REFERENCE PROJECT

Steinweg Medical GmbH

Relocation of the Blister Centre with a Just in Time Schedule - Qualification from DQ to PQ in a Service Package with IT Validation

Customer Profile

In 2006, Steinweg Medical GmbH, part of the NOWEDA group of companies, was the first blister center in Germany to be granted a manufacturing authorization for the production of patient-specific medicinal blisters in accordance with § 13 of the German Medicinal Products Act (AMG) and has been supporting numerous pharmacies ever since. Capacities are continuously being expanded and processes refined. The related machine blistering is considered the most modern and safest form.

The Project

The blister centre is to be relocated to a new site in order to increase capacity. As production can only be carried out a few days in advance, the relocation of technical equipment and IT systems must be completed with maximum reliability within the narrow time frame.

The Task

An existing building is to be adapted to the needs of a blister centre. In the course of the reconstruction, the production rooms, storage rooms, ventilation technology and monitoring system are to be qualified. The IT landscape is to be re-validated. Tasks are CSV concept, validation and documentation, qualification of new IT infrastructure, migration of data and IT systems and validation at the new location.

The Realization

Along a process-oriented concept focused on the essential GMP requirements, all trades were efficiently qualified. Protocol, testing and documentation flowed into each other in a well designed manner. Selective consulting on various GMP aspects complemented the tasks. For IT validation, gempex's CSV concept was tailored, implemented and put into service on the basis of detailed elaborated experience reports. Due to the close interlocking of the individual systems, the interfaces were of utmost importance. In the course of the relocation, IT systems and their data were transferred in a controlled manner to the new qualified IT infrastructure consisting of physical and virtual elements. Intensive preparation, adept planning and the well-organized data transfer ensured success.

The Result

The GMP-compliant production started troublefree and on time for the planned go-live. The authorities immediately issued the manufacturing authorization for the new site.

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

- *Review URS*
- *Superior Qualification Planning*
- *Qualification Reconstruction*
- *DQ, IQ, OQ, PQ*
- *Documentation*
- *CSV Concept*
- *IT Validation*
- *Training GAMP 5*
- *Qualification of New IT Infrastructure*
- *Planning Data Migration*