BioSpectrum
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ASIA EDITION

Sartorius Launches BIOSTAT STRÃ?Â® Generation 3 with BIOBRAIN

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Making Biopharmaceutical Development and Production Faster, Simpler and Safer



- **Rapid process development and seamless scalability from ambr® to BIOSTAT STR®**
- **BioPAT® Toolbox—integrated single-use sensors for monitoring and control of key process parameters**
- **BIOBRAIN automation platform for flexible configuration, rapid upgrades and simple plant integration**
- **Process intensification with automated feed and bleed and integrated cell retention functionality**
- **Connection to Umetrics® SIMCA®—predictive control for bioprocess forecasting and optimization**

Engineered to address the rigorous requirements and complexity of biologics manufacture, Sartorius' BIOSTAT STR® Generation 3 single-use bioreactor and BIOBRAIN automation platform introduce innovations that will change the field of biopharmaceutical process development and manufacturing.

BIOSTAT STR® simplifies biologics production. This robust industrial platform consists of hardware, software and consumables for single-use process development and commercial biomanufacturing. BIOSTAT STR® bioreactors and Flexsafe STR® bags range from 12.5L to 2000L in working volume. The system is powered by BIOBRAIN, a new automation platform that gives biologics manufacturers the flexibility to quickly and easily configure the BIOSTAT STR® system to meet their precise needs. Data-driven software, a comprehensive suite of analytical tools and experienced engineering design and support teams enable manufacturers to produce consistent results, even in the setting of changing demands. The flexibility and responsive nature of the BIOSTAT STR® system deliver outstanding quality and productivity for a stable, predictable process.

Fully integrated and redundant single-use sensors provide real-time data to measure and control key critical process parameters such as pH, DO, viable biomass, glucose, lactate and foam. Non-invasive measurements save set-up time,

prevent interface issues and reduce the need for off-line manual sampling. These elegant monitoring and control systems enhance batch-to-batch consistency and operator confidence.

BIOSTAT STR® Generation 3 is ready for process intensification and includes functionalities such as feed controls, bleed controls and connectivity to Repligen's XCell™ ATF cell retention devices to increase cell density and productivity.

Connection to Umetrics® SIMCA® enables predictive, multivariate modeling and control, allowing manufacturers to predict yield and optimal harvest time points at the early stages of the perfusion process.
Integration into existing process infrastructure can be achieved in multiple ways: local management via the BIOSTAT STR® control tower and BIOBRAIN automation platform with connection to data histories, or full process management via distributed control systems from Emerson, Siemens or Rockwell. An additional exciting feature for BIOSTAT STR® Generation 3 is the optional integration of native Emerson DeltaV® controls supported by a Sartorius DeltaV® library, which affords full access and control from DeltaV® systems.

Sartorius engineering and technical field experts help design and implement new facilities and retrofits, address scaling challenges and manage technology transfers. This level of support relieves internal development and manufacturing teams from the burden of developing master status on new technology.

Mario Becker, Head of Product Management for Cell Culture Technologies at Sartorius,"The biopharmaceutical industry needs solutions for the many challenges involved in bringing life-changing biologics to market. Sartorius has found ways to simplify complex processes and provide proof of safety along the way. We believe the new BIOSTAT STR® platform is a significant advance. It's our way of helping the industry to bring better medicines to patients globally."

Sartorius' BIOSTAT STR® Generation 3 and BIOBRAIN automation platform are a tour de force that reflects the company's 150-year culture of simplifying progress.