REFERENCE

Coperion K-Tron (Schwitzerland) LLC
Individually Tailored GMP Training
for Pharmaceutical Conveyor Equipment Manufacturer

The Customer

Coperion K-Tron (Switzerland) LLC is part of the Coperion Group and a globally operating supplier of process equipment such as feeding and pneumatic conveying components and complete material handling systems. As part of Coperion's Polymer Division, the company manufactures equipment at its Niederlenz site for handling bulk materials for food, pharmaceuticals, plastics or chemicals in sectors of the process industry.

The Project

The rapidly growing company aimed to provide all parties involved with a uniform, up-to-date basic knowledge of GMP. Technical documents of the system manufacturer were to be designed in such a way that the customer could refer to them in the qualification.

The Task

A GMP refresher training was to be designed and held with representatives of the internal Sales, Engineering and Quality Assurance departments with a view to the specifics of technical systems qualification. An ideal progression from GMP-compliant planning, design, review, installation and acceptance to qualification was described. Approaches for optimization had to be pointed out and the comprehension of the respective requirements had to be achieved.

The Realization

The training was divided into two main basic parts. In the first part, the basics of GMP as well as qualification and validation were taught and updated. The second part consisted of a cross-check of the internal system of proceedings and documents with the regulatory requirements. Possibilities for the optimization of internal communication were shown with the aim of accelerating processes.

The Result

The internal understanding of qualification is increased, the quality of the documents is improved and the general process is more efficient. All departments are on the same level and can provide more targeted qualification support to customers. An additional service from Coperion K-Tron for customers.

gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 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

- *GMP training*
- *Technical qualification of pharmaceutical plant components*
- *Disciplines Engineering, Quality Assurance, Sales*
- *Interface communication*
- *Review of the existing system with regulatory requirements*