

Efficient bioprocess development

Eppendorf's bioprocess marketing and communications manager Christiane Schlottbom and product and application specialist Stephan Zelle list the 10 main factors to consider when choosing a bioreactor control software.

Bioprocess development requires software that not only monitors and controls process runs, but also integrates design, execution and evaluation of experiments. In this way, the software supports initiatives to implement QbD (quality by design) principles, ensuring product quality and successful scale-up to manufacturing. There are several points to consider when selecting SCADA (supervisory control and data acquisition) software and associated data and information management.

1. Number of bioreactors

Parallel operation of bioreactors saves valuable time and accelerates process development. Advanced control software should be able to control multiple vessels individually, up to 24, for example, at a time through incorporated batch management. Ideally, it also features parallel cleaning and calibration procedures.

2. Vessel flexibility

Laboratories that use both autoclavable and single-use bioreactors of various sizes call for flexibility in their control software. Advanced packages allow control of different vessels setups in one and the same experimental run.

3. Software knowledge of scientists

An easy-to-use interface can be the difference between good and bad software. In bioprocess control, integrated recipe management with templates for fermentation and cell culture further aid beginners. Experienced users should be able to maximise their processes, through user-defined scripting, for example.

4. Control strategies and levels of automation

Profile and equation-based feedback control provide the ultimate flexibility in bioprocess control. Feed rates based on offline analyser data, oxygen transfer rates (OTR)-based feed control, or temperature shifts that are triggered by cell performance are only a few examples used to automate a process.

5. Third-party laboratory equipment

Real-time analytical data deliver vast insight into the status of a cultivation. Integration of autosampling and analytical devices, such as nutrient analysers, HPLC, mass spectrometry and Raman spectroscopy, enables feedback control and enhanced automation.

6. External alarm notification and remote control

Alarm warnings via e-mail or text message enhance process safety. Progressive bioprocess control systems also enable users to

manage process settings remotely via PC or mobile devices. Users can react immediately to changing process conditions, even from outside the laboratory.

7. Statistical approaches

Design of experiments (DoE) is a structured approach for investigating the influence of critical process parameters and how they interact. Parallel bioreactor systems and easy-to-execute DoE setups streamline process development and facilitate regulatory processes. Advanced control integrates with common DoE tools.

8. Reporting and analysis

Analysis of bioprocess data can be time-consuming. Automated Microsoft Excel reporting, which is based on user-defined templates, saves manual workload and makes complex analyses easier. A powerful chart creation tool, with an unlimited number of data tracks and axes and an export function to Excel, is a plus. When it comes to comparison of historical and current runs, users benefit from intuitive queries and editable query templates.

9. Cross-system analysis

If multiple bioreactor systems, or even multiple sites, need to be evaluated and compared, tools are required to go beyond the possibilities of standard SCADA software. Sophisticated solutions enable mixed-system control and cross-platform analysis of run-time data between systems made by different manufacturers.

10. Data storage and management

Documentation demands can require a central database with managed access. If the bioreactor system is integrated with legacy corporate historians, communication via OPC (object linking and embedding for process control) must be installed. This allows company-wide access to all relevant bioprocess data.

Summary

Efficient bioprocess control software facilitates the implementation of QbD principles in pharmaceutical development and offers flexibility. Sophisticated solutions for interconnectivity of benchtop equipment and bioprocess data and information management provide further tools to integrate processes, reduce the manual workload and accelerate process development. ■

Further information

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