

Validation Toolkit

The Pipette Tracker Pro Validation Toolkit is available to assist in your validation procedure. The toolkit provides the appropriate documentation and test procedures required to complete an IQ/OQ (Installation Qualification and Operation Qualification) validation of the software. The documentation and test procedures related to IQ/OQ include the following:

Installation Qualification

Hardware Verification

Checklist with required specifications (e.g., RAM, hard disk space).

Software Verification

Checklist with required specifications (e.g., operating system, version numbers, location of install media).

System Documentation

Checklist that lists all relevant manuals, verifies that the manuals are available and records where they are located.

Installation Protocol

Complete installation directions.

File Verification

Checklist of filenames, sizes and version numbers. Includes Excel® template with macro to automatically compare expected files to installed files, flagging any missing or installed files with different sizes or version numbers.

Domain Verification

Verification of Logins and User Rights.

Installation Qualification Verification Summary

Yes/No checklist to verify that the above tests were performed and that the results are included.

Operational Qualification

System Setup Options

Verify the settings and instruments selected for use in the Qualification tests.

Method/Test Plan Validation and Versioning

Verify the validation of a method and test plan, the recording of the validated status and incremental versioning of a method and test plan.

Calibration Verification

Using the pre-defined method, actual results will be compared against expected results.

Verify Manual Data calculation

Verify calculations by confirming that entering data manually produces correct and accurate results.

Report Verification

Verify that the reports (and database) provide accurate results (input and output) that reflect the data entered by the user and the calculated results.

Print Validation

Print reports and verify that the data on the printout reports is correct.

Operational Qualification Verification Summary

Yes/No checklist to verify that the above tests were performed and that the results are included.

A Deficiency Report and a Validation Certification document complete the package.

The Pipette Tracker Pro Validation Toolkit is a valuable assistant for any laboratory that is required to perform IQ and OQ on their new Pipette Tracker Pro installation.