

CFR 21 Part 11 compliance- GeneSys and GeneTools software

GeneSys and GeneTools software have a feature within the software that assists users in meeting title 21 of the code of Food and Drug Administrator's (FDA) regulations on good laboratory practices and electronic records and signatures in the pharmaceutical and biotechnologies industries. Part 11 defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.

This feature enables system administrators to ensure that the GeneSys image capture and GeneTools analysis software operates in compliance with Title 21 of the code of Federal Regulations (CFR) Part 11 within a 'closed' system (a 'closed' system is defined as an 'environment' in which system access is controlled by the person(s) responsible for the content of electronic records that are on the system).

- The CFR 21 Part 11 features added to GeneSys and GeneTools must be properly configured and administrated by the system administrator(s) in your organisation in order to be secure and compliant with CFR 21 Part 11.
- Syngene does not make any claim that both GeneSys and GeneTools software are CFR-compliant nor does the company guarantee compliance for the user. Your organisation must establish policies and standard operating procedures that work in conjunction within the tools provided by Syngene to ensure compliance with CFR 21 Part 11.

Installing GeneSys and GeneTools software with CFR 21 Part 11 compliance

- **GeneSys**

In GeneSys setting up CFR 21 compliance is part of the software installer. Select the check boxes to 'Enable the use of Windows login and electronic signatures', 'Prevent GeneSys from overwriting data that is not protected by the operating system' and 'Allow GeneSys to Write-Once-Read-Many drives' (**Figure 1**).

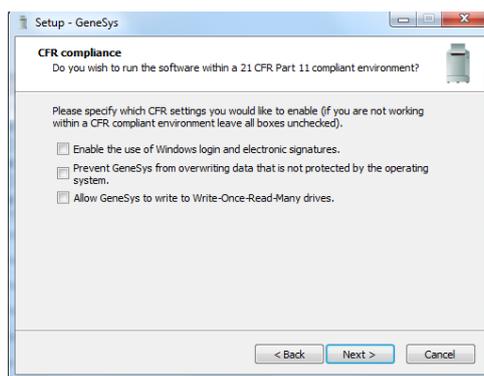


Figure 1- CFR 21 Part 11 compliance GeneSys installation

■ GeneTools

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

On a 64-bit operating system:

Within [HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\SynGene\VTrack]

On a 32-bit operating system:

Within [HKEY_LOCAL_MACHINE\SOFTWARE\SynGene\VTrack]

Configure an Installation

Enable the use of Windows login and electronic signatures.

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 user's 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.

Prevent GeneTools from overwriting data that is not protected by the operating system

DWORD value "WriteOnce" (Appendix 1)

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 (Appendix 2)

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

Within [HKEY_LOCAL_MACHINE\SOFTWARE\SynGene\VTrack]

"WinLogin" = "1"

"WriteOnce" = "1"

"UserLevel1" = "GeneToolsLevel1"

"UserLevel2" = "GeneToolsLevel2"

"UserLevel3" = "GeneToolsLevel3"

"UserLevel4" = ""

User levels and Roles

GeneSys and GeneTools software both use the Windows domain login accounts to identify individual users.

N.B. It is the system administrator's responsibility to ensure that the Windows domain logins meet the requirements of CFR 21 Part 11, particularly in regard to password validity and strength.

- **User levels in GeneTools**

GeneTools software has four different user levels

N.B. GeneSys software does not have any user levels

Each user level has a role assigned that provides the user access to specific features in the software. The default permissions are described below (**Table 1**).

User Group	Role	Description
User Group 1	Administrator	The user has complete access to all functionality in the software 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: Spot blot settings and Report settings.
User Group 2	e.g. Supervisor	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, delete or add. The user can save files and set/alter quantity standards.
User Group 3	e.g. Clinician	Same as level 2 but cannot edit Spots.
User Group 4	e.g. Reviewer	The user can only open images and produce reports. All other access is restricted.

Table 1- User levels and Roles in GeneTools software

N.B. When GeneTools is started the package configures to user level of the currently logged in Window user.

User Restrictions

In the latest version of GeneTools (4.3.9.0) a dialog box has been introduced through which a level 1 operator can determine which features are available to users at the four levels. The menu item is under 'Extras' – user level permissions.

Permission	User Level 1	User Level 2	User Level 3	User Level 4
Import Template	X			
Edit MW Library	X			
Edit integration parameters	X			
Insert/Delete track	X			
Assign MW quantity	X			
Match peaks	X	X	X	
Track Disable/Enable	X	X	X	
Profile Inversion	X	X		
Spot analysis		X (limited)		
Sample properties	X			
Open document (unanalysed)	X			
Report Configuration	X			
Save	X	X	X	

Table 2- User level access to features

Electronic records

GeneSys and GeneTools enable you to create secure electronic records as defined by CFR 21 Part 11.

In **GeneSys** the following electronic records can be generated;

- Protocol files
- Image files

In **GeneTools** the following electronic records can be generated;

- Image files
- Analysis files

When operating within a CFR 21 Part 11 compliant environment, both GeneSys and GeneTools software 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 disc and recorded with the data. The user is prompted to enter a comment regarding the capture or analysis.

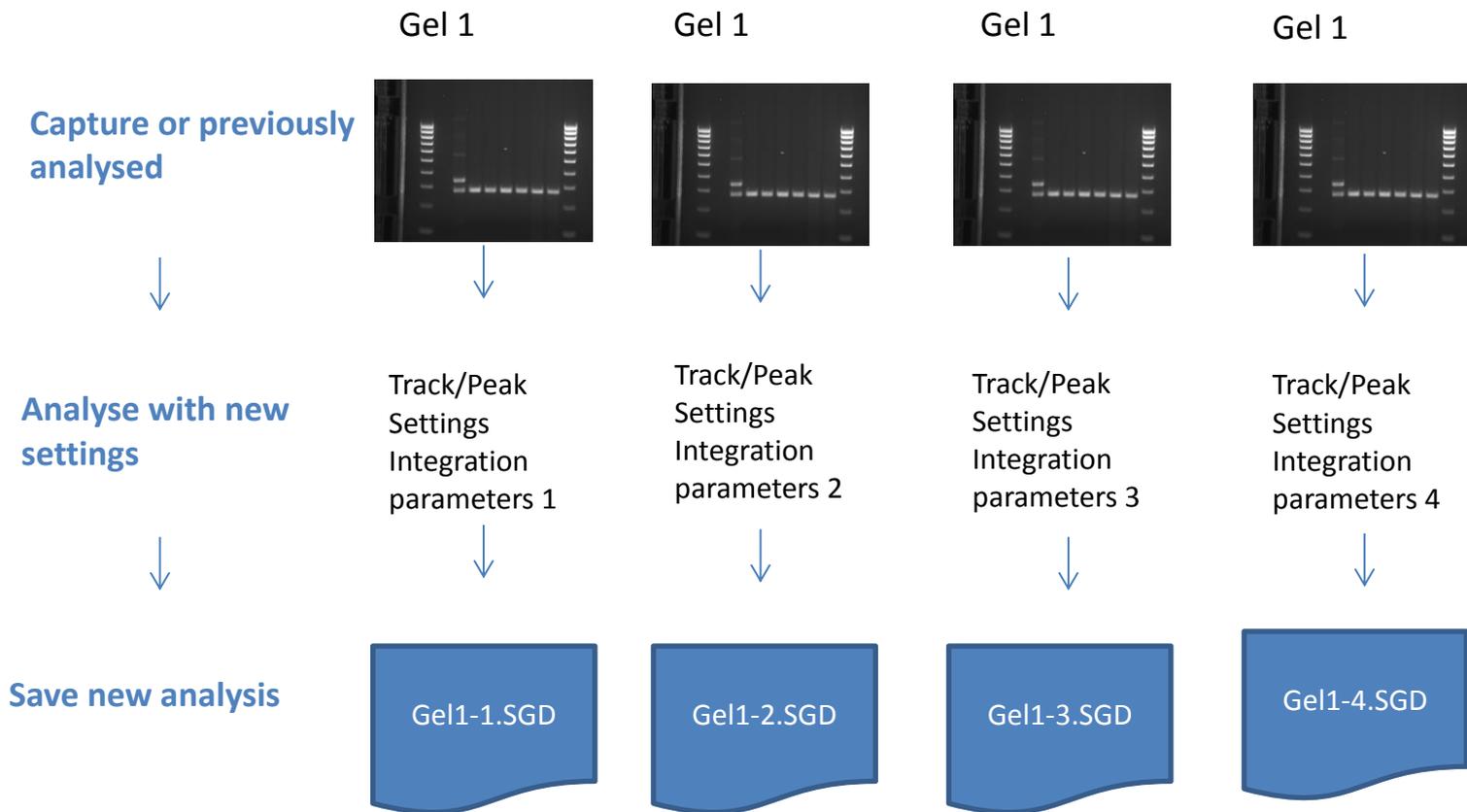
GeneSys can also store a processed version of the image data. This data is stored within the same file and does not overwrite the original data. Whenever a processing operation is chosen the user is prompted to give an electronic signature and this is recorded in the data file.

Modifying Secure documents

You can open and change a signed document in GeneSys and GeneTools software. The original document cannot be overwritten.

Appendix 1

Image saving and analysis with 21 CFR Part 11 “Write Once” and “Windows Login” enabled in GeneTools



We capture an image “Gel 1”. The image data in this file cannot be altered. The only alterations we can make are to add annotations, change the viewing conditions (e.g. contrast, brightness) or perform an analysis. Once we have made these changes we cannot overwrite any previously saved file.

Appendix 2

Suggested Strategy for use 21 CFR Part 11 compliance in GeneSys and GeneTools

- Create a top level folder (ideally networked) which allows all GeneSys and GeneTools users to read
- Create several sub-level folders with read/ write permissions appropriate to desired set up (example)
- Give “Approver” sole permission to write to “Approved folder”

