REFERENCE

Topwell Apotheke Dr. Kreyenbühl

Improvement of the GMP processes and upkeep of the production license for pharmaceutical products in small quantities

The customer

The pharmaceutical laboratory of Topwell Apotheke Dr. Kreyenbühl specialises in the production of pharmaceutical products in small quantities according to “GMP for pharmaceutical products” of the Swiss pharmacopoeia. The pharmacy has a production license for pharmaceutical products and a mail order license for extemporaneous preparations from the canton of Thurgau, underscoring its high level of expertise in pharmaceutical practices.

The project

After the takeover of Topwell Apotheke Dr. Kreyenbühl and its relocation to the new site in Horn on the Lake Constance, the operation faced the challenge of meeting the requirements of the GMP rules for the production of pharmaceutical products in small quantities in the new facilities and with the resulting processes.

The task

All facilities and processes relevant for quality were reviewed in detail so that required adaptations could be made and possible changes implemented.

The services

After taking an inventory of the current state, measures to maintain and improve the GMP status were proposed and implemented. This included preparing master plans and various document templates. A special focus was on raising awareness among the employees and getting them involved, which was accomplished with training regarding GMP content and corresponding working methods. The QA management function was assumed by gempex on a transitional basis by way of support.

The result

The GMP experts from gempex accompanied Topwell Apotheke Dr. Kreyenbühl in designing and implementing tasks relevant for quality in close cooperation with its employees. Ultimately both the understanding of GMP and the processes relevant for GMP were significantly improved. A site-specific QMM and VMP were established among other things, and a new log book system was introduced. The operating approval was renewed without difficulty by the cantonal pharmacist.

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 duing design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.

Key performance

- *Maintaining the production license at the new location*
- *Analysis of the current state*
- *Validation master plan*
- *Process validation*
- *Qualification of equipment*
- *Document management*
- *GMP training*
- *Handling of QA management*