REFERENCE PROJECT

Brüggemann Alcohol HEILBRONN

Comprehensive GMP Upgrade
for obtaining an
official GMP certificate

The Customer

The history of L. Brüggemann KG goes back to the year 1868. Producing alcohol was one of the company's key business areas from the outset.
BrüggemannAlcohol Heilbronn GmbH was founded as part of the Brüggemann Group in 2009 after a restructuring and supplies the food, pharmaceutical and medical product industries with high-purity ethanol. Ethanol in denatured or undenatured quality is used as an active pharmaceutical ingredient and as an excipient in various pharmaceutical preparations.

The Project

Plant-based ethanol of highly pure quality is manufactured in the existing production facilities. Fully GMP-compliant production according to the regulations for pharmaceutical active substances (EU GMP Guideline Part 2) was the objective, confirmed by a GMP certificate issued by the applicable supervisory authority. Technical optimisation measures were implemented in the production facilities and filling lines and the organisation and documentation structures were adapted in order to reach this goal. The facilities, media supply systems and premises were qualified and the production process was validated.

The Task

After gempex reviewed the current state in the course of a preceding gap analysis, determined the need for optimisation and established planned measures, the measures were jointly implemented. Here gempex GmbH's scope of performance consisted primarily of introducing a validation concept, preparing a GMP performance specification and carrying out risk analyses for processes, facilities and automation. The qualification of the facilities and premises and the process validation on this basis were handled by gempex as well.
GMP training tailored to the individual needs of BrüggemannAlcohol Heilbronn GmbH was provided in the course of the entire project and the SOP system was optimised. Preparing for and accompanying the official inspection was also part of the services provided.

The Realisation

In terms of content, the challenge in this project was to maintain the conditions of the existing manufacturing facilities and the documentation system as far as possible, and to ensure the clear separation of GMP production.
The project team consisted of a consultant, a senior validation engineer and a validation engineer. Thanks to smooth and effective cooperation, the project was realised with high quality and the official inspection was successfully passed in the end.

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

Key Performance

- *Gap analysis*
- *Validation concept*
- *SOP preparation / adaptation*
- *Risk analysis*
- *Performance specification*
- *Cleanrooms*
- *Qualification of new and existing facilities*
- *Process validation*
- *Analysis of historical process data*
- *GMP training*
- *GMP compliance consulting*