

REFERENCE



**CureVac**

Continuous, broad technical support in various projects as GMP expert and project manager in the service fields of quality control, project management, qualification, validation and routine GMP operation.

**The Customer**

CureVac is a biopharmaceutical company pioneering the development of a new class of transformative medicines based on the messenger RNA (mRNA). The basic principle is the use of this molecule as a data carrier for information, with the help of which the body itself can produce its own active substances to combat various diseases. The focus is on prophylactic vaccines such as against COVID-19, novel cancer immunotherapies and molecular therapies. Currently, more than 600 employees are committed to realizing the clinical potential of the proprietary mRNA technology. The major goal: to provide mRNA-based vaccines and drugs to combat a wide range of diseases.

*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.*

**The Projects**

The initial project of the ongoing collaboration was a series of laboratory relocations that had to be managed with GMP in mind. This was followed by laboratory management in quality control to bridge a resource bottleneck. Further projects were project management of new laboratory construction, support of method development and analytical technologies, representation of quality control in product development, projects, planning, coordination and execution of qualification activities, methods and cleaning validation as well as support in daily routine GMP operations.

**The Tasks**

The enormous range of tasks extends from consultancy and conceptual to executive and control activities. Several gempex experts support the CureVac team in all tasks related to quality assurance and quality control in the field of biomedical research at the highest level. Flexibility, absolute reliability and also even a little bit of pioneering spirit are required in the field of GMP services.

**The Realization**

In close, alternating cooperation with the QA and QC teams of the customer, new projects are always completed successfully and in an unerring and professional manner despite the enormous time pressure.

Key Performance
• Quality Control, laboratory management, GMP Audit, sampling concept
• Project lead pharmaceutical new construction
• Relocation planning laboratory
• Project representation Manufacturing area
• Data Integrity
• Method and cleaning validation
• Laboratory equipment qualification and SOP preparation
• Analytical Technologies