REFERENCE

MEDIPOLIS INTENSIV

GMP documentation concept
for pharmacy operations
including
validation of aseptic products

The Customer

Medipolis Produktion GmbH & Co. KG is a midsize family company that emerged from a traditional pharmacy business. In the course of time, the company developed into a highly specialised manufacturer of patient-specific pharmaceutical product preparations, and supplies numerous clinics and medical practices.

The Project

Extending the product range with the associated expansion of the company inevitably resulted in higher demands on the quality assurance system. A restructuring of the system description documentation also became necessary as a result. Existing deficits were determined in advance by means of a gap analysis.
The project objective was to optimise and adapt the concept documentation needed for GMP operations to the current requirements. This encompassed revising the instructions based on the existing production processes and adapting them to a previously defined document hierarchy. Numerous individual documents also existed for historical reasons. These had to be converged in a suitable manner in order to ultimately ensure the easiest possible handling and improved manageability. Due to growth of the product range and the related demand for variability of the product-specific manufacturing processes, the optimisation also focused on process validation and the validation concept for aseptic process control (media fill).

The Task

Overall the services provided by gempex GmbH encompassed the revision of about 270 existing individual documents, which were optimised and summarised in around 40 concept documents. Process validation was performed on the basis of a complex, risk-based bracketing concept. Here a total of seven main processes, which in turn were broken down into 18 sub-process variations for the production of five product groups, were subjected to a worst case assessment. The validation of aseptic process control was integrated into this overall approach, and the resulting validation tests were performed in the course of ongoing operations on the basis of the prepared test protocols and successfully completed.

The Realisation

Six months were available for project execution, and the documents were prepared during this time in close coordination with the customer. Highly efficient processing was realised by combining and prioritising synergetically favourable topics into work packages.

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

- *Gap Analysis*
- *GMP Concept Documentation for pharmeceutical operations*
- *Process Validation*
- *Validation of aseptic process control (Media Fill)*