

REFERENCE



Similasan AG
GMP Upgrade for Bulk Production and Aseptic Filling:
Annex 1 Compliance through Intensive Support
in Consulting, Implementation and Inspection



The Customer

Similasan AG develops and manufactures homeopathic medicines. The company, based in Jönen in the canton of Aargau, employs around 100 people in Switzerland. Its product range includes more than 110 homeopathic preparations approved by Swissmedic. Similasan is the world's largest manufacturer of natural eye drops.

The Project

The existing sterile filling line for eye drops, the bulk production clean room area, and the WFI system needed to be adapted to the requirements of the new Annex 1. The challenges included the remediation of the existing plant during parallel running production, upgrading the QM system, flexible resource reinforcement, and passing the related inspections.

The Task

Overall project management for all sub-projects was required as well as comprehensive consulting and intensive active support for all necessary accompanying qualification measures – from URS to PQ. Support was provided for the technical design of the filling line conversion. After replacement, the WFI system had to be brought through phases PQ I-III. Furthermore, the planning and execution of the validations, including the aseptic process simulation, had to be supported. The entire QMS had to be adapted to the new situation. QA tasks were taken on as a temporarily outsourced service. Together with the customer, the inspections had to be prepared, witnessed and followed up. Commissioning support completed the package of tasks.

The Realization

In close coordination with the customer, support was provided primarily on site with a team of up to four people, supported by additional subject matter experts, for example in the field of IT validation. A temporary deputy QA manager was installed. An experienced consultant led the project and was available at all times to answer any critical questions.

The Result

After an intensive upgrade, the old aseptic filling line was successfully adapted to the high requirements of the new EU GMP Annex 1 guideline, the inspections were passed. Future-proof, Similasan AG can now manufacture and distribute eye drops in accordance with the latest and highest quality standards.

gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 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

- GMP upgrade
- EU GMP Annex 1 Consulting
- Project Management
- URS, SMF
- Qualification, Validation, SOPs
- QMS upgrade and QA support
- Construction, design
- CSV according to GAMP
- Swissmedic inspection support and assistance