BioPAT®
MFCS | Win

Recipe Control (S88) Module

Introduction

BioPAT® MFCS | Win is the world standard software for supervisory bioprocess control and data acquisition. Based on over 25 years of experience and more than 3,000 installations, the latest release of BioPAT® MFCS | Win provides various solutions to meet your specific requirements.

Besides the core functionality of a true SCADA system for reusable and single-use bioprocess applications, BioPAT® MFCS | Win offers a number of additional modules for adaptation to individual requirements.

Product Information

The time has come for robust processes – the BioPAT® MFCS | Win Recipe Control (S88) module:
- Improved batch-to-batch consistency
- Enhanced process understanding
- Standardized automation
- Decreased risk of errors
- Simplified tech-transfer
- Minimized number of rejected lots
- Free up operator time

The unique Recipe Control (S88) Module allows bioprocess operators to realize automation strategies for batch, fed-batch and continuous processes, in line with Quality by Design (QbD) principles.

The American ANSI/ISA-88.01 standard and its international equivalent IEC-65112 are industrial standards for the control of all kinds of batch processes. The BioPAT® MFCS | Win Recipe Control (S88) Module follows these standards and contains all functions and models that are of use for biopharmaceutical up- and downstream processes.

Minimize Run-to-Run Variability

The BioPAT® MFCS | Win software package, as well as the Recipe Control (S88) Module, support industrial users as well as researchers in universities and institutes. Whereas the industrial user at the pilot or production plant may need a well-structured, validatable system, the researcher needs a very flexible and open system. The Recipe Control (S88) Module considers both aspects.

In order to achieve a reproducible and fully automated batch process, BioPAT® MFCS | Win recipes are designed to trigger different actions automatically by events. Initialization of substrate feed control after automatic detection of the end of a batch, or to automatic start of harvesting after a specific cell concentration has been reached, are only two examples.

The S88 recipe structure adapts perfectly to constantly evolving recipes in the pilot plant development area. As it provides a common language for process design and specification, an early recipe development enables the implementation of an operator-independent and robust process control strategy across development and commercial manufacturing.

The advanced use of Process Analytical Techologies (PAT), whether in development to gain process understanding or manufacturing to monitor Critical Process Parameters (CPPs), enables the implementation of enhanced control strategies. With its conditional logic and the direct translation of biopharmaceutical unit operations into S88 phases, the Recipe Control Module supports your automation strategy to reduce variability and thus increase batch-to-batch consistency.

Features

- Graphical Configuration and Execution
- Fully mouse-driven recipe editor
- Drag and drop for operations and phases
- Comprehensive toolbar with pre-defined phases
- Color-coded view of current process state
- Operation and Phase library
- Automatic Syntax Check
- Automatic Recipe Version Control
- Possible restriction to equipment classes
- Review and approve functionality

Easy Graphical Programming

The new recipe editor permits graphics-based process automation with loops and jumps, facilitating application-oriented automation in compliance with industry standards. Semi- or fully-automatic operations and pre-defined phases with state or time-dependent transitions enable an organized and structured batch processing as well as flexible manufacturing.

Efficient Workflow Optimization with DoE

A key benefit of applying QbD is the ability to identify critical quality attributes and process parameters. The correlation can be made in a cost-effective and statistically significant manner by using Design of Experiments (DoE). Based on your experimental objective, the unique and additionally available BioPAT® MFCS | Win DoE Module generates an appropriate design and automatically configures an S88 recipe.

Faster Tech-Transfer to Manufacturing

The Recipe Control (S88) Module gives you the possibility to center your process development activities around a recipe structure with a common terminology. As recipes scale-up and become more detailed, S88 is ideal for handling the various stages from research to development to commercial manufacturing. Standardized approaches and straightforward mechanisms across the organization will finally lead to a simplified technology transfer.

Work In-Line with QbD Principles

One of the greatest benefits of implementing QbD is the increased regulatory flexibility as well as a faster regulatory approval of new product applications and process changes. BioPAT® MFCS | Win Recipes support the realization of advanced scientific concepts and the implementation of enhanced control strategies with global regulatory acceptance.

Professional Service and Support

Our team of experienced service engineers has been involved in a number of successful projects world wide. Expertise gained through long-term cooperation with pharmaceutical and biotech companies has been used to develop and refine a comprehensive range of services including computer system validation (CSV) as well as S88 recipe programming based on your specific requirements. In addition, the BioPAT® MFCS | Win Manager or Application Training provide an excellent basis to get started creating your own recipes.

Select the pointer to move phases with drag and drop

Switch on variables and data storage, set alarm limits, change controller properties, start calculations, etc.

Run a time profile and change variable value, controller setpoint or output

Define a controller setpoint and verify that value stays within the defined deadband for a certain time

Start any program (*.exe) and optionally hand over parameters

Start a DCU Sequence which is defined in the configuration of the digital control unit

Enter a prompt message, which will pop up during recipe execution

Link two process units which depend on each other

Empty Operation Editor

Add First Operation

Organize Sequence

Finished Sequence
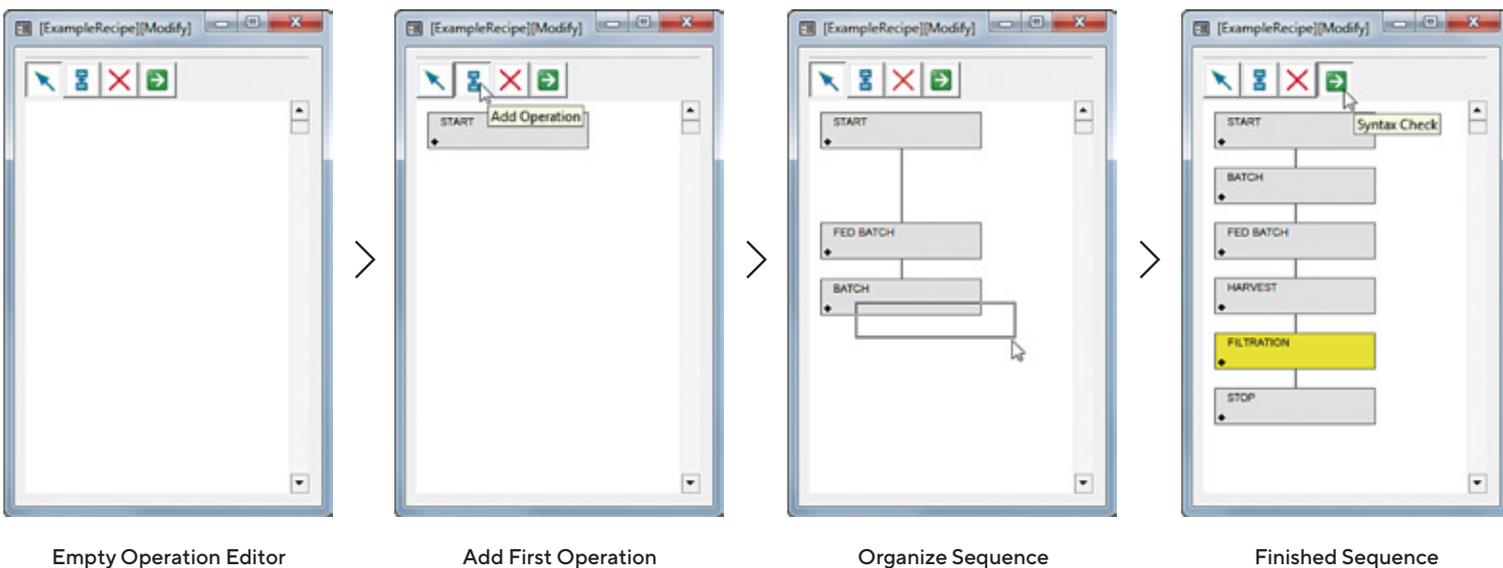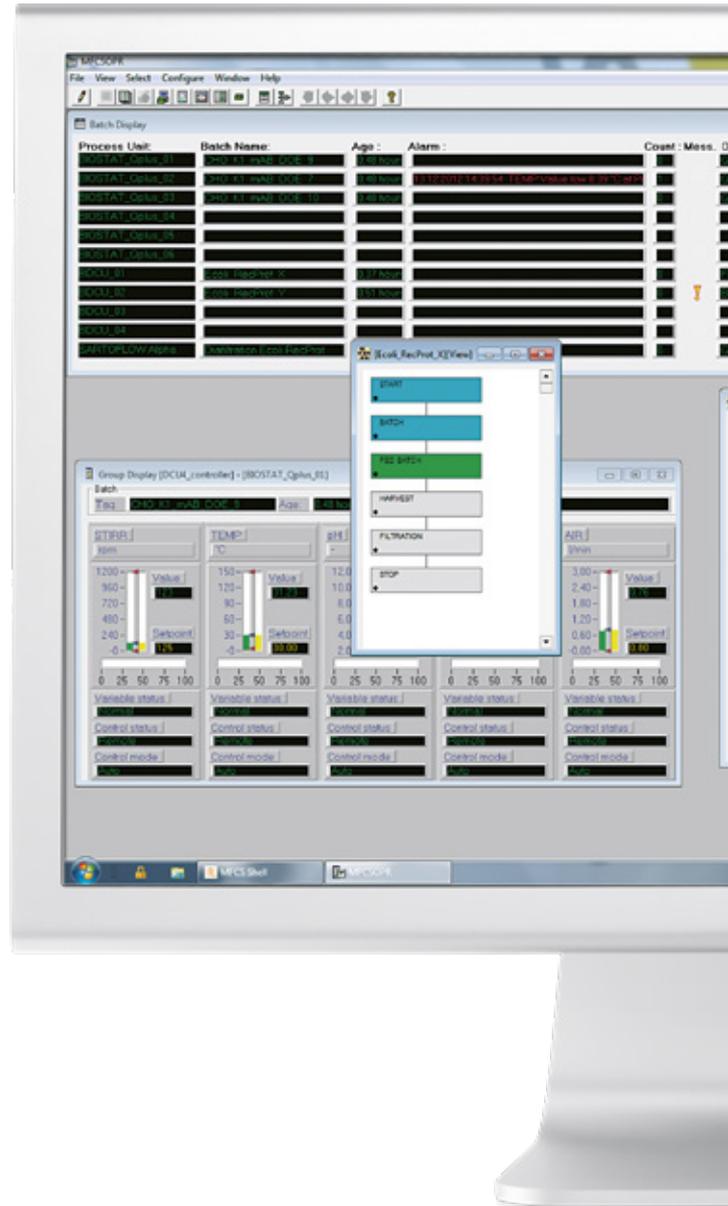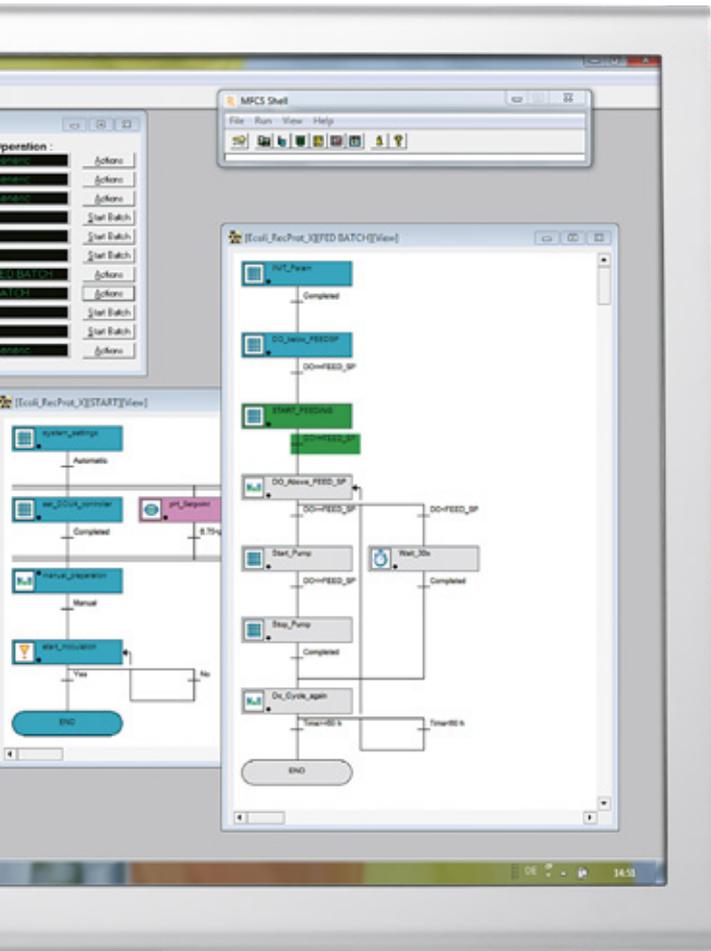
Icon	Description
Null	Empty phase without any function, e.g. as input phase for jumps
⏱	Timer, which will be active until a certain day time or for a given duration
END	Every operation must have exactly one End Phase at the last position
⇄	Create transitions and connect up to four phases, where only one single branch becomes active
⎍	Create multipliers that connect up to 10 phases, where all parallel branches start simultaneously
↳	Use jumps to repeat an entire operation - or only certain parts of it
✕	Delete transitions, multipliers, branches, phases, etc.
→	Mandatory plausability check for errors in order to use a master recipe as control recipe

PAT
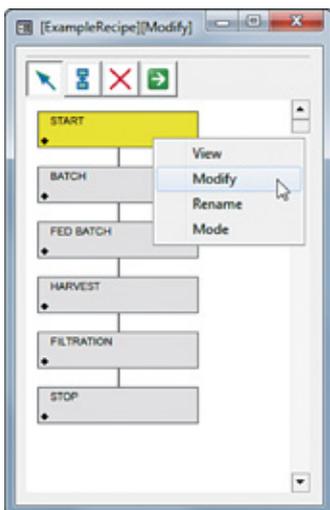
Modify Operation "Start"
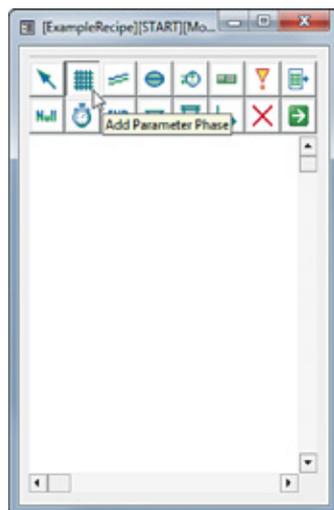
Empty Phase Editor
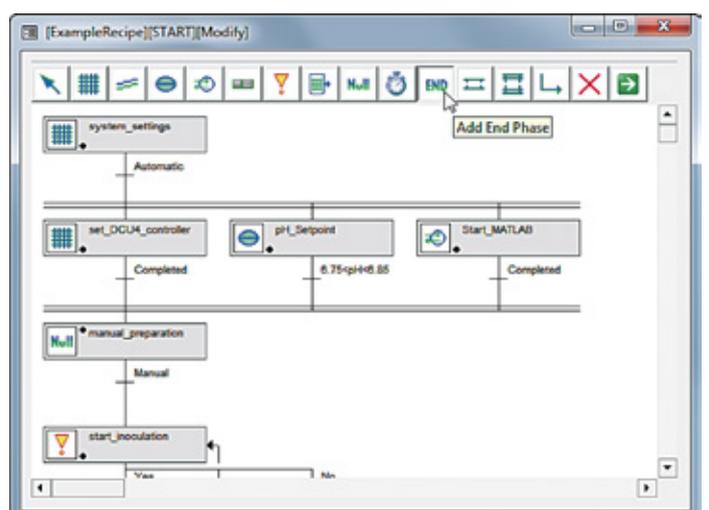
Add Phases, Timers, Prompts, Jumps, Conditions

Applications

BioPAT® MFCS | Win provides connectivity to both upstream and downstream devices, so that the Recipe Control (S88) Module is widely used to establish a sophisticated control strategy across both areas, and even link systems for integrated bioprocessing, to optimize yield and cost-effectiveness of production.

The first common application relates to event detection, which means the identification of process states based on online measurements.

- Automatic batch-end detection, e.g. based on DO/offgas measurements
- Initialization of feed|induction, e.g. based on biomass measurement
- Just-in-time harvest, e.g. based on (by-) product measurement
- Automatic stop of diafiltration, e.g. based on conductivity measurement

Furthermore the implementation of advanced feeding strategies for fed-batch bioreactors can be realized.

- Linear, exponential or pulse-wise feeding of growth and production culture media
- DO-stat or adaptive control techniques
- Open-loop or closed-loop control of cell-specific growth rate μ

Finally, recurrent events can be implemented based on loops and jumps.

- Intermittent medium addition or harvesting
- Activation or deactivation of controllers based on user-defined intervals
- Optimization of cross-flow performance by periodic adjustment of differential pressure

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