

R E F E R E N Z P R O J E K T

ZLB Behring (former Aventis Behring)

The customer

ZLB Behring is one of the world's leading companies in production of plasma derivatives. The company supplies more than 75 % of the market and almost 20 % of all plasma derivative drugs. ZLB Behring offers over 25 products in indications like coagulation failure, immune-defects, wound healing and intensive care. ZLB Bio-Services, a subsidiary of the company, disposes of one of the largest organisation for the collection of plasma donations. The world market for plasma derivatives and recombinant products has an actual value of approximately 6.4 billions US \$. ZLB Behring is one of the leading suppliers in this market.

The project

For the extension of production capacity and for optimization of processes at the main location of the company in Marburg the reconstruction of two production buildings was necessary. New sterilisation channels and an adaptation of clean room facilities, cooling chambers and media systems were required. Especially for the reconstruction of a cooling chamber, with which it was possible to thaw 5000 plasma flasks at defined temperature profiles, a special and high quality planning and qualification service was needed.

The task

All together the service of gempex Inc. was the prospective qualification of facilities and equipment, especially the preparation of qualification documentation (plans and reports for IQ, OQ and PQ) and execution of qualification (IQ and OQ). In addition we managed the organisation and allocation of necessary equipment for calibration and measurements.

The execution

The project was limited to 5 months. This close time frame and the qualification of the cooling chambers were a special challenge for our staff. The gempex project team consisted of a project leader and two validation engineers. During the execution of installation qualification and operation qualification gempex strengthened the team by two additional co-workers resulting in a team of 5 engineers working during this phase at our customer. Due to an excellent preparation and an exact project plan established in advance by ZLB Behring and gempex together, finalisation of the project was reached within the given cost range and time frame and at a high-quality level. Needless to say, that a good and close communication of all people involved was the overall basis for that. The result was an in time production start within this new facilities.



gempex Inc. supports leading companies in the chemical and pharmaceutical industry in the execution of quality aspects according to GMP, GLP, DIN ISO 9000 and others. Main activities are the professional execution of validation and qualification projects including consultancy work during design construction and reconstruction of production plants. This includes continuous support in all questions concerning the running GMP production plant.

Key Performance

- IQ, OQ, PQ
- Sterilisation channel
- Clean rooms
- Cooling chambers
- HVAC systems
- Media systems
- Sterile production technology
- Liquida
- Blood products