

REFERENCE PROJECT

# metabion



**metabion GmbH**

**Certification for the Manufacturing of Excipients According to EXCiPACT**

on the way to GMP for active ingredients manufacturing for clinical investigational medicinal products

**The Customer**

metabion GmbH is a biotechnology company headquartered in Munich, Germany. Founded in 1997, metabion has achieved a worldwide leadership position in the custom nucleic acid synthesis market segment. As a global player in the niche market of custom oligonucleotides, the company delivers to more than 80 countries. The company's mission is to drive and support scientific progress and translate it into diagnostic and therapeutic solutions.

**The Project**

metabion is working on establishing GMP-certified active ingredient manufacturing for investigational medicinal products at its new site in Munich-Kirchheim. The first milestone for this was the EXCiPACT certification for the manufacturing of excipients, incorporating GMP regulations.

**The Task**

The processes, plants, systems, and quality management for the new production of investigational medicinal products had to be designed to meet the requirements of EXCiPACT and implemented in an inspection-safe manner with a view to subsequent GMP certification. Full service as required, from design review to inspection support.

**The Execution**

Based on a gap analysis, a concept for the upgrade of the QMS was developed. Measures included employee training and education, software validation, risk analyses, preparation of SOPs, and support for qualification and validation of the relevant plants and processes. SOPs, process flow and cleanroom plans were developed and finalized in workshops. The design review of the new construction led to the joint development of a project URS for the new site in Kirchheim. GMP-relevant aspects were identified, consultancy was provided on their planning, and contacts with the local supervisory authority were supported. In preparation for the inspection, an internal mock audit was carried out and the last weak points were eliminated. Support during the actual EXCiPACT inspection ensured a successful procedure.

**The Result**

The EXCiPACT certification was passed very successfully without any findings. The report highlights very reliable processes and highest hygiene standards.

*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 permanent support for everything related to the customer's ongoing GMP operations.*

**Key Performance**

- Gap analysis QMS
- Upgrade QMS: ISO-13485 to EXCiPACT
- Design Review
- GMP consultancy
- Qualification and validation concept
- Risk management
- IT validation, change control
- SOP preparation
- Preparation and support of EXCiPACT audit
- Internal audit
- Trainings