

Hound has the features for compliant labs

Introduction

For GxP labs, maintaining proper electronic records and data security is a must. Hound has you covered with a 21 CFR Part 11 compliant software package, providing full sample tracking, data authenticity, and user accountability. This feature enables your lab to remain compliant with 21 CFR Part 11 regulations and includes elements such as system and experiment-specific audit trails, electronic signatures, and data integrity checks.

Hound combines microscopy with dual Raman spectroscopy and laser induced breakdown spectroscopy (LIBS) to identify any particle that comes your way (Figure 1). Dual Raman at 785 nm and 532 nm identifies organic, inorganic, and protein particles while LIBS identifies metal and elemental particles. Samples are prepared on individual rounds; filter rounds isolate particles for chemical ID, adhesive rounds isolate particles for elemental ID, and wet rounds keep particles in suspension for chemical ID.

Key features of the Hound 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 Hound Client software by clicking on the tab from the drop-down menu on the home page (Figure 2).



Figure 1: Hound counts and identifies the composition of visible and sub-visible particles with both automated and manual modes. Hound uses Raman (532 nm and 785 nm) and LIBS to identify the composition of particles, helping users track down the particle source.

These main features are available:

- **Secure and controlled user access:** The administrator can set password requirements, create or disable user accounts, and define user access levels.
- **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, method files, databases, and reports for integrity, and notifies you of any that have been corrupted or altered without authorization.

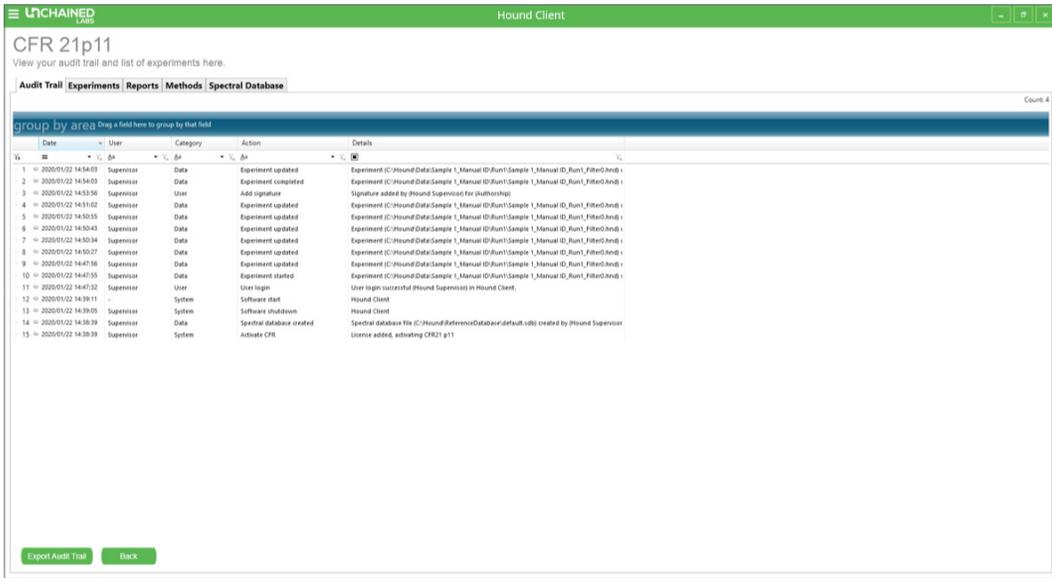


Figure 2: Main 21 CFR Part 11 screen in Hound Client.

System	User	Data	Spectral database
Activate CFR	Add signature	Experiment analyzed	Spectral database file closed
Database integrity check	Add signature (cancelled)	Experiment completed	Spectral database file created
Software shutdown	Add signature (failed)	Experiment opened	Spectral database file opened
Software start	New user created	Experiment recount reverted	Spectral database file updated
Surface correction updated	User login	Experiment recounted	Spectral database closed
	User logout	Experiment spectrum processed	Spectral database created
		Experiment spectrum reverted	Spectral database default updated
		Experiment started	Spectral database opened
		Experiment updated	Spectral database removed
		Method created	Spectral database updated
		Report created	
		Report updated	

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

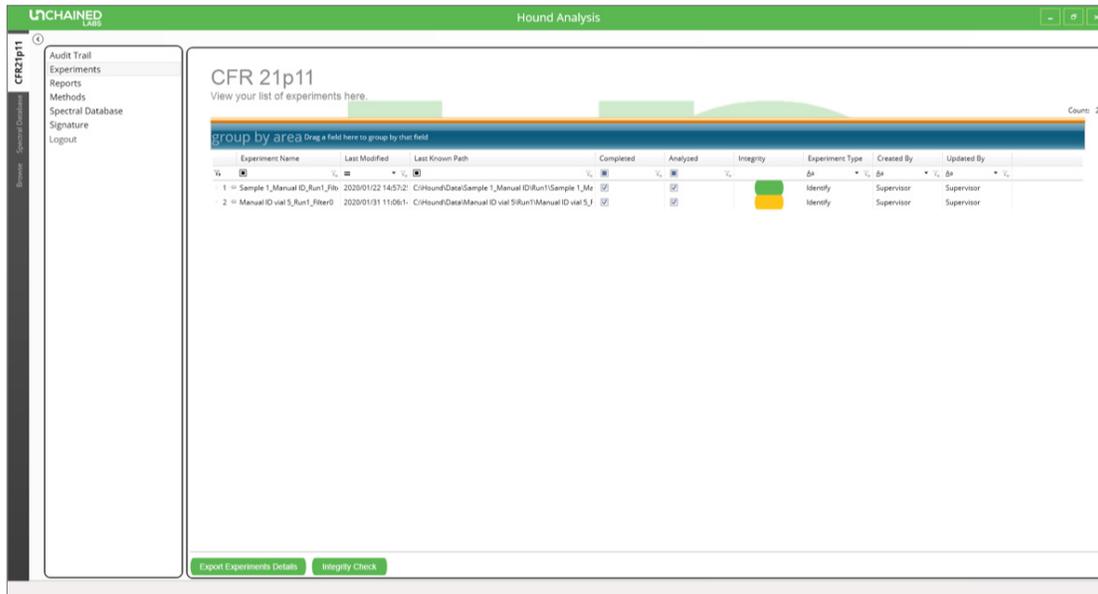


Figure 3: Experiment list in the Hound Analysis software showing an example of one experiment that failed the integrity check and is colored yellow.

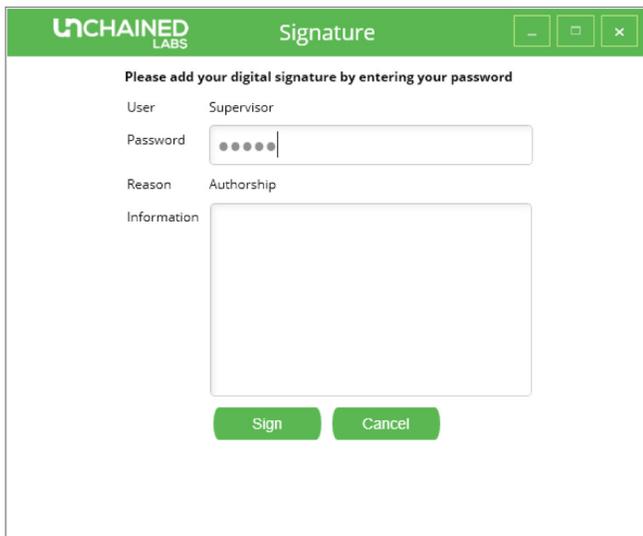


Figure 4: Digital signature request screen in Hound Analysis software.

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 shown 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 Hound Analysis software and selecting the “CFR21p11” tab provides an overview of all experiments completed (Figure 3). 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 yellow.

When a user or administrator performs an experiment, an authorization signature is requested for authorship (Figure 4). 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 reapplied to detect whether that experiment has been compromised.

The report details are 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.

The Hound CFR 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. The CFR database can be transferred to a new computer by an Unchained Labs employee if necessary. This transfer can be done in a way that maintains the integrity of the data.

Conclusion

To meet GxP laboratory requirements, Hound Client and Analysis software offers features to enable compliance with 21 CFR Part 11 regula-

tions. These features include electronic storage of data as HDF 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, method files, databases, and reports 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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