



Solutions for End
to End Bioprocessing
with Integrated
Automation

Simplifying Progress

SARTORIUS

Maximize Your Process Efficiency

At Sartorius Stedim Biotech Integrated Solutions we provide a unique implementation methodology for your bioprocess using single-use technologies wherever possible and hybrid solutions as appropriate for your type and scale of process. Our teams develop the layout, workflow and design of your bioprocess equipment based upon your process needs.

Parallel to your process design, we also consider the need and importance of state of the art automation systems to maximize process efficiency and minimize risk. At Integrated Solutions, we engineer, design, and implement flexible automation platforms and management information systems to match your industrial needs.

Sartorius Core Competences

Customer Single Use Process

Siemens Core Competences

Sartorius and Siemens: Partners for Your Success

- Intuitive Systems Tailored to your Process
- Possibilities for Process Optimization through Flexible Configurations
- Faster Time to Market
- Decreased Engineering Effort through Quality of Design
- Expedited Project Execution
- Accelerated and Reliable Start of Production
- Lower Initial Investment
- Precise Cost Determination and Allocation in Early Design Phases of production

The Sartorius conceptual design approach combines hardware, software and consumables in a unique way to ensure full functionality, best-in-class supply chain, serviceability and hence enables single-use commercial manufacturing.



By working in close corporation with Siemens, we are able to provide core competencies in both bioprocess and automation engineering. This is the key to success for your next Biomanufacturing facility.

“Keeping up with the dexterous industrial trends, the state of the art equipment provided by Sartorius, coupled with our process centric approach and partnership with Siemens allows us to deliver the most optimized solutions to meet the heterogeneous needs of the clients.”

Michael Koch
Head of Integrated Solutions Sartorius Stedim Biotech



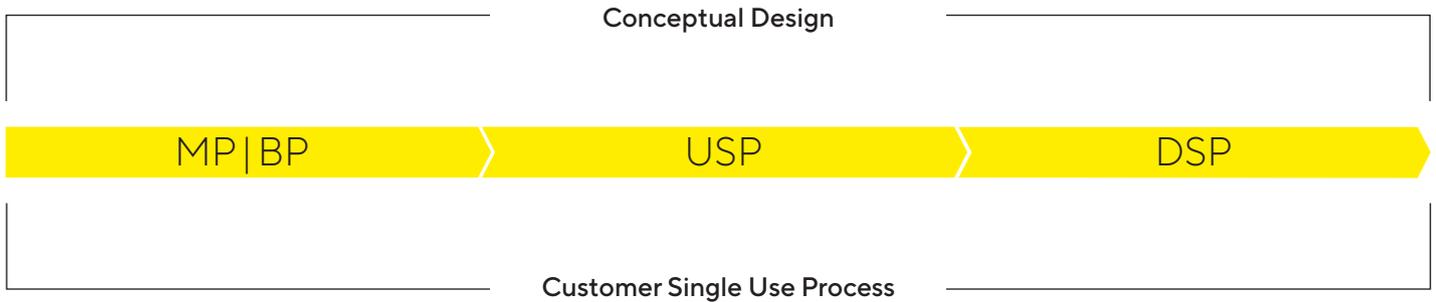
Conceptual Design – Automation Concept

The Sartorius Integrated Solutions **conceptual design services describe** the engineering philosophy for entire single-use processes. Well defined sequences of pre-defined unit operations are combined to the entire process lines. These platform processes will support present and future progress in biopharmaceutical development and production in order to shorten the time-to-market by minimising engineering efforts and installation work.

We Guarantee

- ✓ High Quality
- ✓ High Investment reliability
- ✓ Short Leadtime

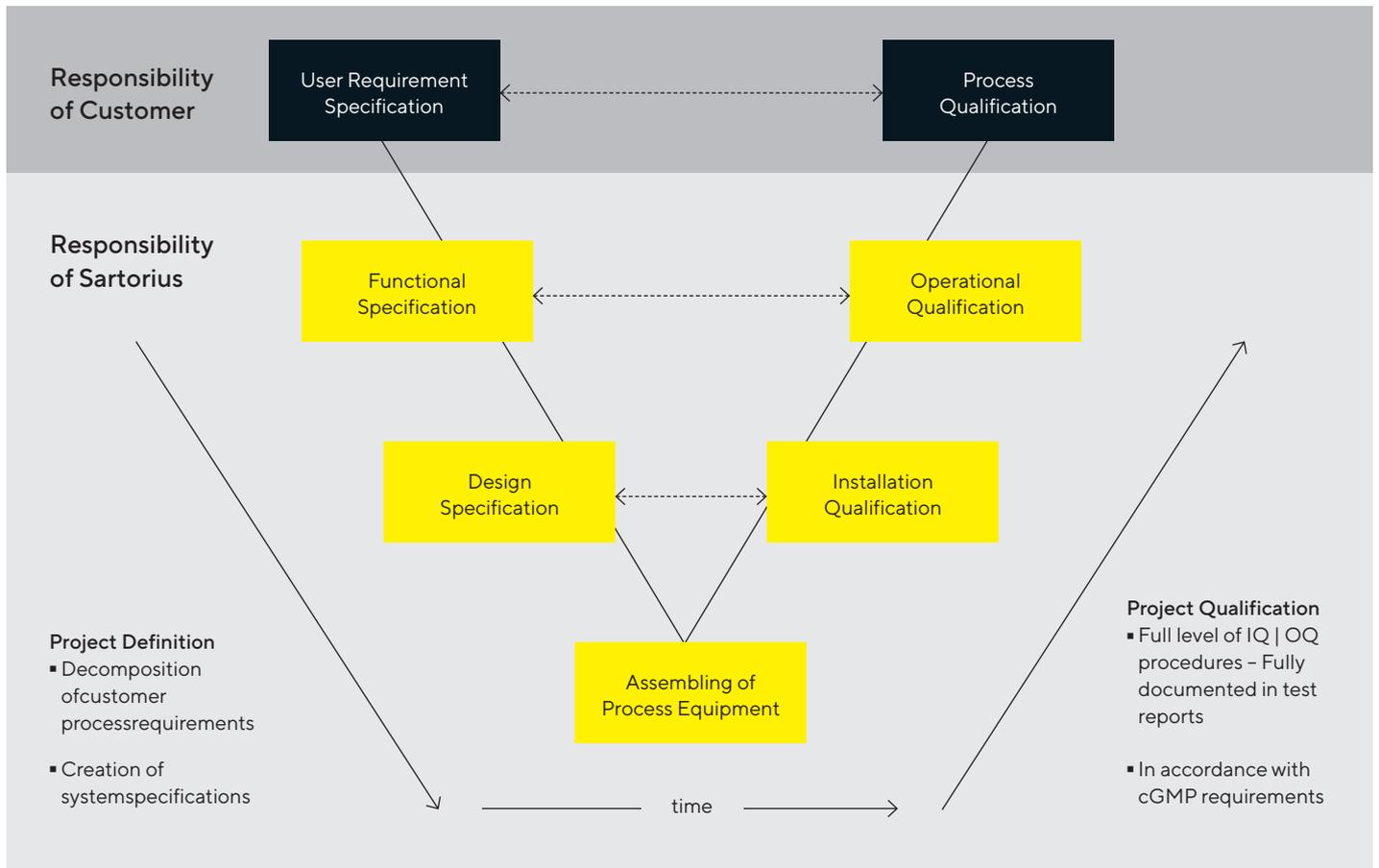




With our individual conceptual design studies, Sartorius offers tailored solutions which meet individual customer process requirements. The customers can concentrate on their core competences, and Sartorius offers the process know-how. From the definition of the process up to the integration into customer IT infrastructures, Sartorius provides the solution – the “all-around carefree package”. Conceptual Design shortens the realization time supporting faster time to market.

Development Lifecycle Model

To ensure our projects meet customer and cGMP requirements, a rigorous development lifecycle model is followed: starting from day one through to all engineering design, manufacturing and qualification test phases.



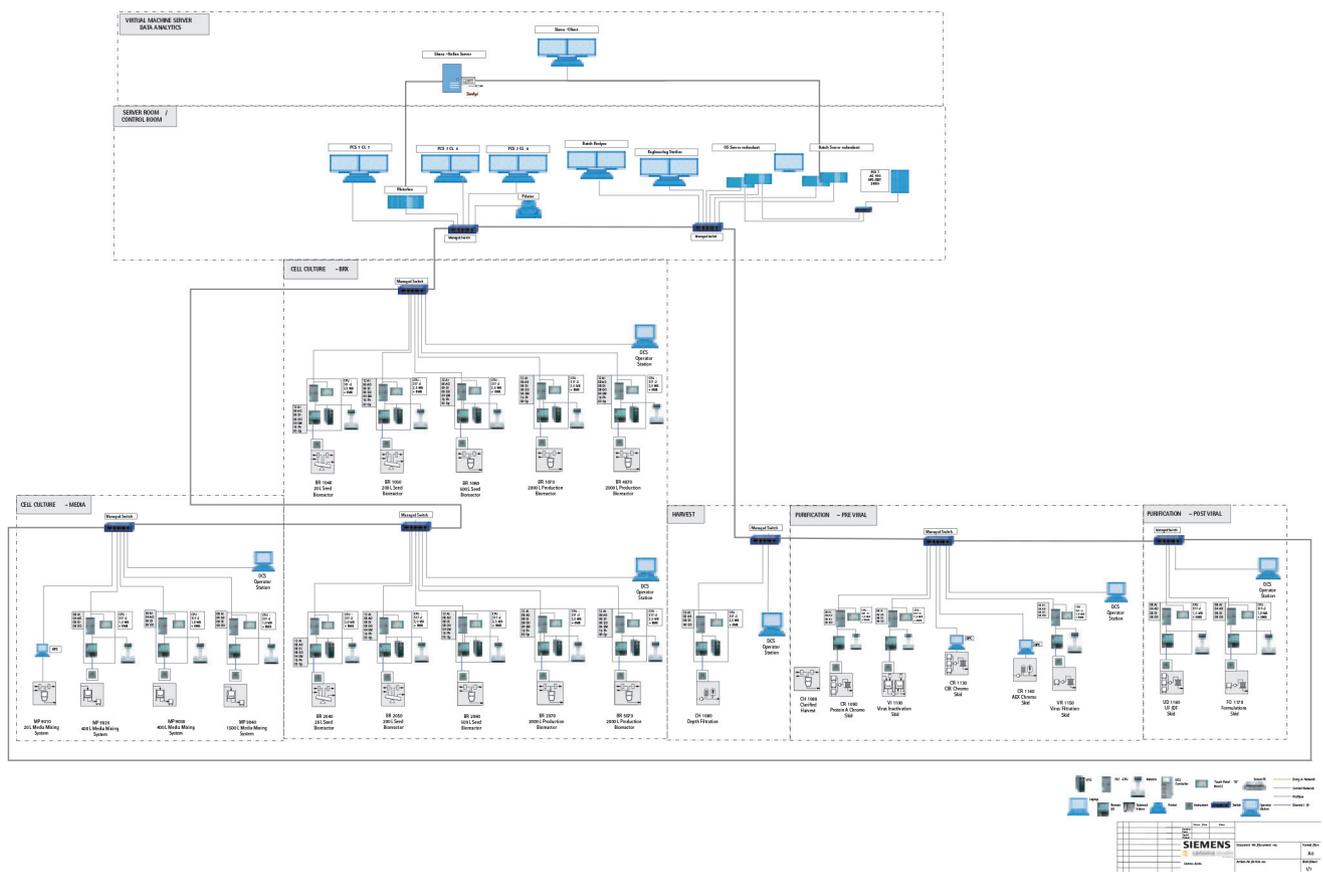
Automation: The Backbone for Successful Project Execution and Smart Bioprocessing

Besides equipment, automation and integration into a control infrastructure are fundamental to a successful project execution. The goal is flexibility in automation.

Sartorius single-use equipment can easily be integrated into a distributed control system (DCS), respectively into a manufacturing execution system (MES). This open system architecture covering the entire production process ensures an efficient interaction of all automation components. This is supported by consistent data management, global standard compliancy and uniform software interfaces.

Our preferred automation solution is based on Siemens technologies. Siemens ensures continuity and reliability regarding availability and support throughout the complete life cycle of the plant.

In addition to the openness of an integrated system architecture, this holistic automation approach paves the way for intelligent bioprocessing by means of Multivariate Data Analytics (MVDA) and real-time data acquisition and monitoring of your bioprocesses. Siemens SIMATIC PCS 7 works together with MVDA software packages provided by Sartorius Stedim Data Analytics.



DCS System Architecture for a fully integrated SU Process Line

Sartorius and Siemens: Partners for your Success



“The turn-key solution offered by the Sartorius | Siemens-Partnership enables pharmaceutical manufacturers to accelerate their digital transformation journey by leveraging highly efficient manufacturing equipment by Sartorius as well as state-of-the-art automation and digitalization technologies by Siemens.”

Christian Korner
Corporate Account Manager Siemens AG

The use of industrial standards in automation guarantees stable systems with minimized risk and faster time to production within the predicted cost frame.

The implementation of a Distributed Control System (DCS), like Siemens SIMATIC PCS 7, fulfills today's requirements of biopharmaceutical industries, like plant-wide recipe control, full electrical batch reporting (eBR), review by exception (RBE) and plant-wide visualization.

The advantages of the Sartorius – Siemens automation approach includes a seamless scalable solution, from fulfillment of basic GMP requirements via batch management up to paperless manufacturing.

Sartorius **Process Equipment Assemblies (PEA)** can be easily drag-and-dropped into Simatic PCS 7, creating an integrated bioprocess line. This not only decreases engineering effort and implementation time, but also provides the flexibility to change and add **PEA's** on demand. Additionally, there is no risk to open an engineering change management process (ECM) for pre-qualified **PEA's**.

Both Sartorius and Siemens share a proven track record and provide full level local support and remote maintenance access as well as personalized service packages and maintenance contracts.

Sartorius Core Competence

Leading provider for end-to-end bioprocess solutions from concept to realization.

Siemens Core Competence

Leading provider of industrial automation solutions.



Customer Benefits

- Decreased Risk
- Increased Quality
- Flexibility
- Security of Investment
- Faster Time to Market
- Maximum Productivity

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