

REFERENCE



Inspection Readiness and Many Years of GDP Consultancy as Lead Consultant

Customer Profile

UPP United Pharma Partners is a medium-sized company specialized in (pre)wholesale of temperature-sensitive medicines for human use for rare and orphan diseases. UPP is a pan-European distribution specialist offering its various partners individually tailored solutions for the logistics of pharmaceuticals under GDP conditions.

The Project

The initial project of the long-term cooperation was the optimization of the Quality Management system in 2016, which was completed with the successful GDP certification. Since then, gempex has been the contact whenever GDP topics are touched upon. With a view to economic efficiency and compliance, individual solutions for sometimes very specific products are required.

The Task

In an initial gap analysis, the need for adaptation and optimization as well as possible solutions were identified. Based on a derived to-do-list, process-describing documents had to be revised and supplemented, and work instructions for the wholesale routine had to be created. In a subsequent inspection, the measures proved their worth and were further optimized selectively. This was followed by the development and implementation of regular GDP training courses for employees on topics such as regulations, the QM-system, storage areas and transport, processes and documentation, claim management and the special features of international shipping. Another project was the qualification of the IT infrastructure.

gempex Services

Since 2016, gempex has been supporting UPP, formerly Med-HS, in all important GDP issues. From consultancy for new GDP projects to direct presence and on-site support, the flexibly retrievable services range. Goal-oriented, efficient and good teamwork ensures a high level of trust.

The Result

UPP is safely positioned in the field of GDP and goes relaxed into the following inspections and customer audits with a strong consulting partner at its side.

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

Key Performance
<ul style="list-style-type: none"> • Gap Analysis • List of Measures and Concept SOP • Creation of QM Documents • Inspection Readiness • GDP Trainings • Qualification IT Infrastructure • GDP Consultancy