

REFERENCE PROJECT



Wiewelhove GmbH

Qualification of existing facilities, solid forms



Customers Profile

Wiewelhove GmbH based in Ibbenbüren near Osnabrück developed from the Stern-Apotheke pharmacy founded by the pharmacist Alfred Wiewelhove in 1957. Today Wiewelhove is a company that, among other things, develops and produces solid oral medications, dietary supplements, weight loss supplements and medical products from natural and synthetic ingredients for national and international customers in the pharmaceutical and food sectors. In the meantime, more than 172 employees at two production facilities in Ibbenbüren support a processing capacity of more than 1,200 tons of raw materials to make two billion single doses per year.

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.

The Project

The project objective was the technical review of all facilities and equipment used for pharmaceutical production in the course of qualification and to document this in compliance with GMP requirements. Within this qualification of existing facilities and equipment, the “existing facility qualification”, a concept for combined installation and operational qualification as well risk assessment, had to be implemented for the customer in addition.

The Task

The services provided by gempex in the first project phase encompassed the introduction of an existing facility qualification procedure, the retroactive qualification of five production machines chosen as examples (mixing plant, screening machine, tablet press, capsule filling machine, packaging line), and overall project coordination. A combined IQ/OQ concept with integrated risk assessment for the existing facilities was introduced at the same time. Complete qualification of the “existing facilities” defined in the validation master plan for the production and packaging of solid dosage forms then followed in the subsequent second project phase. gempex also assisted the customer with the modernization of an existing water purification (AP) system and the qualification of new ventilation systems in course of preparing various performance specifications.

The Realization

On the one hand, the challenge was to perform the qualification of machines while avoiding unnecessary production downtime. On the other hand, the manufacturer and operator documentation provided by the operator had to be reviewed and checked for relevance. The qualification was carried out in smaller sub-projects of five to eight machines per campaign in order to avoid overloading the operation and personnel resources in production and engineering. Thanks to effective and goal-oriented collaboration with the customer along with consistent project tracking, the project was successfully completed within the planned schedule and budget.

Key Performance
<ul style="list-style-type: none"> • Qualification Concept for the existing facilities • Qualification of Existing facility • Risk analysis • IQ, OQ, GMP assessment • Performance specification
<ul style="list-style-type: none"> • Mixing plants, screening machines, mills, tablet presses • Drum hoop mixer, WSG, coating pans • Water purification systems (AP), ventilation systems