered by its subsidiary BioOutsource, they characterize the physicochemical properties and structural attributes of therapeutic monoclonal antibodies (mAbs). The service platform methods have been developed to ensure rapid sample analysis and reporting for mAbs and biosimilars.

This comprehensive range of chemistry testing services complies with the well-established ICH Q6B scientific guidelines for pharmaceuticals for human use, and includes methods to characterize protein structure, carbohydrate profile, post-translational modifications and impurities utilizing UHPLC and LC/MS instruments. To provide these services, SSB has expanded laboratory space by 340 m² at its facility in Glasgow, UK, and has appointed new scientists with extensive chemistry testing experience.

This chemistry testing offer complements the company's existing range of off-the-shelf biological assays for biosimilar products, providing a complete solution from one contract partner. This allows structural and functional analyses to be conducted in parallel to deliver a comprehensive data package for regulatory submissions. As a result, the full-range of services enables SSB to even better support its customers in their drive to bring innovative biologic drugs to market.

"Rapid data-driven decisions at critical stages are crucial for the successful development of biosimilars. Our chemistry testing services enable biosimilar manufacturers to benefit from side-by-side biological and physicochemical analyses to gain the in-depth characterization data required," explained Dr. Daniel Galbraith, Chief Scientific Officer at Sartorius Stedim BioOutsource. "Expanding our portfolio with these new services was a logical step following the successful launch of our Released N-Glycan assay in 2016," he added.

To find out more about BioOutsource's new range of chemistry testing services please visit: <http://www.biooutsource.com/bioanalytical/physicochemical-and-structural-analyses/>.

Photo:

At its facility in Glasgow, Sartorius Stedim Biotech now offers a complete range of chemistry testing services.

Link for Download:

http://microsite.sartorius.com/fileadmin/newsletter/BioOutsource/Chemistry_Services.jpg

A profile of Sartorius Stedim Biotech

Sartorius Stedim Biotech is a leading international supplier of products and services that enable the biopharmaceutical industry to develop and manufacture drugs safely and efficiently. As a total solutions provider, Sartorius Stedim Biotech offers a portfolio covering nearly all steps of biopharmaceutical manufacture. The company focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Headquartered in Aubagne, France, Sartorius Stedim Biotech is quoted on the Eurolist of Euronext Paris. With its own manufacturing and R&D sites in Europe, North America and Asia and an international network of sales companies, Sartorius Stedim Biotech has a global reach. In 2016, the company employed approx. 4,700 people, and earned sales revenue of 1.051,6 million euros.

A profile of Sartorius Stedim BioOutsource Ltd.

Sartorius Stedim BioOutsource provides contract testing services to the biopharmaceutical industry. Our core offering includes a comprehensive range of services to support the testing of biologics, vaccines & biosimilars throughout their development. We possess an unparalleled combination of commercial, regulatory and technical knowledge that enables us to truly stand out as the industry's increasingly preferred testing partner. We understand the importance of our service to support our client's critical testing requirements and as a result, continually strive to provide a world class service globally.

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