

REFERENCE PROJECT



Degussa AG*
*now **Evonik Röhm GmbH**

Target/ actual analysis with subsequent qualification and validation, analysis for the production of UV absorbers

The Customer

Degussa AG is Germany's third-largest chemicals company. As the world's number one in specialty chemicals, Degussa creates system solutions with innovative products that are indispensable to the success of its customers under the motto "creating essentials". The *Personal Care* business area is a leading global supplier of raw materials for the cosmetics industry. In addition to the unique and comprehensive selection of speciality chemicals, tailor-made solutions are offered to customers for sun protection, skin and hair care, antiperspirants, deodorants and decorative cosmetics. The range of mineral UV filters in the sun protection segment was recently expanded with TEGO® Sun T 805 G, a fine, hydrophobic titanium dioxide powder made by Degussa.



The Project

The fine, hydrophobic titanium dioxide is produced at the Rheinfelden site using the AEROSIL® process. Manufacturing is continuous in an existing mono-plant. The titanium dioxide is used as a UV absorber and therefore an active ingredient of sun protection creams. This makes it a pharmaceutical active substance that has to be manufactured in compliance with GMP. Minor structural optimisations were carried out and documentation as well as organisational measures were implemented to meet the applicable GMP requirements. The plants, media supply systems, facilities and process control system were also qualified and the manufacturing process was validated.

gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, GLP, DIN ISO 9000 and comparable quality assurance systems. Main activities are consulting 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 Task

The scope of services included conducting a target/ actual analysis. Risk-based validation planning was performed on this basis, with the introduction of a validation concept, establishment of all operator requirements (performance specification) and risk analyses for procedures, equipment and computer systems. The plants, media supply systems, process control system and facilities were retrospectively qualified while new plant components were examined prospectively. A retrospective validation of the manufacturing process was performed. The documentation concept was amended to include missing GMP aspects. All employees received basic GMP training.

The Realisation

The challenge in this project was to comply with all GMP requirements while simultaneously maintaining the conditions in the existing manufacturing facilities as well as the existing documentation system as far as possible. The project team consisted of a consultant and a validation engineer, assisted by additional validation engineers in labour-intensive project phases. For the most part the project was coordinated and completed from the technical office in Mannheim. Regular validation team meetings were held in Rheinfelden. The project was successfully concluded in just 12 months.

Key Performance

- Validation concept
- GMP performance specification
- Risk analysis
- Qualification
- Validation
- SOP preparation
- Solid substance handling
Pharmaceutical active substance
- Basic GMP training