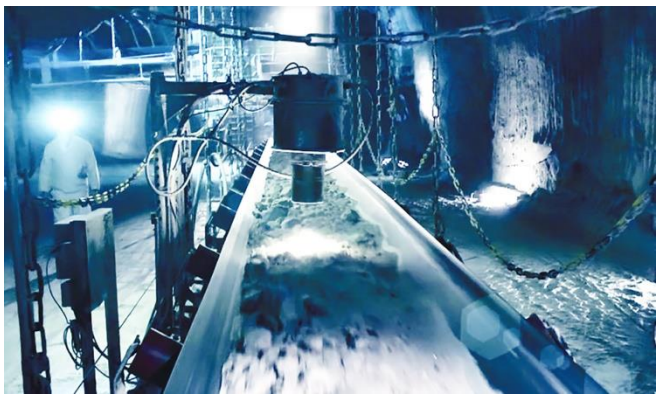
REFERENCE PROJECT



K+S AG

US FDA Inspection Readiness and Inspection Support

The Customer

K+S AG is an internationally oriented raw materials company with more than 11.000 employees and production sites in Europe and North America. At the Rheinberg site, the Borth rock salt plant has been extracting high-quality rock salt from a rich deposit since 1925. Both rock salt and vacuum salt are extracted here for the European market, eg. de-icing salt for winter road services, table salt products and high-purity pharmaceutical salt.

The Project

At the German production site in Rheinberg, Borth, an inspection by the US FDA was due for the manufacturing areas subject to cGMP regulations.

The Task

External consultancy support was required for the preparation, conduction and follow-up of the FDA routine inspection.

The Services

The cGMP areas were inspected on site and the process flows in the mine itself, in the laboratory and in production were examined. Based on the gap analysis, a catalog of measures was developed and implemented, taking into account specific US FDA requirements in the areas of packaging and labeling, for example. Documents were reviewed and, where necessary, optimized and supplemented. In preparation for the inspection, strategies were developed and employees were trained. FDA dos and don'ts were advised. Together with the customer, an opening presentation and necessary documents for the inspection were elaborated to give valuable support for the process. The actual inspection was accompanied with experience. During and in the post-inspection phase the communication with the authorities was supported competently. An adequate written response was delivered to achieve the approval of the site by the US FDA.

The Result

Comprehensive preparation and competent support during and after the inspection ensured the successful passing of the US FDA inspection.

gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, DIN ISO 9001 and comparable quality standards. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes permanent support for everything related to the customer's ongoing GMP operations.

Key Performance

- *US FDA Inspection Preparation*
- *Document Review*
- *Labeling*
- *Employee Training*
- *Opening Presentation*
- *Inspection Translation and Conduction*
- *Communication with the Authority, Response letter*
- *FDA Approval*