REFERENCE PROJECT

medinova

Medinova AG
On-time, Competent Support to Reinforce the Resources for the PQR Preparation

The Customer

The pharmaceutical company Medinova AG is part of the Swiss DKSH Group and is positioned as a niche provider with a clear emphasis on gynaecology, dermatology and other selected therapeutic fields. The product portfolio includes prescription drugs as well as consumer healthcare products available over-the-counter and medical devices. Medinova is thus successful in Switzerland as well as in 65 international markets.

The Project

Medinova needed competent personnel support in the preparation of the Product Quality Reviews (PQR) to be prepared annually in order to reliably prove consistent product quality as required by the regulations.

The Task

For the preparation of PQRs, Medinova has a firmly established process based on a key SOP. The annually required Product Quality Reviews for various products from the product range were to be prepared according to this process. On the one hand, this was a laborious task, and on the other hand, high professional GMP expertise was required.

The Realization

At the start of the project, the company-specific features were communicated in a workshop. A permanent team was established remotely to take over the task. It was important to act as independently as possible in order to relieve the customer. On the customer side, a central contact person was defined. The necessary raw data from production, analysis, quality assurance and licensing were compiled, evaluated and included in the PQR for each product. A jour fixe was arranged for questions and to discuss finished documents. At the same time, knowledge was built up on the job for the accompanying QA. Based on broad GMP expertise, it was possible to assess the data, evaluate it in overview and, where necessary, provide information and recommendations to the customer.

The Result

With the expertise and relieving manpower provided, Medinova was able to prove the required PQRs on time.

gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 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 operations.

Key Performance

- *PQR*
  Product Quality Review
- *GMP Routine Support*
- *External competent support with broad GMP expertise*