REFERENCE PROJECT

SANUM-Kehlbeck

# Sanum Kehlbeck GmbH & Co. KG

GMP-Upgrade and Full-GMP-Service
in the Production of Homoeopathic Pharmaceutical Products
in Preparation for an Official Inspection

## Customer Profile

Sanum Kehlbeck GmbH & Co. KG was founded by the Kehlbeck family in Hoya/Weser in 1975 by taking over all rights and trademarks of IBICA, Hamburg and the company Sanum founded in Berlin in 1932. Sanum Kehlbeck supplies the health market worldwide with homoeopathic products. It produces more than 50 homoeopathic basic materials (isophathics) for this purpose using biotechnology processes. More than 400 different finished pharmaceutical products in various dosage forms are produced from these at the Hoya location. The dosage forms are tablets, suppositories, salves, vials, capsules and drops.

## The Project

The main project objective was the expansion, modernisation and adaptation of the existing production facilities to the increasingly more strict and globally oriented GMP requirements (GMP upgrade). This was prompted by the pending registration of various products, the conversion of the biomanufacturing facility and the associated obtaining of the official operating permit, as well as the introduction of new IT systems to increase flexibility and improve competitiveness.

## The Task

After gempex in the course of a preliminary project defined the specific activities and summarised them in an overall project schedule, project control was the primary task in the subsequent course of the project with consultancy, conceptual design and implementation. This encompassed the preparation of GMP related documentation and the implementation of specific GMP measures.

The project was broken down into the following sub-projects:

- Training and GMP consultancy
- Preparation of master documents
- Biotechnology conversion planning
- Preparation of SOPs relevant for production
- Conducting the process, cleaning and analyzis method validations
- IT and LIMS validation

## The Realization

Since an official inspection related to the conversion had already been initiated and product deliveries were confirmed, the project work had to be completed in a very short time in absolute compliance with official requirements.
The project was completed in a total of 10 months from initial scheduling and conversion planning to finalization of the documents and conclusion of all individual activities. Up to 8 gempex employees were involved in parallel during the busiest phase. This ambitious objective – successful concept planning, implementation, and retrospective and prospective qualification and validation in the shortest possible time – could only be realized through corresponding good coordination of all activities and extremely well optimized collaboration with the customer.

*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**

- *Validation concept*
- *SOP preparation and adaptation*
- *Risk analysis*
- *Conversion planning*
- *Clean rooms*
- *Qualification (retrospective and prospective)*
- *Process validation (retrospective)*
- *IT validation*
- *LIMS validation*
- *Cleaning validation*
- *Validation and verification of the analysis methods*
- *Training*
- *Consultancy*