

Press release



ServoTech GmbH develops validation strategy AQV® with "agile techniques and methods" and registered as an EU trademark.

Langenburg, 26.6.2019

ServoTech GmbH has been qualifying and validating machines, systems and systems for the pharmaceutical and medical industries worldwide for almost 30 years.

These experiences laid the foundation for the development of our validation strategy **AQV®** with agile techniques and methods.

Pharmaceutical companies or manufacturers of medical devices are always looking for a profitable path that combines both quality and productivity while observing all legal requirements.

More and more new trends are seen. One of these is an intensive qualification of automated systems including or excluding computer system validation (CSV), which subsequently take the manufacturing process under very deep consideration. Frequently the V-model is referred for this. However, this model cannot adequately provide the necessary and required flexibility.

Abiding by the classical V-model has become more and more difficult in a more challenging framework of less time and resources. Here ServoTech's new validation model **AQV®** can assist with "agile techniques and methods".

The agile qualification and validation strategy according to cGMP can be implemented independent of the product and the connected validation strategy. In the age of "Pharma 4.0", it is complex and difficult to transfer projects into a holistic planning conforming to the requirements of the regulated industries.

The **AQV®** contributes to transparency on the part of the supplier as well as the operating company.

Requirements, progress and challenges are recorded in a regular and clearly visible way. Results and functionality relating of the automated manufacturing process are continuously delivered and assessed. Requirements for the automated system, plans and procedures are not set in stone. They are adapted continuously and in detail.

AQV® does not reduce the complexity of validation, but structures validation in smaller, less complex elements. This will ensure success at the end of the project life cycle.

Quality and time-critical projects can be successfully, punctually and validated for the production process with the validation model **AQV®** newly developed by ServoTech GmbH with "**agile techniques and methods**".

Contact for questions

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