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Modular Bioprocessing With Biobrain®: Designing A Well-Tuned Orchestra

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Abstract

Speed and flexibility are hugely important in the dynamic biopharmaceutical landscape, as highlighted by the rapid spread of and the production of vaccines in the fight against COVID-19. Meeting changing clinical demands quickly and safely required the rapid supply of manufacturing components and their smooth interaction, which made a modular concept particularly valuable.

The use of modular facilities is also driven by the increasing popularity of cell and gene therapies, the growing implementation of continuous manufacturing processes, and the broader uptake of single-use technologies. Solutions that support the streamlined connection of individual components are essential for their effective implementation in a process.

Together, Sartorius and Siemens offer suitable automation and digitalization approaches for modular production.

Solutions for Modular Production

The flexibility required to keep up with changing demands challenges the individual modules of a production chain both horizontally (process direction) and vertically (information and control direction), as units might need to be linked differently for a new production process. The interaction of individual modules and their communication with each other is crucial for a rapid, optimized, and cost-reducing conversion or set-up.

Moreover, the rising interest in cell and gene therapies has pushed manufacturers toward the development of drugs for smaller patient populations. These new demands mean there is a growing need for multi-product facilities, where several products are manufactured in succession in the same production environment.

The following section describes various solutions for responding to these market requirements.

Components for Modular Production

Local Automation: Biobrain®
Flexible production processes are already relatively widespread, as single-use technologies and modular unit operations, such as bioreactors and filtration units that can be variably linked with one another, have become established.

With the Biobrain® automation platform, Sartorius has taken a further step towards modularization and has developed a new standard solution for GMP production that allows individual instruments or unit operations to be operated both independently and in conjunction with DCS, Historian, and MES solutions. The solution is based on a Siemens PLC, which takes over the basic control, combined with an HMI that functions for visualization, data handling, alarming, and the interface to higher-level systems.

DCS: SIMATIC PCS 7
The SIMATIC PCS 7 process control system is a modular automation system for process management and control. The open, robust, and scalable automation system is a modern, future-oriented, all-round system for the process industry. The core of the automation system is a SIMATIC controller designed for these diverse process engineering tasks, whose performance and range of functions can be expanded with additional components. This high degree of modularization allows the SIMATIC process control system to solve any task in the process industry. Other key features include maximum availability, system expansions during operation, and a reliable basis for long-term investment protection thanks to its proven use in thousands of applications.

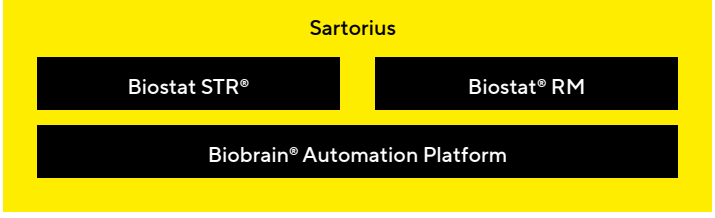
MES: Opcenter Execution Pharma
Siemens Opcenter Execution Pharma is the digital platform that enables pharmaceutical companies to accelerate the development and production of new drugs and vaccines. Opcenter Execution Pharma seamlessly integrates MES functionality, automation, and enterprise resource planning (ERP) systems. Processes and workflows can be streamlined in full compliance with all regulations thanks to completely paperless manufacturing and end-to-end electronic batch reporting. In summary, Opcenter Execution Pharma represents a critical tool for increased competitiveness.

Process Scenarios

Standalone

Sartorius Biobrain® is an automation platform for bioprocess devices. Based on Siemens hardware and software components, it allows customers to operate their devices under GMP conditions in production without the need for initial integration into higher-level systems. The recording and reporting of process data, alarms, and events, as well as the audit trail, is included in the device. Without integration into higher-level systems, this scenario allows the production of materials particularly quickly (speed-to-facility) and thus an early market entry (speed-to-market), which is often business-critical. Integration into a higher-level system is easily possible in the following steps.

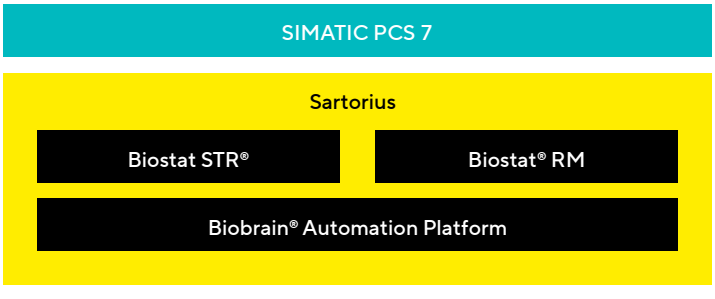
First Solution: Stand-alone operation



Integration DCS

Instruments can be integrated into DCS systems in the classic way via remote I/O and then automated in this DCS. Sensors and actuators are addressed via digital and analog interfaces, and the process data is handled by the system to be integrated. In the classic use of intelligent single-use skids, existing and tested functionalities (controls and phases) in the instruments are reproduced again in higher-level systems and tested again. This step is not only time-consuming in terms of reproduction but also harbors the risk of errors. With the introduction of Biobrain®, Sartorius has realized a phase-level interface (PLI) that allows the phases of the unit operation to be executed and documented by the DCS according to the ANSI-88 standard as part of a comprehensive batch. Together with Siemens, an integration of this PLI interface with the SIMATIC PCS 7 DCS system was realized, successfully demonstrating that Sartorius devices can be effectively integrated and orchestrated in PCS 7 without additional reproduction of functionalities.

Second Solution: Integration into batch recipe management system

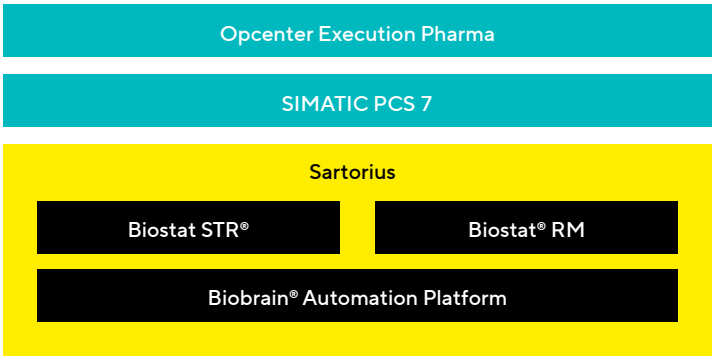


Integration MES

The integration of the DCS into the MES is the logical continuation of the standardized procedure for the efficient and fast integration of Sartorius devices into the overall system. The MES is connected to the DCS via the standardized Batch Integration Layer, whereby the link between DCS and MES is event-triggered. This procedure considerably reduces the integration effort and avoids duplicate entries in the overall system and, thus, sources of error. For efficient operation and operator guidance, it is possible to integrate the MES operating windows directly into the DCS. Parallel display and operation of the DCS and the MES are possible from one operator station.

This integration approach for paperless production is the basis for efficiently guiding the operator through production, thereby reducing, and even avoiding errors, rejects, and overheads

Third Solution: Paperless manufacturing



Conclusion

The advantages of Biobrain®-supported single-use instruments in combination with Siemens DCS and MES solutions demonstrate the importance and effectiveness of integration concepts that aim to establish GMP production early, safely, and cost-effectively. In an increasingly dynamic, fast-paced, and competitive environment, the modules presented together enable a well-coordinated orchestration of production.

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