

Using GeneTools in a 21 CFR Part 11 compliant environment

This document applies to GeneTools version 4.01(c).

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Overview

GeneTools uses the Windows domain login accounts to identify individual users. It is the system administrator's responsibility to ensure that the Windows domain logins meet the requirements of 21 CFR Part 11, particularly in regard to password validity and strength.

User levels

When used in a 21 CFR Part 11 compliant environment GeneTools has four levels of user privileges. An individual's user level is determined by membership of a particular Windows domain user group.

Gel analysis

User level 1:

The user has complete access to all functionality in the package. This includes the ability to create analysis template files for non-Level 1 users. The analysis template file contains most of the configuration settings including:

- Integration Parameters
- MW/ Quantity Standards
- Report Settings
- Autolocate Tracks
- Autodetect Peaks

User level 2:

To open a new file the user must import using the analysis template from a saved file. They cannot alter any of the normal editable settings with the exception of peaks which they are allowed to move, alter the boundaries of, delete or add. The user can save files and set/ alter matching standards.

User level 3:

As level 2 but cannot edit peaks

User level 4:

The user can only open images and produce reports.

Spotblot/ Manual Band Quantification analysis

User level 1:

The user has complete access to all functionality in the package. This includes the ability to create analysis template files for non-Level 1 users. The analysis template file contains most of the configuration settings including:

- Spotblot Settings
- Report Settings

User level 2:

To open a new file the user must import using the analysis template from a saved file. They cannot alter any of the normal editable settings with the exception of spots which they are allowed to move, alter the boundaries of, delete or add. The user can save files and set/ alter quantity standards.

User level 3:

As level 2 but cannot edit spots

User level 4:

The user can only open images and produce reports.

When GeneTools is started the package configures to the user level of the currently logged in Windows user.

Stored Data

All Information pertaining to an image is saved in a single “private format” file, along with the image data itself. Aside from the data that is normally stored in a sgd file the private file format also includes:

- The path of the file used as a template (if appropriate)
- Records of an electronics signature, the details of a Windows user account, including the account unique Id.
- A comment indicating what actions have been performed.

The image data and associated capture data are not modifiable within the package.

Data Protection

GeneTools can save data onto disk areas configured with “write once read many” or WORM access rights. This prevents users from deleting data at the system level (out of GeneTools) or by overwriting an existing image.

GeneTools can also be configured to record an internal “write once” flag in the private file format. This prevents GeneTools from overwriting or modifying data stored on “write many” media.

Electronic Signatures

When operating within a 21 CFR Part 11 compliant environment GeneTools records who saved a particular file by recording details of a Windows domain user account, including the unique account Id, within the private format file containing the image data. When saving an image the user is prompted to enter a user name and valid password. These are then verified against the

Windows domain before the data can be saved to disk and recorded with the data. The user is also prompted to enter a comment regarding the analysis.

Electronically signing a document whilst saving to disk does not alter the current user level.

Configuring an installation

The features that allow GeneTools to be operated within a 21 CFR Part 11 compliant environment are controlled by setting specific registry entries on each computer on which GeneTools is installed.

Within [HKEY_LOCAL_MACHINE\SOFTWARE\SynGene\VTrack]

DWORD value "WinLogin"

Setting to "1" enables use of Windows login, electronic signatures and user levels. When this is set four user level keys must be present for the package to operate. These values are:

String values "UserLevel1", "UserLevel2", "UserLevel3" and "UserLevel4"

If all four values are left empty then all users will be user level 1

To restrict access to GeneTools configure a Windows domain group, for example "GeneToolsLevel1" and set **UserLevel1** to this value.

If a users Windows account is a member of this group then they will have level 1 access within the package.

A user's level is determined by which user level values are configured in the registry and which group he/she is a member of. So if a user logs into the system who is not a member of the level 1 group and neither "Userlevel2" or "Userlevel3" have been assigned domain groups then the user will have level 2 access. Similarly if "UserLevel2" has been assigned a domain group but the user is not a member of that group either then they will have level 3 access.

If the user name is not found in the user groups but all the groups have values GeneTools will not open for this user.

If an invalid combination of user group values and absences are found GeneTools will not open.

DWORD value "WriteOnce"

Setting this value to "1" enables the internal "write once" flag. This prevents GeneTools from overwriting data that is not write protected by the operating system.

Typical Setup

The registry entries for a typical system running in a 21 CFR Part 11 compliant environment would be:

Within [HKEY_LOCAL_MACHINE\SOFTWARE\SynGene\VTrack]

"WinLogin"	=	"1"
"WriteOnce"	=	"1"
"UserLevel1"	=	"GeneToolsLevel1"
"UserLevel2"	=	"GeneToolsLevel2"
"UserLevel3"	=	"GeneToolsLevel3"
"UserLevel4"	=	""

Choosing **Help... About GeneTools...** displays a dialog box that includes diagnostic information about the package's configuration and the current user level:

