

REFERENCE PROJECT



Wacker-Chemie GmbH

**Validation Concept Preparation
Including Qualification and Validation
of an Existing Fine Chemicals Plant**

Customer Profile

Wacker-Chemie GmbH is a globally operating chemicals group based in Munich, Germany with 20 production facilities around the world. Its Burghausen location is the leading production facility and also Bavaria's largest chemical industry site. Around 10,000 employees in over 150 production operations on the factory premises produce several thousand different products. As an expert in biotechnology, organic synthesis and silane chemistry, the WACKER FINE CHEMICALS business area delivers tailor-made solutions for customers in the life sciences and consumer care industries around the world.

The Project

The objective was to redesign an existing fine chemicals plant of the WACKER FINE CHEMICALS business area so that pharmaceutical active ingredient intermediary products for oral and topical applications could be produced in the future in compliance with the applicable GMP regulations and requirements. This required both the fundamental implementation of a validation concept and the structural optimization of the multi-product plant in regards to infrastructure, facilities and auxiliary equipment. Among other things a filling booth with ventilation to clean room standards was installed, the entire nitrogen network was completely replaced, and input filters for raw and auxiliary materials were acquired.

The Task

The services provided by gempex in the first project phase encompassed the introduction of a validation concept, the preparation of an operational performance specification, conducting risk analyses for the manufacturing plant, production processes, automation and cleaning procedures, and compiling the validation documents in a validation master plan.

In the subsequent second project phase, consultancy for GMP compliance and validation coordination were provided along with qualification of the existing and new parts of the plant as well as cleaning validation for an established reference product. gempex also assisted the customer with optimizing the GMP documentation system, including preparation of the SOPs.

The Realization

From introducing the validation concept to the conclusion of cleaning validation, the project was completed in about 1 year. The schedule for the first project phase was tight with a duration of 3 months. The main challenge in the second project phase was to integrate the prospective tests (DQ through PQ) for structural plant optimization into the retrospective qualification activities. Thanks to regular validation team meetings, effective and goal-oriented collaboration with the customer, and consistent project tracking, the project was successfully completed within the planned schedule and budget.

gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, GLP, DIN ISO 9001 and comparable quality assurance systems. Main activities are consultancy and the professional execution of validation and qualification projects, including consultancy during design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.

Key Performance

- Validation concept
- URS
- Risk analyzis
- Retrospective qualification
- DQ, IQ, OQ, PQ
- Cleaning validation
- SOPs
- Agitator vessel, centrifuge dryer, utilities
- Multi-product plant
- API, intermediate products