

REFERENCE PROJECT

SARTORIUS

Sartorius Stedim Biotech GmbH
Coordinating, Reliable Test Management between
Product Development and Quality Management
in the Field of Laboratory Products and Bioprocess Solutions

The Customer

Sartorius Stedim Biotech is a global partner of the biopharmaceutical industry and helps to develop production processes and manufacture biotech medications and vaccines more efficiently. Technologies cover, inter alia, cell line technologies, cell culture media, bioreactors, and a wide range of products for separation, purification, and concentration of biological intermediates and finished products, as well as solutions for their storage and transportation.

The Project

A new centrifuge system for the purification of biotechnology products for industrial downstream processes was to be developed, tested and made market-ready at the Göttingen site.

The Task

For the development verification and qualification of the new centrifuge system, an external test manager was to act as an interface between product development, quality management and project management, providing coordination support and ensuring GMP compliance.

The Execution

As part of the team, the role of test manager was implemented at the customer as a coordinating interface between project management, quality experts and development engineers as well as laboratory specialists. In close coordination, the necessary hardware and software tests were derived in the respective product development phase and optimized planning was carried out, taking into account resource availability and given milestones. Qualification plans were drawn up to demonstrate compliance with the respective requirements. The aim was to ensure compliant and traceable test documentation that could be used by practitioners in the laboratory. Specifically developed templates were used to generate test reports and verification documents that fit neatly into the customer's quality management system. With regard to GMP, competent consultancy and support was provided in the creation of test specifications, derivation of acceptance criteria and measurement uncertainty analyses. Risk analyses were used in the evaluation of deviations.

The Result

The new Ksep® 50 System was, comprehensively tested and qualified, successfully launched on the market.



gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 and comparable quality standards. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes also permanent support for everything related to the customer's ongoing GMP operations.

Key Performance

- Test management
- Project management for product testing
- Verification and qualification
- Test planning and support test specification
- Measurement uncertainty evaluations
- GMP and quality management consultancy
- Qualification documentation
- Strengthening resources and external expertise