

REFERENCE



BASF SE

Review and Adaptation of the Zone Concept for Active Substance and Auxiliary Material Filling Areas



The Customer

BASF creates chemicals for a sustainable future. The group's portfolio is organized into the segments Chemicals, Materials, Industrial Solutions, Surface Technologies, Nutrition & Care and Agricultural Solutions. BASF is represented with over 360 production facilities in more than 90 countries. In the Nutrition & Care segment, BASF is a leading supplier of ingredients and solutions for customers in the food, cosmetics and pharmaceutical industries, among others. GMP compliance in line with the relevant regulations around the world plays an important role.

The Task

The GMP-compliant design of manufacturing departments for active substances and auxiliary materials frequently poses a major challenge, and not only because processes and products can vary widely. There are also few or no regulatory provisions for this product class, including for open product handling and here, in particular, the filling area. No fixed regulations define the required hygiene or clean room classes. In order to establish a progressive, state-of-the-art approach, uniform at sites around the world, and a standard design, the existing zone concept at BASF was to be revised and expanded for the configuration of the clean zones and primarily the filling areas.

The Realisation

gempex has already been assisting BASF SE for many years in various areas and a variety of GMP topics. This encompasses GMP-compliant basic design (preparation of user requirement specifications) and implementation in the areas of qualification, validation and the establishment of QA systems (preparation of SOPs).

In the task at hand, the know-how and experience from numerous projects completed with BASF in the area of GMP-compliant filling was utilised along with current knowledge of regulatory requirements and the state of the art. The existing zone concept was reviewed in detail. In addition to defining a user-friendly structure, it was adapted to meet the minimum regulatory requirements and supplemented with provided practical examples and descriptive graphical material. The challenge in this project was to ensure a high level of product safety while simultaneously meeting the various product and process requirements. The result is a zone concept that is US FDA, EU GMP and WHO-compliant, flexible and pragmatic.

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
<ul style="list-style-type: none"> GMP consultancy Clean room concept Provisioning of planning examples Instruction on determining a suitable design US FDA, EU GMP, WHO