

Guidance for Installing and Updating Quality Window 5 Software



The Quality Window products are employed in a variety of uses within manufacturing and other environments for the monitoring and reviewing of results based on parameters established by a customer. Some of these uses are for the producing of regulated products (or components of regulated products) and may have a customer or agencies' expectations for software and computerized system validation. The purpose of this guidance is to create awareness of the controls Busitech has established, the documentation Busitech provides and considerations for our customers on additional testing and documentation that may be needed at each site applying Quality Window software to establish and maintain validation.

Busitech does not assume responsibility for validation or verification of the customer's application of Quality Window software and overall computerized system. Where required, this is the customer's responsibility and can only be completed at each site in context of customer applications and computer systems which include hardware, operating systems and interfaces.

Busitech has established a Quality Assurance program to ensure that Quality Window software performed per its design intent. Busitech has established procedures and controls to ensure that changes to Quality Window software have been evaluated and tested and documented prior to being released for customer use.

The following documentation is available to the customer on the Busitech website. The customer can utilize this documentation as well as this guidance to complete site validation and verification activities.

1. System Requirements <http://busitech.com/products/quality-window/>
2. Release Notes <http://busitech.com/products/quality-window/maintenance-releases/>
3. Validation Documentation (with each release)
<http://busitech.com/products/quality-window/validation-documents/>

Functional Requirements for Quality Window software are documented within Quality Window software under "Help" and described in training materials provided on <http://busitech.com/help-and-support/>. Additional User requirements, if needed, are relevant to each application and are the responsibility of the customer to establish.

Busitech tests each change and each release of Quality Window software as described by its procedure. The purpose of this testing is to provide assurance that Quality Window software will perform as intended when properly installed, configured and operated. The purpose of user testing is generally to provide assurance that their application using Quality Window software will perform as they intended as actually installed, configured and operated...throughout its expected range of operation and use.

Quality Window 5 software may be applied to a wide variety of customer applications and is designed for flexible configuration and integration. Where validation or verification of the application is required, the Customer is responsible to meet these requirements. The purpose of this document is to provide guidance to the customer on additional validation / verification activities (e.g. test, check, document) to consider. Busitech does not assume responsibility for this activity or warrant that this guidance is complete or meets any specific agency expectation. This is the responsibility of the customer.

1. Customers should consider testing to identify potential conflicts with other software installed on the same computer or network. In some cases, Companies will create their own install/uninstall programs, or will use libraries and drivers that are not the same version as those installed with the Busitech install program.

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2. Customers should review the release notes found at this link:
<http://busitech.com/products/quality-window/maintenance-releases/>
As part of that review the customer should make note of all revisions to the QW 5 product since their last update and develop the appropriate strategy for assessing the impact of those changes on their use of the QW 5 Product.
3. Customers should consider the following procedure, found at this link:
http://assets.busitech.com/documents/qw5_installation_checklist.pdf This document guides the user on verifying that this latest release of QW 5 is properly installed. The Document can be printed, completed and filed as documentation for upgrading to this new release.

Now that the Quality Window 5 product has been installed and verified it is time to focus on the specific use of the Quality Window 5 and how it is being adapted to the customer's specific environment and use.

4. The customer should consider the following checks, depending on their application. Testing should consider the full range of likely operation, potential failure modes, extreme and worst case conditions that demonstrate actual ongoing operating conditions in the environment in which they are using the Quality Window products. Some of this functionality is dependent on Quality Window software being correctly installed and configured. Other functionality is dependant on operating systems, interfaces, etc. The following is a list of items to be considered but not limited to:
 - Security Access control to software (e.g. folders, data, templates)
 - Backup, archiving and audit trails.
 - User authentication to programs, read/write access and transaction logging features have been configured and working. See also <http://busitech.com/meeting-the-21-cfr-part-11-requirements-with-quality-window-5/>
 - Software has been properly installed with hardware/software meeting defined system requirements (<http://busitech.com/products/quality-window/>). Note that you may also use the QWVersion utility that is installed with QW software to identify files that may not have been installed or to evaluate the difference in release dates of software libraries and drives.
 - Software has been properly licensed to the workstation with a permanent license. (This is viewable within QW Software. See Help – About QW5). Server licensing requires additional checks.
 - Interfaces with PLCs, databases and instruments (e.g. scales, calipers) are accurately and reliably working.
 - Configuration of fields (also known as variables) within each QW template (to include limits, calculations, control rules and other field information).
 - Verification of the results of calculation based on the variables and data within a QW Application
 - Configuration of Macros and Views (as well as Reports generated with Views).
 - Configuration of Options (to include Statistics included in standard views).

Principally, the rigor of such testing and documentation should be commensurate to the consequence of failure/inaccuracy/mistake in the end user application(s). The actually testing conducted and documented is the responsibility of the customer.

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After the completion of initial validation and verification activities, the site should establish a change control process to ensure that each change to Quality Window software or the computerized system (hardware, operating system, interfaces, etc) are evaluated, tested and documented to maintain validated status.

The guidelines above are not intended to be a comprehensive list of considerations for site validation or verification. As Quality Window software is configurable and used in many types of application and can be integrated with various databases and interfaces, the customer must be responsible for any required site validation or verification.

There are many published guidance's on the topic of software and computerized system validation that the customer may use to learn more about this topic. The following is one example.

Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility

<https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/BIood/ucm072560.htm>

Credit: U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research