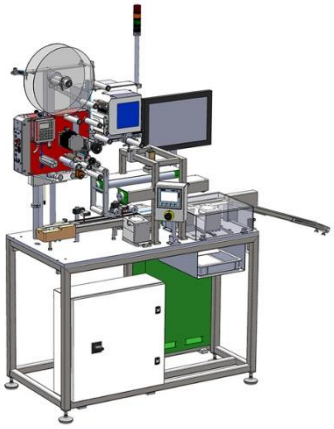
REFERENCE PROJECT



**WILUX Print AG**
**Efficient Qualification of a Labelling System from Development to Delivery: System Suppliers, Operators and Qualification Hand in Hand**

### The Customer

For over 40 years, WILUX PRINT AG as a purely Swiss manufacturer of labelling and marking solutions has been actively shaping its industry, supporting companies from industry, logistics and trade with solutions to optimize workflows, to shorten processes, to simplify handling and to save costs.

### The Project

For a company in the medical devices industry, a labelling system is to be developed that labels auto-injectors directly and, after blistering, the associated packaging as well. The print data of the batch is to be sent directly to the printer, and OCR-based verification is desired.

### The Task

Consultancy support was required to complete all phases of the qualification quickly and safely. GMP requirements had to be checked and supplemented, and the necessary qualification documents for the two systems had to be prepared.

### The Realization

In the first step, a URS was prepared and the basic GMP requirements were specified in it. On this basis, a Requirement Traceability Matrix was developed and evaluated with regard to risks. This central document was authoritative throughout all phases of the qualification process. The respective test points were clearly and comprehensibly assigned to the qualification phases and carried out. Targeted support was also provided in the preparation of the FAT/SAT documents so that referencing to them became possible. Training of all parties at the beginning enabled close interaction between qualifiers, engineers and the QA department of the later system operator. The organizational framework has been set out, and defined workflows, release processes and regular jour fixes ensured a clearly structured process.

### The Result

The intelligent design and integration of the FAT/SAT made it possible to complete the qualification in a particularly efficient, time- and cost-saving manner. Only critical points had to be verified during the qualification process, no tests had to be repeated. A successful project.

*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 also permanent support for everything related to the customer's ongoing GMP operations.*

**Key Performance**

- *Qualification planning*
- *Qualification: DQ, IQ, OQ*
- *Trainings*
- *Preparation URS*
- *FAT/SAT protocols*
- *Risk analysis*
- *Traceability Matrix*
- *Project coordination*