

Sartorius Stedim Biotech offers services for characterization of new biological entities (NBE)

Goettingen, GER | Glasgow, UK – January 23, 2019: Sartorius Stedim Biotech (SSB), a leading international supplier for the biopharmaceutical industry, announced the launch of services for new biological entities, called NBE Product Characterization. These services are offered by its subsidiary, Sartorius Stedim BioOutsource, an experienced, industry-leading contract testing organization based in Glasgow, UK, and in Cambridge, Massachusetts, USA.

Sartorius Stedim BioOutsource provides a comprehensive range of testing for innovator molecules available either as off-the-shelf assays or custom assay development for more complex proteins. Such tests include cell-based potency assays, bioassays and binding assays, as well as physicochemical and structural analyses, enabling customers to benefit from a fully integrated package. These testing services are fully customizable for clients to ensure their innovator drugs are tested based on the right regulatory requirements by expert scientists. Robust data packages proving the safety, purity and potency as required by the regulatory authorities will smooth the submissions process for approval by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

As a result of these fully customizable methods and data packages available for monoclonal antibody characterization that complement BioOutsource's and Sartorius Stedim Cellca's existing innovative offer for biologics, pharmaceutical companies can now work with one contract partner from cell line development to qualification and validation of analytical and biological product characterization assays.

"We are really excited to bring to market this combined package of assay development and customizable off-the-shelf solutions for product characterization. With our unrivalled experience in biosimilars testing, combined with our proven expertise in NBE assay development, we have developed a panel of assays suitable for mAb characterization. This allows drug developers to fast-track complex bioassay development using our platform methods. With fully compliant cGMP facilities, we support our customers from early phase development to late phase and commercial release," commented Jennifer Lawson, Product Manager for Testing at Sartorius Stedim BioOutsource.



Image Files:



Sartorius Stedim BioOutsource's testing services are fully customizable for clients to ensure their innovator drugs are tested based on the right regulatory requirements.

Links for Downloading:

Photo 1 (above): [SSB New biological entities 1](#)

Photo 2: [SSB New biological entities 2](#)

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 2017, the company employed approx. 5,100 people, and earned sales revenue of 1,081 million euros.

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