

Creating and Verifying an Electronic Signature Using the TOC Control V Software

Due to the requirements of the 21 CFR Part 11 rule, software systems must include features such as user access rights, audit trails, and electronic signatures. The Shimadzu TOC Control V software strives to fully comply with 21 CFR Part 11 by adopting these features. This quick guide will focus solely on the implementation of electronic signatures using the TOC Control V software.

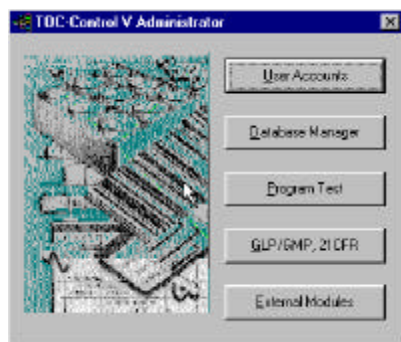
What is an electronic signature?

An electronic signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

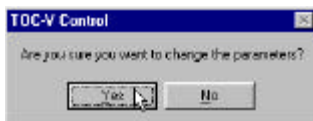
Note: It is assumed that during the software installation process, that the automatic digital signature radio button is not checked. If the user enables automatic digital signatures during software installation, then the steps listed below do not have to be executed.

Electronic Signature Initial Setup

From the TOC-V main window, click on Administration and enter username and password. In the TOC Control V Administrator dialog box, click [GLP/GMP, 21CFR].



In the 21CFR, GLP/GMP dialog box, click [INIT] once. This will initialize the registered electronic signature of the user. Click OK to close this window.



Click [YES] in order to enable electronic signatures.

Note: To completely fulfill the 21 CFR Part 11 rule, all checkboxes in the [21CFR, GLP/GMP] dialog box must be checked.

Note: If you do not click INIT in the 21CFR, GLP/GMP dialog box, and you attempt to use the electronic signature feature, the following error will be displayed: “CryptAcquireContext Error- The Registry entry for the key container could not be opened and may not exist”. If you choose the “Automatic Digital Signature” in the 21CFR, GLP/GMP window, it is not necessary to click [INIT].

Signing a Sample Table

Create a sample table and save it. Once a sample table has been saved, you can assign an electronic signature.

From the menu bar, choose [Signatures]. From the drop down menu, select [Sign sample table...].



The Digital Signatures window will indicate that the sample table has been signed.

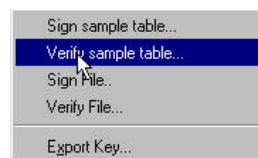


Note: A sample table can also be signed after an analysis has been completed. To do this select [Sign sample table...] from the [Signatures] drop down menu and the digital signatures window will pop up showing that the table has been signed.

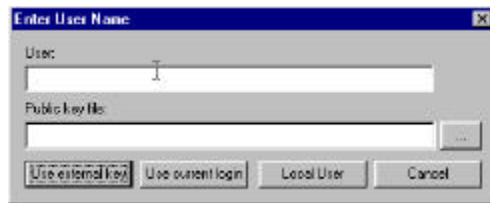
Verifying a Signed Sample Table

Open a sample table that has been electronically signed.

From the [Signatures] drop down menu, select [Verify sample table...].



The “Enter User Name” window will open.



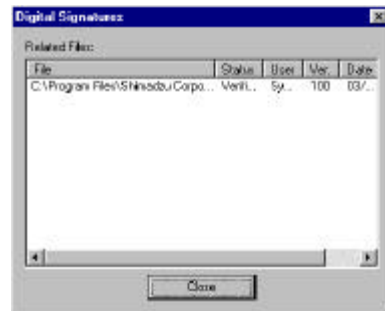
If you are evaluating the signature of the current login user, then click [Use current login].

If you are evaluating the signature of a different user who uses the same PC, then click [Local User]

If you are evaluating the signature of a user who signed the sample table from another PC, then enter in the User column the name of the external user who applied the signature. Enter the Public key file name in the Public key file column. Then, select [Use external key].

Note: A Public Key file refers to an external file which is generated on a PC where a signature is performed. To evaluate a public key file using a PC other than the PC associated with the signature, the key file must be outputted. To do this select [Export] under the [Signatures] drop down bar. When [Export] is selected, the [Save File As...] dialog box appears. Enter a public key file name to be outputted and click [Save].

When any of the above buttons, [Use current login], [Local User], or [Use external key] are selected, the Digital Signatures dialog box opens and indicates that the signature is verified.



Note: Electronic Signatures can be created and verified for files that were generated using an application other than TOC Control V. To create a signature for this type of external application file, select [Sign file] from the [Signatures] drop down menu. To verify this file, select [Verify file] from the [Signatures] drop down menu.