

Uncle suits up with compliant features

Introduction

For GxP labs, maintaining proper electronic records and data security is a must. Uncle has you covered with a 21 CFR Part 11 software package, ensuring full sample tracking, data authenticity, and user accountability. This add-on makes your system compliant with 21 CFR Part 11 regulations and includes features such as system and experiment-specific audit trails, electronic signatures, and data integrity checks.

Uncle encompasses DLS, SLS and full-spectrum fluorescence capabilities for a one-stop protein stability assessment with 12 applications (Figure 1). Small sample volumes are loaded into Unis, which are sealed tight, so you don't lose sleep over sample contamination or evaporation (Figure 2). The built-in sample analysis software means you can run and analyze up to 48 samples in just 3 minutes.



Figure 2: The Uni requires only 9 μ L of sample and is sealed, so you can run up to 48 samples whenever you want.



Figure 1: Uncle offers 12 stability applications in an all-in-one protein characterization platform.

These main features are available:

- **Secure and controlled user access.** The administrator can set password requirements as well as create or disable user accounts.
- **Audit trails.** All events or actions performed by users, including changes to the software (user settings, experiments, and reports), are catalogued in this database.
- **Digital signatures.** Before an experiment is started, a signature, as login credentials, is required.
- **Integrity check.** This button checks all experiments in the experiments list for data integrity, and notifies you of any that have been corrupted or altered without authorization.

Key features of the Uncle 21 CFR Part 11 package

21 CFR Part 11 main screen

The main 21 CFR Part 11 screen can be accessed at any time in Uncle Client software by clicking on the tab from the drop-down menu on the home page (Figure 3).

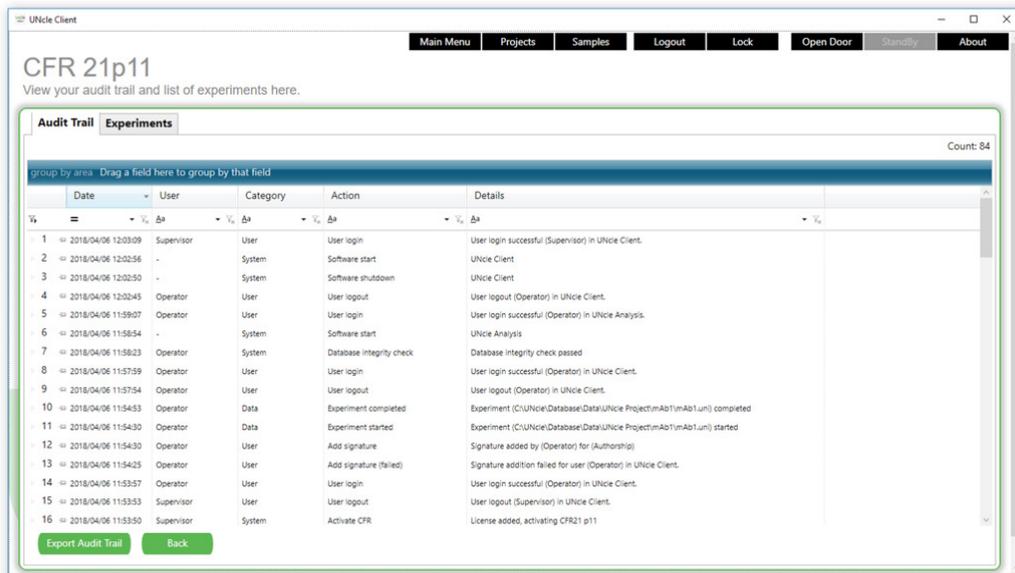


Figure 3: Main 21 CFR Part 11 screen in Uncle Client.

System	User	Data
Activate CFR	New user created	Experiment started
Software start	User login	Experiment completed
Software shutdown	User login (failed)	Experiment opened
Database integrity check	User login cancelled	Experiment analyzed
	User logout	Report created
	User password changed	User setting saved
	User enabled	
	User disabled	
	Add signature	
	Add signature (failed)	
	Add signature (cancelled)	

Table 1: A list of actions in the audit trail by which a user can filter or sort.

An overview of the audit trail is available in the 21 CFR Part 11 main screen. The user can sort for specific parameters by applying the filters in Table 1.

The audit trail can be exported with or without applied filters as a PDF by selecting the “Export Audit Trail” button.

Experiment-specific information and audit trails

Opening the Uncle Analysis software and selecting the “Experiments” tab provides an overview of all experiments completed (Figure 4). The last user who modified the experiment file is also shown in the experiment list. An integrity check can be performed on the list of experiments and the ones that have been modified without authorization will appear red.

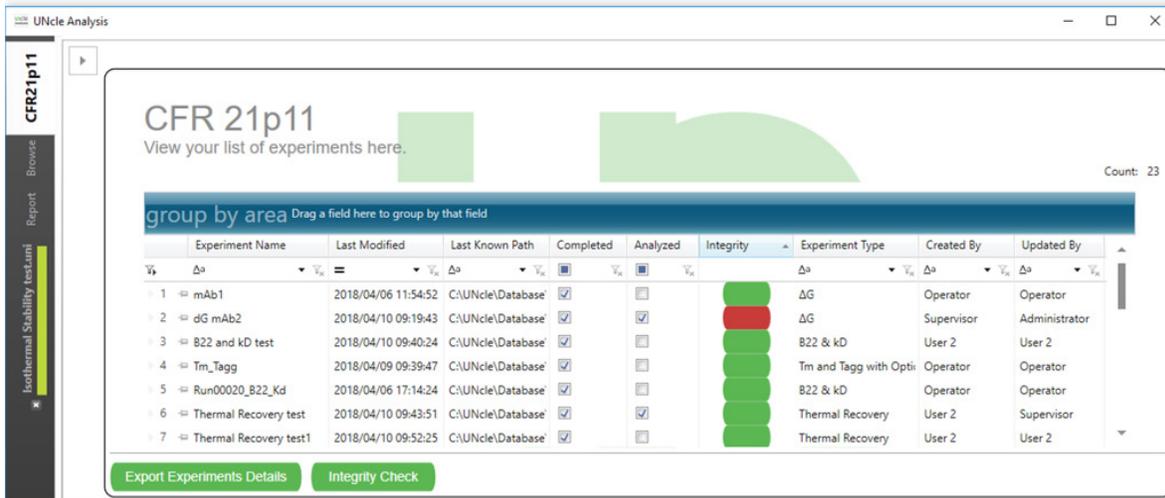


Figure 4: Experiment list in the Uncle Analysis software showing an example of one experiment that failed the integrity check and is colored red.

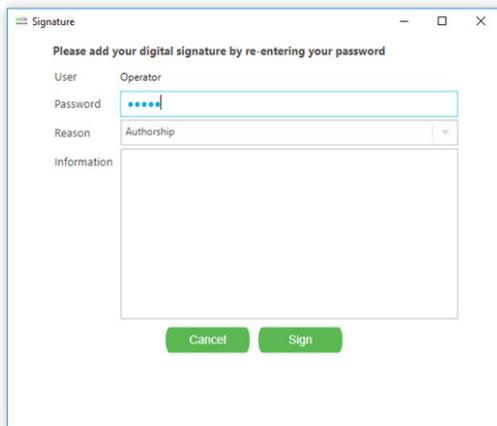


Figure 5: Digital signature request screen in Uncle Analysis software.

There are 2 actions in Uncle Analysis that will prompt a signature request:

- A user exports the report as a PDF.
- A user re-calculates the data and saves the file as a new version in Analysis Settings.

When a user or administrator performs an experiment, an authorization signature is requested for authorship (Figure 5). Additionally, all experiments can be signed for review, approval, and responsibility, by users or the administrator. Every time an experiment file is opened, the integrity check is re-applied to detect whether that experiment has been compromised.

When a report is generated from one or more experiments, the experiment-specific audit trails are provided at the end of the report. The report details are also generated automatically, including the file name of the experiment, the sample name and the analysis settings. Users are unable to modify data or text in the report, so you know the information is legit. Whenever new items are added to the report, the file must be saved again, prompting a signature request.

The Uncle database contains experiment identification information specific to the data integrity of all experiment files. Each computer has its own individual license, so a file created on one 21 CFR Part 11-active computer cannot be transferred to another while maintaining the integrity of that file. Using the Backup feature in Uncle Client, the administrator can easily back up the database and data files to a secure location, such as a network drive or external disk. This backup function enables the database and data files to be restored on a new computer, if required, while maintaining the integrity of the data.

Conclusion

To meet GxP laboratory requirements, Uncle Client and Analysis software offers features to enable compliance with 21 CFR Part 11 regulations. These features include electronic storage of data as bin

files, from which the user can create reports at any time. The audit trail archives experiments and reports, and provides an overview of all actions performed by the user. Integrity checks can be performed on experiments to identify corrupt or altered files. Extra features include an advanced user management system, full audit trail capabilities, and signature requirements on electronic records.



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