REFERENCE

b+b
Automations- und Steuerungstechnik GmbH

**Validation package for serialisation software,
IT validation documents for software solutions**

Customer Profile

b+b Automations- und Steuerungstechnik GmbH is a supplier of complete solutions in the fields of automation, serialisation and labelling. 9,000 of the midsize company group's installed solutions are in use worldwide. Both the hardware and software of the modules that are offered are developed and produced in-house. The customers of b+b are found in segments ranging from air bags to toothbrushes. It's track & trace solutions for example are also used by companies in the GMP-regulated industry.

The Project

The serialisation software consists of base modules selected and configured to meet the customer's specific needs. b+b plans to offer a validation package with standardised documents in the course of a pilot project. This package will enable customers to independently perform a GxP-compliant validation of the software quickly and efficiently. In parallel the software development process at b+b will be reviewed for conformity with the GAMP®5 guideline.

The Task

The serialisation software consists of base modules selected and configured to meet the customer's specific needs. b+b plans to offer a validation package with standardised documents in the course of a pilot project. This package will enable customers to independently perform a GxP-compliant validation of the software quickly and efficiently. In parallel the software development process at b+b will be reviewed for conformity with the GAMP®5 guideline.

gempex Services

A validation concept was drafted and subsequently presented and refined in the course of a workshop. Subsequently the existing validation documents were integrated into the new package structure and documents required for completion were prepared. The existing URS was adapted to the templates of the newly developed validation concept and linked to the existing software design specification. Extensive possible customer requirements were recorded, standardised and transferred to a clear document structure in this process. Then an exemplary validation according to GAMP®5 was performed with the newly prepared documents and approved for the pilot project by a b+b customer.
The software development modules were reviewed and mapped in the GAMP®5-compliant documentation where required.

The Result

The internal software development process at b+b conforms to the GAMP®5 guideline. Thus the respective software is standardised and can be efficiently validated by the customer. The validation package to implement the serialisation software that was developed for this purpose has been used successfully in the course of a pilot project.

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 pro-jects, including consultancy duing design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.

Key Performance

- *GMP Consultancy*
- *IT Validation Concept*
- *Gap Analysis*
- *Risk Analysis*
- *Software Validation*