

Sartorius Stedim BioOutsource Contract Testing Facility in Glasgow Successfully Passes FDA Inspection

Certified quality of analytical services for developers of biologics and biosimilars

Goettingen, GER | Glasgow, UK – March 2, 2016: Sartorius Stedim Biotech (SSB), an international leading supplier for the biopharmaceutical industry, is pleased to announce that the Glasgow facility of its subsidiary Sartorius Stedim BioOutsource Ltd. has successfully passed an inspection by the U.S. Food and Drug Administration (FDA).

In January 2016, the FDA Compliance Safety Officer spent two days at BioOutsource's facility reviewing its quality systems and their application to the analytical services that support the testing of biologics, vaccines and biosimilars. The inspection confirmed that the Glasgow site is compliant with the principles and guidelines of Good Manufacturing Practices (GMP). Not a single Form 483 observation for non-conformance was issued.

At the closing meeting, the FDA inspector was very satisfied with the facility and complimented Sartorius Stedim BioOutsource on its GMP systems, organisation during inspection and the expertise of its team members. The success of this FDA inspection, combined with the positive feedback from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in 2015, as well as reports from numerous biopharma clients that have visited and audited the Glasgow facilities in recent years, demonstrates BioOutsource's commitment to maintaining excellence in its quality systems.

Gerry Mackay, CEO at BioOutsource stated: "We're delighted with the positive outcome of our FDA inspection, because it shows that we are committed to offering quality analytical and safety testing. This provides biopharma firms with confidence that we are a partner they can trust with their biologic and biosimilar drug development programmes."

To find out more about accessing Sartorius Stedim BioOutsource's portfolio of analytical and biosafety testing services, scientists can click this link: <http://www.biooutsource.com>

Photo:



Laboratory at Sartorius Stedim BioOutsource facility in Glasgow, which was inspected by the U.S. FDA

Link for Download:

<https://www.sartorius.com/fileadmin/media/global/company/biooutsource-2016.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 a global network of sales companies, Sartorius Stedim Biotech has a global reach. The company employs approx. 4,200 people, and in 2015 earned sales revenue of 884.3 million euros.

A profile of Sartorius Stedim BioOutsource Ltd.

Since 2015 part of Sartorius Stedim Biotech Group, BioOutsource provides contract testing services to the biopharmaceutical industry. Its core offering includes a comprehensive range of services to support the testing of biologics, vaccines & biosimilars throughout development and manufacture. The company is dedicated to providing innovative solutions and delivering excellent customer service. With an unparalleled combination of commercial, regulatory and technical knowledge, BioOutsource truly stands out as the industry's preferred testing partner.



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