REFERENCE

# QUISISANA Pharma AG


GMP concept implementation
international pharmaceutical product manufacturing, trade, wholesaling and shipment including inspection preparation and support

## The Customer

QUISISANA Pharma AG was founded in 2006 as a subsidiary of QUISISANA Holding AG with its registered office in Zurich. Going forward, its international business activities will encompass the import and export of ready to use pharmaceutical products, the wholesale trade in Switzerland and international trade. Applications for approvals are also being submitted in Switzerland for pharmaceutical products covering the full therapeutic spectrum. Dr Wenzel as Managing Director and long-term partner of renowned pharmaceutical companies guarantees compliance with the high quality standards that are required today.

## The Project

The applications for initial issuing of the establishment licences for the import and export of ready to use pharmaceutical products, the wholesale trade with market approval in Switzerland, and foreign trade were submitted to Swissmedic. A GDP-compliant quality management and quality assurance system was introduced to meet regulatory requirements. First the new company's GDP-related business processes had to be defined and described in SOPs. The project objective was accomplished with the successful inspection by the authority and the granted approvals.

## The Task

The scope of services encompassed the introduction of a GDP documentation concept in line with the requirements and the corresponding preparation of all required SOPs. Regulatory requirements in Switzerland and other country-specific rules had to be taken into account. The SOPs cover topics such as quality management, personnel, documentation, approval, facilities and equipment, goods receiving and warehousing, delivery to customers, returns, self-inspections, supplier qualification, pharmacovigilance and quality control. Accompanying the official inspection concluded the project.

## The Realisation

The challenge was to introduce the future GDP-related business processes in a very short time while taking the current size of the company as well as its development potential into account. This was realised through a pragmatic yet high-quality concept. The project team consisted of a consultant and an experienced project team member. Coordination and implementation were handled mainly from the office in Winterthur. Regular meetings were held in Zumikon. The project was successfully concluded with the official inspection within just two months.

*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 pro-jects, including consultancy duing design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.*

**Key Performance**

- *Initial issuing of establishment licence*
- *Good Distribution Practice*
- *Import and Export of medicinal products including market approval*
- *Wholesaling with market approval*
- *Foreign trade*
- *SOP preparation*
- *Official inspection*