

REFERENCE PROJECT



Full-GMP-Service
including Qualification and Validation for
manufacturing naturopathic products

Customer Profile

A group of people who came together in Marburg as the "Verein für Leukämie- und Krebstherapie e. V." in 1971 developed a gentle process for the production of mistletoe preparations through many years of research. The new preparation was tested by interested doctors and a major clinic in Vienna. HELIXOR Heilmittel GmbH & Co. was founded in 1975 on the basis of this work. Helixor based in the idyllic Rosenfeld in the Alb-Zollernkreis district with a total of 85 employees produces various mistletoe preparations for subcutaneous administration to cancer patients and distributes these pharmaceutical products worldwide.

The Projects

The projects' objective was to advise the customer on all matters related to the topics of GMP, qualification and validation (cleaning, process, computerised systems) in the course of comprehensive cooperation and ongoing support (full GMP service), and to provide personnel resources for implementation as needed. In particular, a concept for the validation of computerised systems and the validation of cleaning procedures was introduced and implemented within various sub-projects.

The Task

The services provided by gempex in the first cooperation phase encompassed the introduction of a validation concept for computerised systems and the retrospective validation of various systems (IT infrastructure, labelling software, measurement recording system and weighing software) including project coordination. A validation concept with integrated risk assessment for computer-based legacy systems was introduced as part of the project. Various existing facilities and equipment (including transport containers, a centrifuge, extraction vessels and a washer) were retrospectively qualified as well in the course of ongoing support. Temperature distribution studies were also conducted with external logger systems and bio-indicators on the systems within the sterile process.

In a subsequent ongoing support phase, gempex is assisting with the introduction and implementation of a concept for the validation of cleaning procedures, including the validation of select facilities and equipment. gempex is also advising the customer regarding the risk assessment of the manufacturing processes to prepare for process validation.

The Realisation

The challenge was to avoid overloading the operation and the existing personnel resources in production and engineering in the course of the project. Thanks to goal-oriented collaboration with the customer, the sub-projects were completed successfully.



gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, GLP, DIN ISO 9000 and comparable quality assurance systems. Main activities are consulting and the professional execution of validation and qualification projects, including consultancy during design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.

Key Performance

- Full-GMP-Service in the form of ongoing support
- Validation Concept for computerised systems
- Retrospective IT-Validation
- System Qualification
- Concept for Cleaning Validation
- Multi-level Risk Analysis
- Cleaning Validation