

COST-EFFECTIVE AND RELIABLE VALIDATION



**API PRO
Validation
Package**

Validation Support

Validation is, according to GAMP 4 Guide – Validation of Automated Systems, defined as:

“Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.”

API Maintenance Systems has many customers within highly regulated industries, such as pharmaceuticals and food. These industries invest time and effort to achieve and maintain regulatory compliance. The validation is used to verify that the system reliably performs exactly as specified in the requirements. Several validation projects have been performed when implementing API PRO in these regulated industries. There has never been any difficulty receiving on time validation of the system.

API Maintenance Systems has skilled and experienced personnel, regarding FDA requirements and GAMP guidelines, and can therefore offer assistance when performing the validation project. Several validation options can be provided, from handling the full validation project to provision of test plan templates.

The test plan templates have been carefully developed under a long period of time by people with a long-time experience of API PRO. With help of these documents the validation process can be performed professionally and within a time limit impossible to achieve if having to develop the test plans from scratch.

Validation Process

The main activities in the validation process are presented below. For more detailed information regarding what tests are performed, please refer to the Validation Test Plan Templates provided on the next page.

IQ Installation Qualification
The purpose of the Installation Qualification is to make sure that the system is correctly installed and that the installation requirements are fulfilled.

OQ Operational Qualification
The OQ has the purpose to make sure that the system has the functions specified and that it works properly as specified in the functional specification.

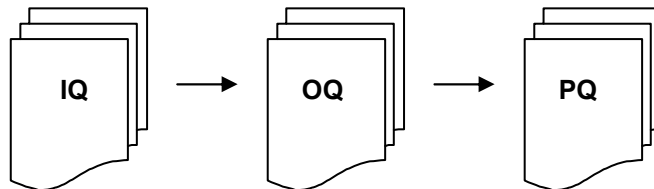
PQ Performance Qualification
The purpose of the PQ is to qualify that the process can perform as specified in the User Requirement Specification.

Upgrade Qualification

A validation performed when upgrading API PRO from an earlier version to a newer version also contains an extra step – namely verification of the transferred data. API Maintenance Systems can perform this verification on-site.

Validation Test Plan Templates

Assistance can be provided when performing validation tests and documentation. API Maintenance Systems can either be an active part of the entire validation process or can provide Validation Test Plan Templates which are of significant help when performing the Validation process without active help from API Maintenance Systems.



Test Plan Templates are provided for all the phases of the Validation Process:

IQ Test Plan Templates

Test of Installation Requirements

Tests based on the installation requirements of the customer in question.

Test of Module Installation

A straight forward test which has the purpose to verify that the installed modules are available in the installed system.

OQ Test Plan Templates

Test of basic functions

An extensive test where all basic functions for the API PRO version in question are tested. If wanted, this test can be performed as a FAT – Factory Acceptance Test – at the AMS office. The FAT is thoroughly documented.

Work flow test

For each installed module a work flow test is available. The work flow test verifies that the functions presented in the functional specification are available. Specific customer requirements are tested in the PQ.

PQ Test Plan Templates

Test based on User Requirement Specification (URS)

All requirements in the URS, which have not yet been tested during the Validation Process, are tested during the PQ.

References

Example references from our pharmaceutical reference list are Alk Abello, Bavarian Nordic, Chr. Hansen, Ciba Vision, Fertin Pharma, Fresenius Kabi, Lundbeck, Octapharma, Schering-Plough etc.

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API Maintenance Systems

API Maintenance Systems in Denmark is the head office of the API group and responsible for the development, sales, implementation and support of the API PRO Maintenance Management System throughout the world. This software is used by many leading companies worldwide in a variety of industries and organizations to maintain high-value capital assets such as plants, facilities and equipment.

www.apipro.com – for more information