QPLIANCE

COMPUTERIZED SYSTEM VALIDATION (CSV)

IMPLEMENTATION, DEMARCATION AND STRUCTURATION

Audit Security is the high priority for pharmaceutical companies, especially when computerized Systems are used. The everchanging GxP regulations, the focus on data integrity, the Data Audit Trails review and the current expertise of auditors increase the need for validation specialization in the regulated environment. Qpliance as a GxP validation expert, is working with several software manufacturers in the pharmaceutical and life science sector to bridge the CSV gaps of their clients with a cooperative and partnership approach.

SOFTWARE VALIDATION VS. CONFIGURATION VALIDATION

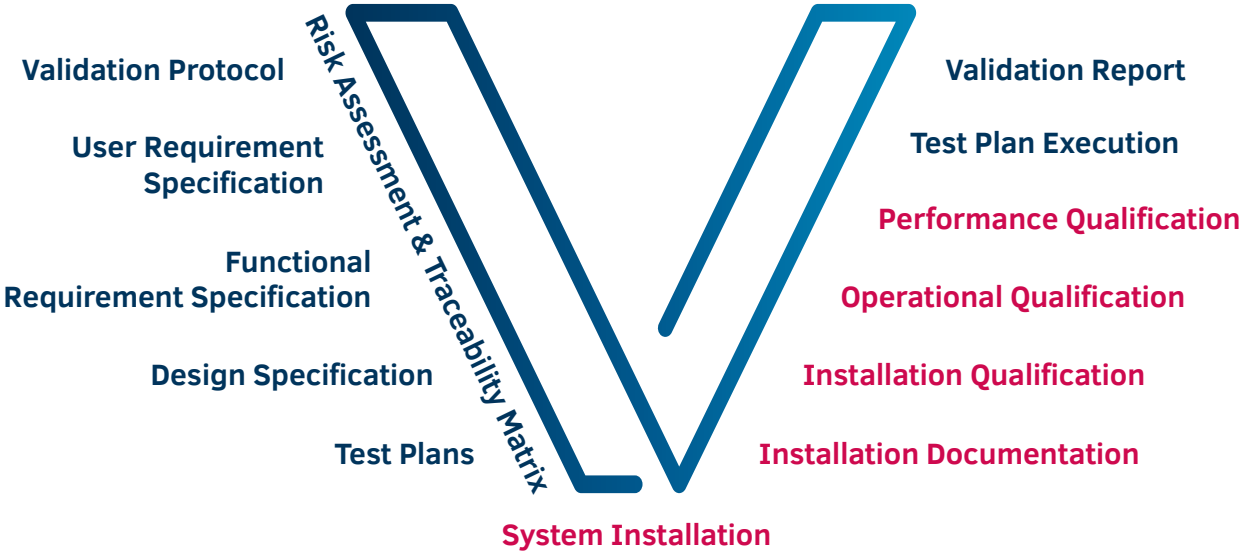
To clearly identify the CSV gaps in manufacturing companies, it is necessary to understand the differences between Software Validation and Configuration Validation.

SOFTWARE VALIDATION is a non-customer specific activity, which is entirely performed by the software manufacturer. A proof of a reasonable implementation of the Validation software is done through a supplier qualification by the customer as part of the procurement process of the software. The actual Software Validation documentation stays with the software manufacturer.

CONFIGURATION VALIDATION designate the software validation configuration, which is the main part of software introduction in the regulated environment. Frequently, the pharmaceutical industry software is a configurable software that must be classified as a category 4 or 5 as per software classification ISPE GAMP©5. A clear consequence of this classification is the requirement of a complete validation of the installed and configured system. The configuration of hundreds settings is highly customized for each client and needs to be validated and tested individually. The Configuration Validation and all necessary activities is the customer's responsibility and requires specific documentation and specific tests.

V-MODEL

For a further demarcation and as an established and known process, we are using the V-Model to perform Computerized System Validation. In the V-Model, the left side of the “V” demonstrates the specification phase before implementing the system. The right side of the “V” combines the test phase after the system installation. The test phase includes all required tests (acceptance tests, system tests and integration tests) against the corresponding specification to ensure a minimum risk and maximum audit safety. The V-Model is used in different variants, figure 01 shows the most important validation documents and activities as part of the introduction of the software in the pharmaceutical industry. The model generally provides a simplified and easy-to-understand representation of the validation procedure between specification and test phases. To represent the entire life cycle system and all validation measures (e.g. training, installation, etc.), however, a different form of representation is required (e.g. workflow diagrams or similar). Qpliance is supporting with the identification and creation of all required documents for a complete configuration validation.



Service Qpliance - Configuration Validation
Service Software manufacturer - Software Qualification

Figure 01: V-Model documentation elements

VALIDATION PROTOCOL

A written validation protocol should be established to specify how the validation of a particular process will be conducted. The protocol should be reviewed and approved by the quality unit(s) and other designated units. The validation protocol should specify critical process steps and the acceptance criteria as well as the type of validation to be conducted and the number of process runs. We ensure that all required steps and objects are covered, to assure a consistent validation execution.

URS - USER REQUIREMENT SPECIFICATION

For security audits, we create or further develop the URS involving the latest GxP regulations and ensure that all following documents are correctly referenced to the URS, so that there is a consistent documentation at the end of the validation process.

FRS – FUNCTIONAL REQUIREMENT SPECIFICATION

We create or further develop the Functional Requirements as response to the URS by the software manufacturer for a consistent and audit save documentation as part of the validation process.

DESIGN SPECIFICATION

The Design Specification or Configuration Concept is the core of the validation and needs to be created in very detailed process. Within the Design Specification the user requirements and the regulatory needs are implemented in the optimal system configuration from a customer perspective. In close cooperation with the software manufacturer, we ensure the correct and secure audit documentation as a basis for the system installation process.

TEST PLANS

The purpose of the test is to proof the system configuration against all user requirements defined in the URS, to verify the suitability of a technical system and to confirm problems and errors. Depending on the outcome of the risk assessment and other measures, the tests can be reduced or become very extensive. We support our customers to identify the effort necessary for a maximum safety.

RISK ASSESSMENT AND TRACEABILITY MATRIX

For qualification and validation activities, a quality risk management approach should be chosen. It should be clearly documented how risk assessments are used to support the qualification and validation activities. The Traceability Matrix as a part of the risk assessment and a concomitant document through the CSV contains all requirements and specific configuration activities that are necessary to reduce risks. Therefore, Qpliance is using a dual FMEA approach to cover all existing risks for a software introduction. The risk assessment, including the Traceability Matrix is the most important document to ensure and demonstrate a guideline through all relevant validation documents.

SYSTEM INSTALLATION

After completing all preparatory activities and documents, the computerized system is installed according to the project specification by the software manufacturer or the customer.

INSTALLATION DOCUMENTATION

To ensure proper installation and verify the system configuration, the installation documentation provides a clear process on how to install and configure the system and on the other hand all the activities performed to install and configure the system as defined in the design specification.

IQ – INSTALLATION QUALIFICATION

The installation qualification is constituted by the documented verification of the facilities and equipment according to the approved design and the recommendations of the manufacturer. The corresponding technical documentation including plans and report are provided by the software manufacturer.

OQ – OPERATIONAL QUALIFICATION

The operational qualification contains documented verification that facilities and equipment are installed or modified within their anticipated operational range, as expected. This includes the check of all software functions, especially all interfaces used for connected systems and instruments. The corresponding technical documentation including instructions for operating, calibration, maintenance and cleaning of the system are provided by the software manufacturer.

PQ – PERFORMANCE QUALIFICATION

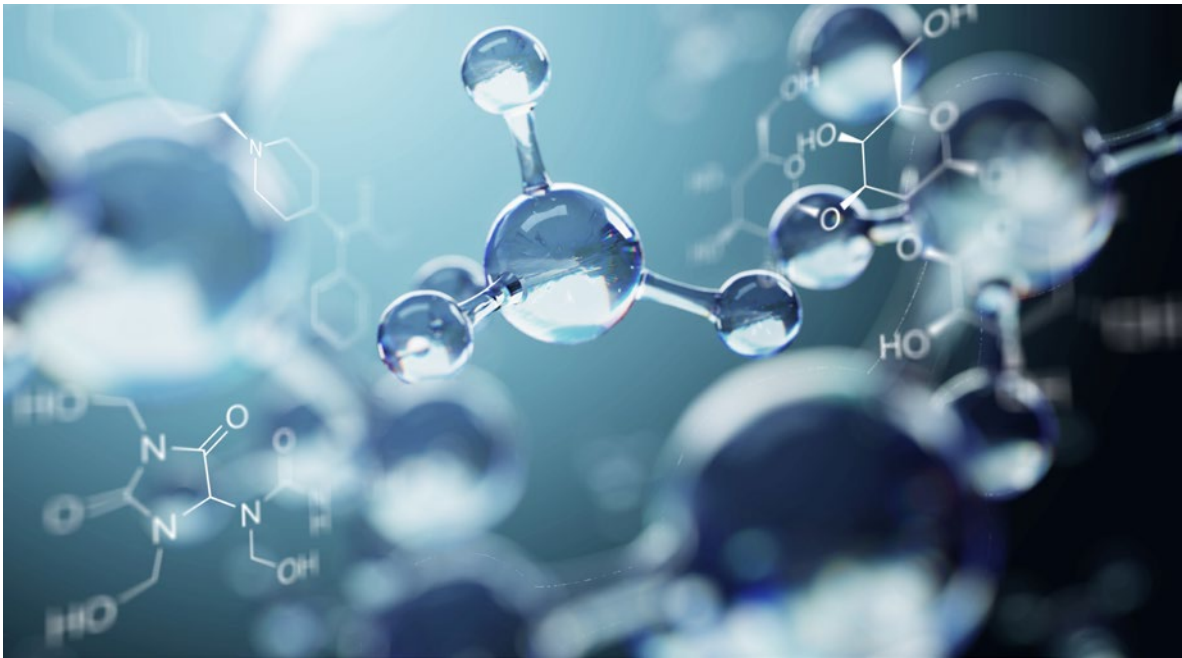
The performance qualification contains documented verification that facilities and equipment, as interconnected, operate effectively and reproducibly based on the approved process method and product specification. The performance tests of the interaction of all individual components of the equipment must prove the total system performance within its intended ranges, as expected. The corresponding technical documentation is provided by the software manufacturer.

TEST PLAN

Execution During the execution of the created test plans, all identified deviations are documented. If necessary, additional tests should be created and performed. All test plans can be implemented by the client. If there are not enough resources available, we will be happy to support the execution through one of our experts to save time and budget.

VALIDATION REPORT

A validation report that cross-references the validation protocol should be prepared, summarising the results obtained, commenting on any deviations observed from the execution of the test plans, and drawing appropriate conclusions, including recommendations for changes to correct deficiencies. The validation report is the final document of the CSV.



ADDITIONAL SERVICES

Computerized System Validation is a very integrated task with several thoughts and follow-up topics. As a comprehensive specialist in GxP, we offer a wide range of additional services to support our customers globally in all regulated matters. That includes:

- Expert Leasing
- Audit Accompaniment
- Data Migration (SQL & Oracle)
- Interface Development
- GxP Trainings and Concepts
- Method Validation
- …

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