REFERENCE PROJECT

Risk Analysis FMEA

The Customer

The Children's Hospital of Eastern Switzerland is one of three independent children's hospitals in Switzerland. For its foundation sponsors it takes over the task of a regional center of excellence at the highest level of medical care for pediatrics, pediatric and adolescent surgery, as well as in adolescent medicine and pediatric psychosomatics.

The Project

As part of a modernization project in the central sterilization unit of the Children's Hospital in Eastern Switzerland, the structural measures and associated process change were risk-based evaluated in order to ensure the quality requirements for the reprocessing of medical devices. The HMG, the MepV and the "Good Practice for the Reprocessing of Medical Devices" are the basis of the requirements.

The Task

The risk analysis required to define the measures should be carried out in the form of a FMEA Failure Mode and Effects Analysis, which enables a number-based risk assessment taking into account the influencing variables probability of occurrence, severity of the error and probability of detection. A corresponding concept had to be introduced and hospital employees involved had to be trained.

The Services

A risk analysis concept specifically geared towards the reprocessing medical devices was established and the employees involved were instructed in the methodology and implementation. This was followed by moderation with critical questions about the reconstruction concept, the planned measures and the resulting material and personnel flows. It was important to have an external view in order to identify risks that were difficult to recognize, scrutinize individual sub-processes and verify the overall concept with a final review by gempex.

The Result

Thanks to the targeted support with focus on the specific requirements, the task was completed on time and the modernization was successfully completed.

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.

Key Performance

- *Training Risk Analysis FMEA*
- *Participants Certificates*
- *Process Documentation*
- *Consultancy and Moderation During the Implementation*
- *Final Document Review*
- *Ispection-Readiness*