

REFERENCE PROJECT



**Evonik Operations GmbH | Health Care
Constant Project Support and Qualification
of a New Spray Drying System in New Construction
in Accordance with GMP**



The Customer

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of € 15.2 billion in 2024. The group’s Health Care business line is a global innovation hub for the companies from the pharmaceutical and medical device industries, supporting customers along the entire product cycle.

The Project

Evonik planned the construction of a new spray drying plant for EUDRAGIT® dispersions, including a new building at the Darmstadt site. The GMP concepts established at the site and in the business line apply here.

The Task

Consulting and conceptual support for the implementation of GMP requirements were required to accompany the conceptual and detail engineering. This included a higher-level user requirement specification, a project master plan, the documentation for the qualification stages DQ, IQ and OQ for the production plant, the clean room area and the media supply. In addition, GMP project management and support for overall project coordination until all qualification stages were provided. During detail engineering close coordination with the plant supplier was requested.

The Realization

Initially, a user requirement specification was worked out in cooperation with the customer while the conceptual engineering was carried out. With the beginning of the detail engineering, a GMP project master plan was created that defined the concept, approach and templates. Thereby, the project was implemented in the higher-level site quality system. After internal approval, the detailed GMP planning was developed using risk assessment. The results of existing risk assessments were incorporated. Integrated into the commissioning phase, the qualification activities DQ, IQ and OQ were carried out using supplier documentation. The necessary documents were worked out in cooperation with the customer’s quality unit.

The Result

The new production plant for spray drying of aqueous dispersions was successfully put into operation. All GMP requirements were implemented reliably and smoothly thanks to constant support from concept engineering to the completion of qualification.

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 the design, construction and reconstruction of facilities. This includes ongoing support for everything related to the customer’s ongoing GMP operations.

Key Performance

- GMP user requirement specification
- GMP risk assessments
- Detail engineering support
- Qualification master planning
- Qualification DQ, IQ, OQ
- Project support