

REFERENCE



New Plant for PVDC Coating

Customer Profile

Perlen Packaging is an international group of companies in the field of film manufacturing and film coating for primary packaging for pharmaceutical products. The group is the only systems provider of packaging films with a clearly defined pharmaceutical profile. Processes, facilities, products and environment are geared to the needs of the pharmaceutical industry. The Perlen Packaging companies form the packaging division of the CPH Group (Chemie + Papier Holding AG).

The Project

gempex supports Perlen Packaging in numerous GMP-related projects. The business relationship began in 2015 with the major new construction and technology transfer project "New Plant for PVDC Coating" to expand the capacity in Asia.

The Task

In the major construction project, gempex was responsible for GMP compliance right from the initial idea to the current final point. The GMP service provider is justly proud of accompanying such a project from start to finish: from the design review to planning and project organization, qualification and validation to successful certification and now to the verified completion of all GMP-related tasks.

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 projects, including consultancy during design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.

gempex Services

GMP full service: from GMP consultancy to final project completion

- Comprehensive GMP Consulting and Execution Services
- Concept Design Submission and Consultancy
- GMP Specifications, URS and Risk Assessment
- Detailed Design Review
- GMP Basic Training
- Qualification and Validation of Premises, Utilities and Equipment (VMP, IQ, OQ, PQ, Process Validation)
- Validation of IT systems
- Documentation
- Project Coordination and Management
- Drug Contact Packaging Material Manufacturing License Application
- Successful Certification in China

Key Performances

- GMP Full Service
- GMP Consultancy
- Design Review
- Qualification IQ, OQ, PQ
- Validation
- Project Coordination and Management
- IT Validation