

## **FlexAct: Integrated, systematic single-use solutions**

**A flexible operational unit simplifies the use of disposable equipment and ushers in a new level of biomanufacturing; FlexAct BP first in line of a whole new series**

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Goettingen/Aubagne, December 1, 2009 – Sartorius Stedim Biotech, a leading provider of state-of-the-art equipment and services for the biopharmaceutical industry, presents an innovative system for pre-configured single-use solutions to meet process requirements: FlexAct. Supporting the latest trends in biomanufacturing, FlexAct will enable biomanufacturers to utilize integrated single-use equipment for entire biomanufacturing steps in upstream and downstream processing. As a full-fledged workstation, FlexAct offers new possibilities for designing efficient and flexible production processes by using out of the box disposable unit operations. This new level of integration and standardization makes it easy for anyone who still uses stainless steel equipment or individual disposable components to convert to single-use unit operations.

FlexAct BP, the first member of a whole new series that Sartorius Stedim Biotech is launching, is designed for preparation of buffers that are essential for stabilizing target molecules and providing for their optimal production conditions. In biopharmaceutical processes, buffers, such as sodium phosphate, Tween and Tris, are particularly used in cultivation and fermentation as well as purification to maintain pH, salt content and other parameters of biologics within a desired range. The FlexAct BP system is based on a multifunctional central operating module (COM), which accommodates pre-configured single-

use assemblies and, moreover, a pump and a control unit. FlexAct BP addresses the entire development cycle and production capacity needs from 50 to 1,000 liters for buffer preparation. The integration of monitoring and control features for pH, temperature, pump speed and fluid level control reflects a new milestone for implementing process-relevant analytical tools. The integrated controls enable users to perform other tasks during the buffer preparation process without the need to supervise the system. In combination with a Flexel LevMixer®\* system and multiple Palletanks, the multifunctional COM lets users install, operate and monitor a unit operation completely based on single-use components.

The entire configurable FlexAct BP solution consists of a Flexel LevMixer® system, a weighing platform, a multiple bag assembly with Palletanks and the central operating module. Moreover, the COM takes up exceptionally little space. Its compact design enables users to easily maneuver it even in tight production spaces. Despite its space-saving dimensions, FlexAct provides ample room for accommodating extra equipment, such as a Sartochek filter integrity test system.

From lab to process, FlexAct features full scalability of all single-use components. Bags, filter capsules, tubing or connectors, whatever the components, Sartorius Stedim Biotech designers have these already pre-configured and assembled. As a result, these components are easy to install on the central operating module. Since they are single-use, they do not require lengthy set-up or cleaning. FlexAct systems support the reduction of production cycles and requested capacity improvements.

FlexAct makes it easy for users to find the right application-specific combination straight away: they can choose from a range of fully pre-configured system solutions. The standardized single-use components utilized in FlexAct harmonize and simplify validation and procurement.

Sartorius Stedim Biotech will soon introduce additional FlexAct solutions for media preparation (MP), cell harvesting (CH), ultrafiltration/diafiltration (UF/DF) crossflow, virus removal (VR), virus inactivation (VI), virus adsorption (VA), polishing (P), form /fill (FF) and for form/transfer (FT).

\* LevMixer is a trademark or registered trademark of ATMI, Inc. in the United States, other countries or both.

#### **A Profile of Sartorius Stedim Biotech**

Sartorius Stedim Biotech is a leading provider of cutting-edge equipment and services for the development, quality assurance and production processes of the biopharmaceutical industry. Its integrated solutions covering fermentation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry around the world to develop and produce drugs safely, timely and economically. For next-generation processes, Sartorius Stedim Biotech focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Strongly rooted in the scientific community and closely allied with customers and technology partners, the company is dedicated to its philosophy of "turning science into solutions" on a daily basis.

Headquartered in Aubagne, France, Sartorius Stedim Biotech is listed 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 enjoys a worldwide presence. Its key manufacturing and R&D site is in Germany. The company employs over 2,300 people, and in 2008 generated sales revenue of 368.0 million euros.

## Photos | Image Files for Press Release



**Caption:** The new FlexAct system of Sartorius Stedim Biotech focuses on biomanufacturing unit operations and can be used with pre-configured single-use equipment

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