

# Bioprocess Automation ...

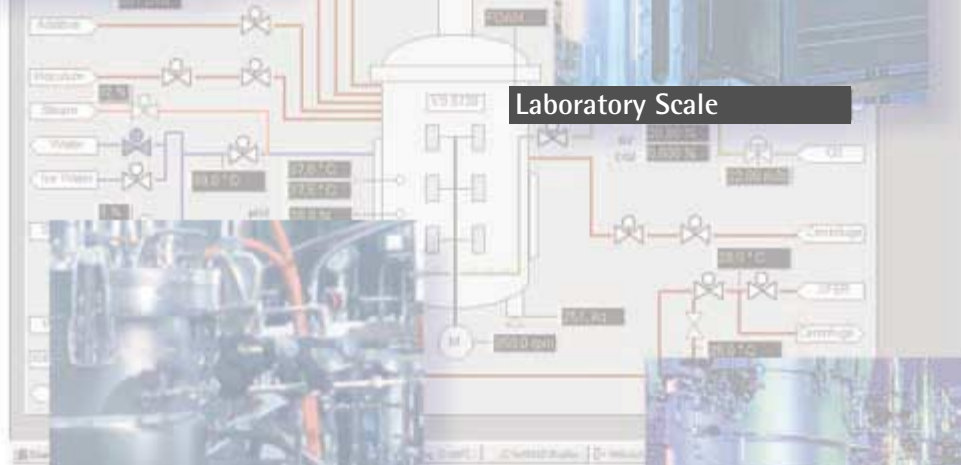


Bench Scale

MFC5/win



Laboratory Scale



DCU



Pilot Scale



Production Scale

BIOSTAT®



B. Braun Biotech  
International  
●●● sartorius group

# From Screening ...

**BIOSTAT® and SARTOFLOW® range of fermentation and cross flow filtration systems**

**Micro-DCU and DCU flexible local control systems**

**MFCS/win multi-fermentor supervisory control and data acquisition software (SCADA)**

**Customized gas blending and feeding strategies**

**Automation upgrading for all brands of fermenters**

**Turnkey project engineering and validation support services**



BIOSTAT® C fermentor with micro-DCU local controller

Our key platform to automation is based on the use of flexible Digital Control Systems (Micro-DCU and DCU), which are specifically tailored for fermentation and cell culture applications.

First level automation is available using the Micro-DCU platform, which is delivered, together with our standard range of fermenters, in pre-configured versions according to the type and size of the fermentor.

## Creating bench-top control

Since the introduction of our first digital fermentor controller (DCU) we have delivered several thousand systems to leading pharmaceutical and biotech companies world-wide.

Use of a modular system design has enabled us to offer a range of cost-effective solutions for new users as well as providing an upgrade platform for existing installations.



SARTOFLOW® benchtop cross flow filtration unit

When combined with our MFCS/win Supervisory Control and Data Acquisition (SCADA) system this solution provides the most cost-effective platform for small to medium scale research and pilot plant applications.



BIOSTAT® B-DCU, advanced multi-purpose fermentor system

PROCESS AREA

# ... through Laboratory and Pilot Plant ...

## Process automation at a single touch

BBI's DCU fermentor control system utilises 'state of the art' technologies and software which have been specifically developed for use in biotech equipment control. Incorporating an intuitive touch panel operator interface for ease of use, DCU can be supplied in bench top or control panel mounted versions complete with integrated amplifiers for all standard measurements.



DCU controller with customized gas mix system



DCU local fermentor control system

Standard DCU firmware provides full functionality for execution of all basic control tasks (i.e. calibration, alarm monitoring, control loops and sequences) and can be configured according to individual process requirements. A range of advanced control features (e.g. gravimetric flow controllers in combination with high precision Sartorius balances) can also be realised at this level.

## Retrofitting made easy

Hardware expansion plus software configuration capabilities are combined with BBI's experience in bioprocess control to make DCU the ideal platform for replacing of older fermentor control systems. Customized control panels or interface boxes ensure trouble-free integration with existing fermenters ranging from laboratory to production scale.

With classification as GAMP Category 4 (Configurable System), DCU is a validatable local control system which can also be used in regulated cGMP production environments.

A range of supporting functions, including multi-level password and operator logs, are standardly provided together with comprehensive documentation for validated systems.



Fermentor control retrofit of an existing plant

Connection of DCU controllers via Ethernet/TCP-IP to MFCS/win SCADA software provides a range of extended control and evaluation facilities including:

- Recipe based batch processing (ISA-S88 standard),
- Visualisation,
- Data acquisition, evaluation, storage and reporting
- Advanced control algorithms.



Integration of Sartorius balances in fermentor automation

# ... to Full Scale Production

CONTROL ROOM

## Servicing your automation needs

With options ranging from dedicated local controllers to high-level system integration using PLC/SCADA or DCS control systems, our expertise is available to ensure the optimum solution to any demanding biotech production process.

We provide standardized PLC control systems for both fermentation and crossflow filtration package units. These controllers, in combination with SCADA systems, are based on platforms offered by leading European and US PLC vendors in satisfying the 'in-house' standards of our customers.

For full-scale automation of complete biotech production facilities, DCS systems are the preferred choice for performing batch control according to ISA-S88 standard.

Our involvement in providing automation solutions, together with leading automation system suppliers and system integrators, has focussed on specification and commissioning, resulting in the realization of a number of successful projects world-wide.

PROCESS AREA



SARTOFLOW® - industrial crossflow filtration system

FERMENTER 1



Large scale industrial multiple fermentor installation

## Experience the support

Expertise gained through long term co-operation with pharmaceutical and biotech companies has been used to develop and refine a comprehensive range of validation support services.

The scope of these services includes validation of computerized systems as well as the qualification of automated process equipment.

In addition to the generation of comprehensive 'as built' documentation, our team of experienced engineers has developed an extensive library of qualification protocols for Installation Qualification (IQ) and Operational Qualification (OQ).

For projects requiring validation the key factor to successful realization is through expertise in project management. BBI, with well established methods for defined project execution according to GAMP guideline and S88 models for batch control, is today uniquely placed to guarantee delivery on schedule and within budget.

OPERATOR STATION

CONTROL CABINET

CONTROLLER

ASI PROFIBUS CLASSIC

ASI-BUS

PROFIBUS-DP

VF

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## BBI Making the Difference

FERMENTER 2

# ... with Advanced Software Solutions

**MFCS/win SCADA software for multiple fermenters and bioreactors**

**Easy configuration by the user according to individual process requirements**

**Batch control according to ISA-S88 standard**

**OPC client/server for easy connectivity**

**Validatable System for operation in cGMP environments**

MFCS/win, the 4th generation of BBI's Supervisory Control and Data acquisition software package can be considered as the 'de facto' standard for SCADA in the field of bioprocess applications.

Based on standard PC hardware and operating under Windows NT or Windows 2000, MFCS/win can be supplied as a single user system, or integrated in a local area network (LAN) environment.

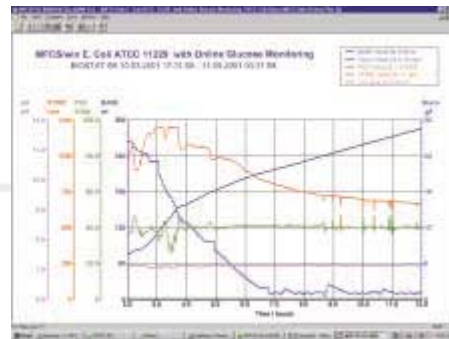


Supervisory control of multiple process units

MFCS/win functionality is specifically designed for bioprocess applications involving data acquisition and storage, sample data management, on-line calculations, process visualization and batch reporting.

Supplied preconfigured and 'ready to use', the configuration can easily be adapted by the user to any change in process requirements.

MFCS/win is designed as an open system, with an OPC (OLE for process control) interface, resulting in simple connectivity to third party software packages for expanding the functionality of an entire system.

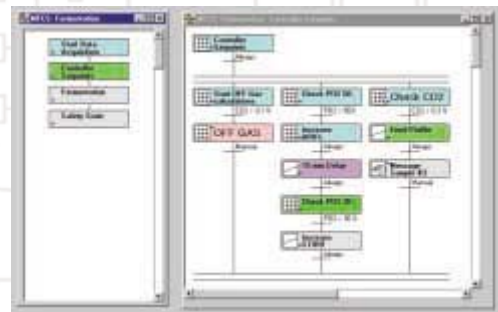


Comprehensive plot and report functions

Current versions incorporate batch management features, compliant with ISA-S88, allowing utilization of procedural batch control already on small systems, resulting in consistent process operation.

Fully validatable according to GAMP category 4 (Configurable System), MFCS/win has all the necessary functionality for operation in a regulated cGMP production environment and supports 21 CFR Part 11 compliance for electronic records and signatures.

A comprehensive driver library and OPC Client functionality are included for easy connection to all brands of fermenters and auxiliary process instrumentation, making MFCS/win the ideal choice for laboratory or pilot plant automation retrofit projects.



Batch recipe according to ISA-S88

### **Company Profile**

B. Braun Biotech International (BBI), incorporated in the Sartorius Biotechnology Division, is a world leader in design and manufacture of fermenters, cell culture bioreactors and bioprocess automation systems.

This division, which also incorporates Vivascience and Sartorius Filtration activities, is a leading supplier of high performance products and systems for the Life science, Bioscience, Fermentation and Cell Culture markets.

We are proud of our global reputation, established over more than 35 years, in providing a range of innovative,

systems and support services to major biotechnology and pharmaceutical companies extending from bench top, laboratory and pilot scale operation through to fully validated, high volume automated production plants.

With engineering and production facilities in both Germany and the USA coupled to an active presence in over 50 countries we are fully committed to continuous growth in providing an ever increasing level of customer satisfaction.

*For further information regarding the complete range of BBI products and services contact us at:*

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