

# BioPAT® MFCS

The Standard in Bioprocess Data Management and Automation Simplifying Progress

SARTURIUS

# Developed for the Process – Designed for You!

BioPAT® MFCS enables you to incorporate a new standard in bioprocess data management and automation. Its reliable data acquisition, efficient trend monitoring, and advanced recipe control make it an ideal tool for all upstream and downstream processes, no matter if you prefer single-use or reusable systems. The new BioPAT® MFCS is your solution for robust and reproducible processes in R & D and GMP environments – all backed by our expertise since 1986.





**Focus on Essential:** Get the right focus for a fast and clear operation with our award-winning UI.

**Quick Overview:** Support of up to 32 process units and get all relevant information at a glance.

**Connectivity:** Integrate PAT sensors and analyzers as well as third-party instruments via OPC for enhanced process knowledge and control.

**Process Safety:** Let the alarm management system take care of process limits.

**Advanced Charting:** Display real-time monitoring of 12 process values and benefit from batch analysis.

**Calculation Capabilities:** Calculate important bioprocess parameters and non-direct measurable variables with the calculation module.

**Full Process Control:** ANSI-88-compliant batch control for robust process automation

**Data Integrity and Security:** High-quality data collection for on- and offline process data, in a fast, powerful, and searchable SQL-database.

**Compliance:** Technical features ensure compliance with common regulations like 21 CFR Part 11 or EU Annex 11.

# Compliant and Reliable Operation

BioPAT® MFCS gives you audit-safety. Its functionality to support GMP, EU Annex 11 and 21 CFR Part 11 regulations brings the highest degree of data integrity and data security from research to production scale.



#### **Traceability**

The comprehensive automatically generated audit trail records all system changes and batch-related activities.



#### **Data Integrity and Security**

Data integrity & security of your data over the whole retention period is ensured by a Microsoft SQL database.



#### Electronic Record Management

Benefit from using compliant digital batch records and electronic signatures to streamline documentation and review processes.



#### **Access Control**

The advanced role-based user management system, capable of integration with LDAP, allows controlled access based on your organizational rules.

### Confident Service

Sartorius support with planning and implementation during all phases of the installation and validation. From assistance with writing the functional design specification over the installation and configuration up to the execution of FAT/SAT.

As your BioPAT® MFCS SCADA system is a critical component for your bioprocess, it is important to have confidence that your software is up-to-date and properly supported. Our Service and Support Agreements providing regular product updates and dedicated expert support.



# Turn Advanced Process Strategies into Reality

### Recipe Automation

- Intuitive, graphically guided configuration
- Drag-and-drop operations and phases
- Sequential, parallel, and repeated execution of phases
- State and time-dependent transitions
- Pre-defined phase types for setpoints, feeding profiles, or timers

## Customized and Perfusion Recipes for BioPAT® MFCS

Creating recipes is a complex and time-consuming task requiring experienced user that know the process and the specific unit operations capabilities. The BioPAT® MFCS engineering team can support recipe writing or provided template recipes including perfusion leveraging their extensive systems and process experience.

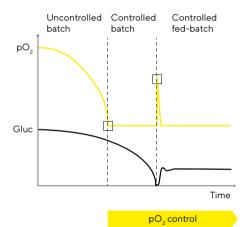
### Benefits

- Improved batch-to-batch consistency
- Decreased risk of errors
- Minimized number of rejected lots
- Automated processing to free up operator time
- ANSI-88-compliant, standardized automation

### Application Example

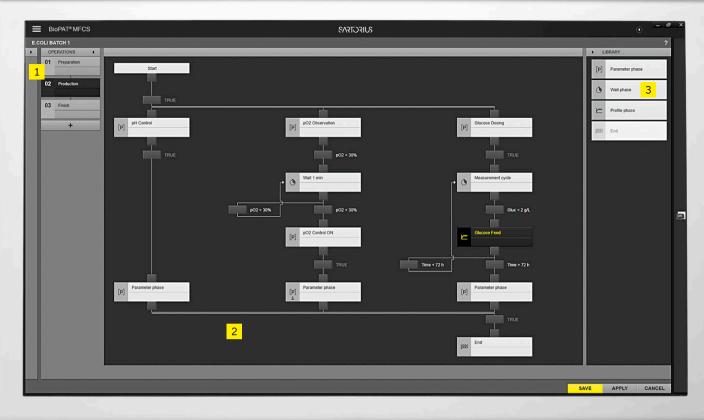
- Event-based activation of control loops
- Automatic batch end detection, e.g., based on pO<sub>2</sub> off gas measurements
- Implement advanced feeding strategies for fed-batch processes
- Control complex perfusion processes with predefined perfusion recipes

# Automatically Switch Between Process Phases



Glucose control





BioPAT® MFCS Recipe Control Module

#### 1: Easy Configuration

Get started immediately, and implement your process strategies.

#### 2: Intuitive Use

Clear workflows for maximum productivity.

#### 3: Quick Access

Pre-defined functions are right where you need them.

# Extend the Possibilities of BioPAT® MFCS



#### Recipe Control Module

ANSI-88-compliant batch control for robust process automation



#### **OPC UA Client Module**

Connect to Biobrain® and additional equipment, e.g., BioPAT® Trace, BioPAT® Xgas



# Sample Data Module

Integrate and manage off-line sample data



#### **OPC Server Module**

Connect BioPAT® MFCS process data and alarms to your historian or MES systems (e.g. SIM API)



#### Calculation Module

Create soft sensors to monitor non-directlymeasureable quantities, e.g., OUR, RQ



#### 21 CFR Part 11 Module

Capabilities to ensure compliance with 21 CFR Part 11 or EU Annex 11 regulations



#### User Management

Centralized user management with domain connectivity and flexible permission rights configurations



#### Multi User Option

Monitor and control your process from up to 30 BioPAT® MFCS clients simultaneously (RDP supported)

# Ordering Information

Software	
BioPAT® MFCS	Core Software
Additional Software	e Modules and Options for BioPAT® MFCS
21 CFR Part 11 Mod	dule
Recipe Control Mod	dule
OPC Client Module	
OPC Server Module	9
Sample Data Modul	le
Calculation Module	
Charting Module	
Multi-User Option (	small and large size)
User Management I	Module
Microsoft® SQL Serv	ver 2019 Standard run time (Server, 64-bit)   University
Remote Alarming Pa	ackage
Services for BioPAT	" MFCS
Perfusion Recipe	
Customized Recipe	s (simple, medium, and complexe size)
System Qualification	n
Basic User Training (	(remote and on-site)
	ng (remote and on-site)
Administrator Traini	
Administrator Training (ren	note and on-site)
Recipe Training (ren	note and on-site) remote and on-site)

BioPAT® MFCS is available for up to 32 Units.

Please contact your local sales representative regarding a license for more than 1 unit.



Learn more about BioPAT® MFCS by downloading the demo version. Stay up to date about the latest product and security updates by visiting the BioPAT® MFCS website for more information.

₩ Visit the BioPAT® MFCS website: www.sartorius.com/biopatmfcs

### Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

#### USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178

For further contacts, visit www.sartorius.com