REFERENCE PROJECT

RÜHL AG & Co.
Chemische Fabrik KG

Qualification and validation of a fully automated multi-product filling plant for disinfectant production

The customer
Rühl AG & Co. as a contract manufacturer of disinfectants for healthcare applications manufactures products at its headquarters in Friedrichsdorf im Taunus, among others for the medical device industry. The DIN ISO 13485 certified company, which is part of the RÜHL Group, is engaged in the ongoing development, production and filling of new products ranging from alkaline, non-foaming disinfectant cleaners to acidic, non-foaming cleaning agents to conventional disinfectants.

The project
To meet customer requirements and comply with applicable standards, RÜHL required the qualification and validation of a new, fully automated multi-product filing plant for disinfectants.

The task
The focus was on processes relevant for quality, such as the installation of screw tops, the scales and camera in order to guarantee flawless filling of the manufactured disinfectants and ensure the correct sealing and labelling of the two to ten-litre canisters.

The services
Following the analysis of the current state, a qualification and validation concept was developed and concept SOPs were prepared. The process steps relevant for quality were documented in the validation plan and subjected to a risk analysis, focusing on identifying the points critical for quality and the interplay of the various plant elements. The GMP experts at gempex summarised all relevant tasks and steps in the individual qualification and validation phases in a to-do list and comprehensively briefed the employees involved.

The result
The gempex consultants attended the implementation of measures critical for quality. In the end, RÜHL was able to put a GMP-compliant, fully automated multi-product filling plant into operation. Thanks to extensive training of the employees in project management, their state of GMP knowledge and their understanding of roles in ongoing GMP operations, the company will be able to ensure GMP conformity itself going forward.

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. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes permanent support for everything related to the customer's ongoing GMP operations.

Key performance

- *Qualification and validation concept*
- *Concept SOPs*
- *Validation master plan*
- *Risk analysis*
- *DQ, IQ, OQ, PQ*
- *Validation*
- *Documentation*
- *Training*