

REFERENCE PROJECT



SternMaid GmbH & Co. KG

Validation planning, concept development including GMP compliance consulting, qualification and validation in the production of foodstuffs, food additives and auxiliary materials



Customer Profile

SternMaid GmbH & Co. KG operates as a contract manufacturer of powdery foodstuffs, food additives, dietary supplements, pharmaceutical auxiliary materials and sensitive mixtures. The broad range of business areas is also reflected by the scope of services offered by the company: compounding, refining, filling and decanting as well as logistics for these goods are the order of the day. New high-tech mixing plants support production according to pharmaceutical standards, meeting even the strictest requirements.

The Project

Products for the pharmaceutical auxiliary materials industry will also be mixed and packaged on an existing SternMaid mixing and filling line in the future. Minor technical optimisations were realised and organisational as well as documentation measures were implemented in order to ensure compliant manufacturing of the products according to the applicable GMP rules. The plants, media supply systems and facilities were also qualified and the cleaning procedures were validated.

The Task

The services provided by gempex GmbH in the first project phase encompassed the introduction of a validation concept, compiling a validation master plan, the preparation of an operational performance specification, and conducting risk analyzes for the manufacturing plant and cleaning procedures. Individual GMP training tailored to the needs of SternMaid was also conducted in this early phase of the project.

In the subsequent second project phase, consultancy for GMP compliance was provided along with qualification of the existing plant components as well as cleaning validation for an established reference product.

The Realization

The challenge in this project was to comply with the GMP requirements while simultaneously maintaining the conditions in the existing manufacturing plant as well as the existing documentation system as far as possible. The project team consisted of a consultant, a senior validation engineer and a validation engineer. Thanks to purposeful project management, the high level of motivation among all participants and effective cooperation, the project was completed at a high level of quality within the specified 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
•	GMP performance specification
•	Risk analysis
•	Retrospective qualification
•	Cleaning validation
•	Training
•	Mixing and filling line
•	Rooms, HVAC
•	Multi-product plant
•	Auxiliary materials