

Reference



BASF SE

Biotech Pilot Plant GMP Readiness and Long-term Support as External GMP Office



The Customer

BASF creates chemistry for a sustainable future. White or industrial biotechnology is a key technology for BASF. Projects for the new or further development of procedures and processes are again and again being carried out in the biotech pilot plant at the Ludwigshafen site. This is where BASF researches methods and procedures for the efficient, resource-saving production of chemical and biochemical products. Fermenters on a technical centre scale are used, complete with a process control system.

The Task

gempex has been providing GMP-related support for the BASF SE biotech pilot plant on the consulting, conceptual and operational levels for many years already. Initially this cooperation started with the preparation and implementation of a GMP system tailored to meet the requirements for the production of a biotech development product. GMP compliance was required. Meanwhile, the system is established and gempex as the external GMP office assumes the function of a supporting quality unit.

The Services

A validation concept had to be established and a complete quality assurance system according to GMP had to be set up for the introduction of the product and GMP system. This included conducting risk analyses and planning as well as carrying out qualification and validation tasks. Since these tasks were successfully completed, gempex has served as the external GMP office for the biotech pilot plant, handling the following tasks among others:

- Reminder service for upcoming revisions of instructions, including preparation/finalisation of the documents
- Revision of process instructions relevant for quality
- Organisation of the management of documents with archiving, administration and distribution
- Carrying out self-inspections
- Annual review for the purified water system (Aqua Purificata)
- Consulting accompaniment for changes and deviations
- Training on topics related to quality and GMP

Thus, the customer is competently and completely relieved at this point.

gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, DIN ISO 9001 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 permanent support for everything related to the customer's ongoing GMP operations

Key performance
<ul style="list-style-type: none"> • GMP consultancy • Quality assurance system development and implementation • SOP preparation • Validation concept • Risk analyses • Qualification • Documentation and archiving • Self-inspection • Product quality review • Training