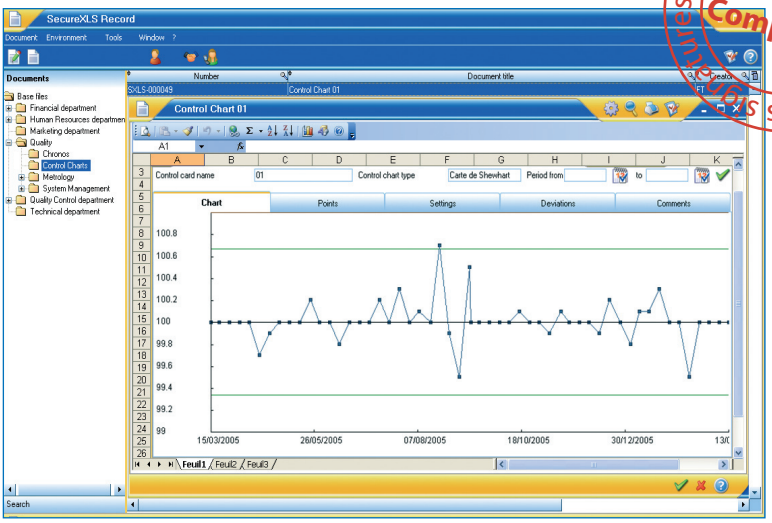
A1 = Excel is one of the most widely-used supports for raw data, so…

SecureXLS

Make your Excel spreadsheets secure

Laboratories today require solid protection of Excel spreadsheets to satisfy regulatory authorities such as MRHA, FDA, UKAS, etc.

IN LABORATORIES



electronics records - electronic signatures - 21 CFR Compliant

- *User authentication*
- *Access rights management*
- *Password management*
- *Automatic locking of user accounts*
- *File version management*
- *Spreadsheet indexing*
- *Protection of models*
- *Protection of processed spreadsheets*
- *Content security*
- *Automatic audit file*

• Raw data spreadsheets

Excel is very practical for setting up laboratory calculations. However once the «model spreadsheet» has been approved, you still have to be able to control its use so that the laboratory technician can only enter data in authorised cells to do calculations.

Once the raw data sheet is approved by an authorised person, it must be completely locked but still accessible thus becoming an **incontestable electronic record.**

• Control chart

As the very definition of a control chart stipulates, the aim of this type of Excel spreadsheet is to observe the evolution of a measurement over a certain period of time.

The difficulty lies in **automatically tracking modifications** to the spreadsheet so that the control charts, as well as your other data storage spreadsheets, are under complete control.

• Monography

Monographies or specification files are often produced using Excel. In this case, it is crucial to **control version changes** for spreadsheets and their circulation in order to avoid copies being made locally.

Changes to versions should also be automatically tracked, and only be implemented by authorised persons.

"SecureXLS is the quickest and most cost-effective way to ensure that your Excel spreadsheets comply with 21 CFR Part 11"

Labo. / A.Q.

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A1 = Give Excel all the security your raw data deserves

Security aspects

• 2 user modes :

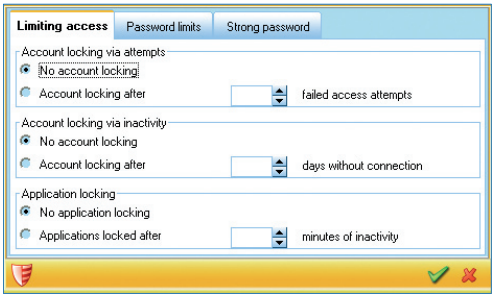
- An Excel spreadsheet evolves over time and this evolution is under total control.
- Using a template spreadsheet, creation of a calculation spreadsheet, once signed becomes a tamper-proof electronic record representing an element of proof.

• Tracking file (audit trail)

- Access audit :
  To track Excel file opening
- Data audit :
  To know what data was modified, when, who by and for what reason
- Print audit :
  Monitoring printing (who by and when) of Excel files. Printed files are identified by a barcode (printing date, who by, etc.)

• Access control

As standards stipulate, use of «strong» passwords (number of characters, regular changes, etc.) is mandatory. SecureXLS takes this constraint into account giving customers peace of mind when audited.



• Logical security

- Our application is based on a secure 3-tiers architecture
- Rights management is an integral part of the application

The validation package

The validation package is available as an option : it was put together following practices and recommendations from the most demanding laboratories.

Delivered on a CD-ROM with modifiable files in Word format. At your request, we can assist you with your validation procedure.

Regulations

• 21 CFR part 11 (§ 11.10 and §11.30)

"...Persons who use closed/open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authentiticy, integrity, and, when appropriate, the confidentiality of electronic records...»

• European GMP – Vol 4 – Annex 11 (Computerised systems)

"...The system should record the identity of operators entering or confirming critical data. Authority to amend entered data should be restricted to nominated persons. Any alteration to an entry of critical data should be authorised and recorded with the reason for the change. Consideration should be given to building into the system the creation of a complete record of all entries and amendments (an «audit trail»)....

• ISO/CEI 17025 - Chap 5-4-7-2 B

«...procedures are implemented and applied to protect the data; such procedures must cover, although not exclusively, the integrity and confidentiality of the data entry or collection, storage, transmission and processing....»

• GMP and electronic records

An electronic recording is created every time a piece of information subject to the regulations is copied on a storage medium such as a hard disk, diskettes, cassettes, tapes, CD-ROM, etc. The electronic recordings stored on an IT system must be subject to procedures ensuring that the creation, modification, approval, storage and archiving of these recordings are undertaken with a security level equivalent (no more, no less) to that applied to printed recordings.

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Labo. Q.A.

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