REFERENCE

# Kettenbach GmbH

GAP analysis and implementation
of resulting measures
to prepare for an FDA audit
including support in the context of
dental product manufacturing


## Customer Profile

Kettenbach GmbH, a midsize company in the medical device sector based in Eschenburg, Germany is a leading international supplier of dental impression materials. Lastic ®55 was the world's first condensation cross-linking impression material developed and produced by Kettenbach. In addition to polysiloxane-based impression compounds, the product range includes a unique, differentiated selection of highly cross-linking impression materials as well as relinings and highly absorbent sterile sponge materials.

## The Project

The project objective was to prepare the customer for an already scheduled FDA compliance audit within the scope of short-term cooperation and comprehensive support (full GMP service). In the course of these activities, gempex provided the services of various experts in all matters related to the FDA audit, GMP in general, qualification and validation. The existing GMP system was optimised and adapted to meet the FDA requirements.

## The Task

Initially gempex GmbH conducted an overall gap analysis to establish the required measures across all departments. An individual validation concept for Kettenbach was prepared based on the results. This concept encompassed all required work instructions (SOPs) and forms for implementing the specific activities. Kettenbach was able to complete the retrospective qualification of the production facilities with the help of these specification documents. The QM processes (change control and CAPA) were also adapted to the regulatory requirements and optimised overall in the subsequent course of the project. Preparation and functional support for the FDA audit was the final element of this project. An optimised GMP concept adapted to customer requirements and successful completion of the FDA audit were the final results.

## The Realisation

The objective was to prepare the existing GMP system and the customer for an FDA audit within a few (four) months and to complete the audit successfully. Meeting the tight schedule was the greatest challenge for all project participants. The schedule was met and the project was completed successfully thanks to excellent collaboration and the extraordinary motivation of all team members.

*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*
- *Validation Concept*
- *Validation Masterplan*
- *Risk Analysis*
- *Qualification*
- *IT-Validation*
- *CAPA*
- *Change Control*
- *Audit Management*
- *FDA Audit*