BILFINGER INDUSTRIETECHNIK SALZBURG

A Software Platform for Quality by Control Realization of Bioprocesses

Introduction

The state of the art industrial production of complex biopharmaceuticals is usually represented by fixed process conditions and extensive testing of the end-product.
In 2004 the US Food and Drug Administration launched the process analytical technology (PAT) initiative, aiming to guide the industry towards advanced process monitoring and control. Implementation of process analytical technology into the bio-production process enables to move from the quality by testing to a more flexible quality by design approach.

FDA: "Quality cannot be tested into products; it should be built-in or should be by design."

Advanced Process Control

In order to build quality into the production process, advanced process monitoring and control (APC) becomes indispensable. Hereby, the application of advanced sensor systems in combination with mathematical modelling techniques offers enhanced process understanding and allows online estimation and control of critical quality attributes (CQAs).

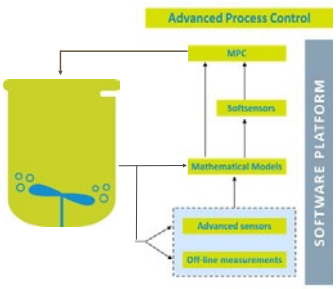

Fig. 1: Advanced monitoring and control of bioprocesses

Requirements for APC:

- Integration of advanced sensor systems
- Profound off-line data
- Mathematical process models
- Soft-sensors

APC Implementation

The implementation of Advanced Process Control into bioprocesses requires the generation of an extensive data set, on which base mathematical models can be developed (soft-sensors, process models). In combination with on-line measurements these models allow the estimation of the actual state of the bioprocess or anticipate certain developments.

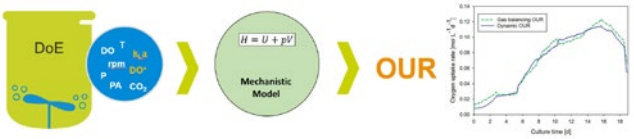

Fig. 2: Example: Mechanistic model for oxygen uptake rate calculation as key process indicator (KPI)

However, the integration of advanced sensor data as well as mathematical models into basic automation systems remains challenging. Therefore we developed a novel, higher level, software platform for advanced process monitoring and control, paving the way to superior control strategies like feed-on-demand.

QUBICON - Software Platform

The GMP conform software platform Qubicon can be used as an add-on to basic automation systems of bioreactors and other process equipment. OPC-UA is used for communication between Qubicon and the basic automation level. Integration of advanced sensors without OPC-UA interface is realized using the PATBox.

Benefits:

- Central interface for all PAT tools
- Finding relations between all relevant data (in-, at-, on- and off-line) leads to increased process understanding
- Observation of real-time KPIs and CQAs
- Implementation of advanced control strategies
- Shift from lab testing towards real-time release testing
- In-process product quality control
- Prevention of batch rejection

Fig. 3: Software platform for advanced monitoring and control of bioprocesses

Fully automated software platform for data-integration, -processing and -management, modeling and control.

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Bilfinger Industrietechnik Salzburg GmbH
Urstein Nord 31
5412 Puch/Salzburg
Phone +43 662 8695-0
office.salzburg@bilfinger.com

University of Natural Resources and Life Sciences, Vienna

bio Industrial PILOTPLANT

www.it-salzburg.bilfinger.com

www.boku.ac.at