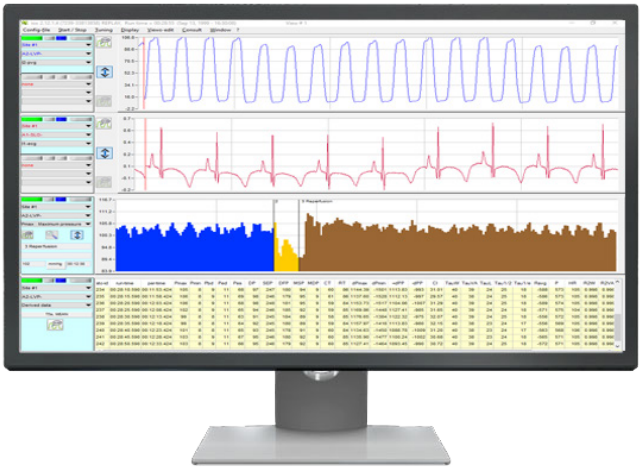
emka TECHNOLOGIES

Validation service

For reproducible, high quality results



WHAT IS VALIDATION?

The Food and Drug Administration defines validation as:

"Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled"

Main steps of the validation process are:

Installation Qualification

Does the installation take place as expected?

Operational Qualification

Does the system perform tasks as expected?

Performance Qualification

Does the system, in its normal operating environment, continue to function as expected?

OUR ADDED VALUE

Save time

Get assistance

Focusing on regulatory developments and validation activities consumes time and resources.

As an experienced technology provider specializing in hardware and software for preclinical research, emka TECHNOLOGIES can assist you in meeting the increasing demands and complexity of regulations.

The result of a validated system is highly dependent on comprehensive software testing, inspections, analysis, and other verification tasks.

The proper documentation must be written to provide evidence that a system meets user requirements and operates as specified.

emka TECHNOLOGIES guides you all along the process.

VALIDATION PROCESS

emka TECHNOLOGIES Validation service includes the following tasks:

1 **Write User Specification Requirements (USR)**

This document is the baseline of the validation project. It clearly defines the Functional Requirements Specification (FRS). It will be the baseline of the risks assessment, which determines the parts of the system that must be validated and the complexity and extent of the tests to be done. The Qualification of the system will then demonstrate this system conforms to regulatory requirements, as well as user requirement specifications.

2 **Create a validation plan (VP)**

This document includes the following information:

- Software and hardware description
- Functions to be validated
- Tests extent established following the risks assessment
- Definition of the responsible parties for the validation
- Validation acceptance criteria

3 **Create Installation and Operational qualification (IQ/OQ) test scripts**

emka TECHNOLOGIES provides scripts that are a guide for the tester, but that also act as a reference to compare the expected outcome to the actual outcome. They consist of a list of actions (what the tester does) and the expected results of those actions (what the program should do based on what is programmed in the application's code). These scripts are tested and optimized during a dry run.

4 **Perform the Installation and Operational qualification (IQ/OQ)**

Once the test scripts have been approved, each step is executed faithfully and then checked for compliance with expected outcomes.

5 **Create the IQ/OQ report**

The correspondence between the tests done and the user & functional requirements specifications is the key point to validation and the focus in the IQ/OQ report. A traceability matrix is presented as a table directly linked to the user & functional requirements specifications, recalling the identification number of each specification.

6 **Create the final Validation Report (VSR)**

The final validation report summarizes the entire validation project and states on the acceptance of the system. If it answers the acceptance criteria, the validation team can approve the report, authorizing the use of the system in real GLP studies.

This report is contingent upon the client successfully competing the Performance qualification (PQ) and sharing the results with emka Technologies validation specialists.

Note: The Performance qualification (PQ) protocol and the Standard Operating Procedures writting is done by the customer.

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Let us help you advance your research, contact us !

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