

## REFERENZPROJEKT



## BASF ChemTrade GmbH

### The customer

BASF ChemTrade GmbH is a medium-sized company based in Burgbernheim. The 100 % subsidiary of BASF AG supplies active ingredients and excipients for the pharmaceutical, food, feed, cosmetic and aroma chemicals industry. The product range includes polymers, conditioners, UV-absorbers, thickeners, polyethylene glycols, oils, solubilizers, complexing agents, neutralizing agents, emulsifiers, surfactants, colorants, aroma chemicals, active ingredients, excipients, beta-carotenes and a variety of vitamins. Besides standard package sizes, BASF ChemTrade GmbH delivers small and medium quantities in customised package sizes.

### The project

About 200 products are stored in Burgbernheim and, depending on customers' requests, either distributed in smaller quantities or refilled in smaller package sizes. Therefore, diverse storage areas and several filling rooms for different product requirements exist. For implementing actual requirements of GMP and introducing a HACCP concept, few constructional improvements and actions in documentation and organisation were established and implemented. Furthermore the critical room areas were qualified and refilling-processes were validated. The constructional designs of the rooms as well as material and personal flows were almost completely retained.

### The task

Based on a detailed GMP GAP analysis the scope of services of gempex Inc. included the implementation of a validation concept, the introduction of a documentation system for SOPs as well as execution of risk analysis according to HACCP and GMP. Furthermore, the filling rooms for GMP products were qualified and the refilling processes were validated. Staff was trained on GMP and HACCP topics.

### The execution

With a view to this project, the challenge was meeting all requirements of HACCP on one hand and to supplement specific GMP topics on the other hand. Furthermore, the concept had to consider the actual size of the company and its dynamic development. During the entire project, the gempex team consisted of a consultant and a validation engineer. The project was coordinated from the Technical Office in Mannheim. Validation team meetings were held in Burgbernheim on a regular basis. The project was successfully finished within 12 months only.



*gempex Inc. supports leading companies of the chemical and pharmaceutical industry in realization of quality aspects according to GMP, GLP, DIN ISO 9000 etc. Main activities are the professional execution of validation and qualification projects including consultancy work during design, construction and reconstruction of production plants. This includes continuous support in all questions concerning the running GMP production plant.*

#### Key Performance

- Validation concept
- Risk analysis
- HACCP
- Qualification
- Validation
- SOPs generation
- Clean Rooms
- Manual product handling
- Handling solids
- APIs, Excipients
- Food additives