



QUALITY MANAGEMENT SYSTEM FOR PHARMACEUTICALS AND MEDICAL DEVICES

Our customer is an independent Swiss wholesale partner for bakery, gastronomy, home, and hospital supplies. When expanding the home and hospital sectors, the health needs of residents and patients are at the forefront. As an independent partner, our customer supports healthcare institutions with specific product ranges and services.

Establishment of the legal framework and adaption of documents

For a more flexible response to future requirements, the company worked together with konplan and an additional partner to establish a separate quality management system for the pharmaceutical and medical device divisions which also enhances the existing system for the food division.

Initially, the team conducted a workshop to determine which regulatory frameworks were required for the long term. The existing documentation and process descriptions were then adapted to the new situation. Using our comprehensive expertise, we were able to categorize and separate the documents related to pharmaceuticals and medical devices from those related to the food division. Despite a tight four-month project schedule, the documents were revised and quickly issued to the new healthcare division in close collaboration with the customer.

Overview with requirement mapping

The requirement mapping process provided the customer with a comprehensive and detailed overview. It defines which paragraphs from the applicable regulations must be addressed in the individual quality documents. Future changes to the regulations can be monitored at regular intervals, and, if necessary, the relevant documents can be revised immediately.

Result

- Requirement Mapping
- Separate quality management system for pharmaceuticals and medical devices

Methodology & Technologies

- Visio
- MS Teams
- Kanban

Scope of Services

- Establishment of a proprietary quality management system
- Adaptation of existing documents



4 months



3 employees – konplan
4 employees – customer
2 employees – Partner



Analysis & idea generation
through to production

