

Sartorius Stedim Biotech introduces new BIOSTAT STR® bioreactor range

- New generation of bioreactors combined with new Flexsafe STR® bags offer a fully scalable, single-use system
- Systems enable significant reduction of bioprocess development timelines and costs

Goettingen, Germany | Aubagne, France, April 27, 2017 – Sartorius Stedim Biotech (SSB), a leading international supplier for the biopharmaceutical industry, announced the launch of its next generation BIOSTAT STR®, a fully scalable, single-use bioreactor family based on a conventional stirred-tank design. This new bioreactor range featuring upgraded hardware and software, as well as a fully integrated, new design of Flexsafe STR® single-use bags, ensures quick and easy bioprocess scale-up of biologics and vaccines.

The BIOSTAT STR® bioreactors are equipped with an improved stainless steel bag holder for user-friendly installation of the single-use Flexsafe STR® bag. The bioreactor series consisting of five systems in different sizes offers working volumes from 12.5 L to 2,000 L. Because the bioreactors are designed with the same geometries as SSB's ambr® 250 mini bioreactor, the industry gold standard for scale-down, linear scale-up and process transfer from 250 mL to 2,000 L can be achieved in weeks rather than months using this innovative technology platform.

The new bioreactors and the newly introduced single-use Flexsafe STR® bags are a perfect match. The bags with advanced single-use sensor solutions are manufactured from a proprietary, robust multilayer S80 polyethylene film. The formulation of resins and additives for the film are fully characterized, and extrusion process parameters are controlled within established ranges, providing consistent batch-to-batch extractable and leachable profiles. The fully self-contained design of the new bioreactor with its single-use bag prevents product cross-contamination, saving time in set-up, validation, clean-in-place procedures and sterilize-in-place operations.

Besides using bags of the highest purity, the system is designed for efficient oxygen transfer, mixing and CO₂ stripping. These combined features ensure excellent cell culture performance with reproducible high-density growth of even sensitive cell lines. As a result, BIOSTAT STR® bioreactors are ideal for achieving very high cell densities in continuous processes and for safe manufacture of vaccines and recombinant proteins in cGMP environments.

The new bioreactor range provides greater flexibility in bioprocess control and data acquisition as software connectivity has been upgraded to allow integrated control by either BioPAT[®] MFCS software or commonly used third-party industrial distributed control systems (DCS), such as Emerson DeltaV[™] or Siemens SIMATIC PCS7.



Dr. Thorsten Adams, Director of Product Management for Fermentation Technologies at Sartorius Stedim Biotech, stated: "Direct linear scalability is crucial for ensuring the efficiency and cost-effectiveness of bioprocess development campaigns. Compared with conventional stainless steel vessels, our next generation BIOSTAT STR® bioreactors in combination with the ambr® 250 technology will help reduce process development timelines significantly. These highly scalable, single-use bioreactors are an intelligent, low-risk bioprocess development solution for use in multi-product facilities, as well as at contract manufacturing organizations, for the production of biologics and vaccines."

For more information about SSB's new BIOSTAT STR® bioreactor family and new Flexsafe STR® bags, click these links: www.sartorius.com/biostat-str and www.connect-upstream.com

Image Files:



Figures: top row, left to right, shows SSB's new BIOSTAT STR® 500L (open and closed view) and single-use Flexsafe STR® bag; bottom row: complete BIOSTAT STR® series of single-use bioreactors



Links for downloading:

Single-use bioreactor BIOSTAT STR® (500L) – closed and open view: www.sartorius.com/fileadmin/media/global/company/biostat str 500.jpg www.sartorius.com/fileadmin/media/global/company/biostat str 500 2.jpg

Single-use bioreactor series BIOSTAT STR®: www.sartorius.com/fileadmin/media/global/company/biostat_str_series.jpg

Single-use Flexsafe STR® bag: www.sartorius.com/fileadmin/media/global/company/flexsafe_str_bag.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.

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