Auditing e-data

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Topics

- Validation
- Auditing Raw Data
  - Notebooks
  - Sample Tracking
  - Temperature Data
  - Reagents/Solutions
  - Equipment Maintenance
  - Analytical Data
- Spreadsheets

Validation

- Any electronic system must be validated, including how it will be used at the facility.
  - Simple or complex system? Fully electronic process or hybrid?
    - Interfaces with other systems or programs?
    - Data flow
  - Audit Trail
    - Turned on; not able to be turned off
  - Reporting feature
  - Periodic review
- Quality Assurance (QA) involvement in the validation project
  - Helpful to understand how system designed, how it works

Auditing in General

- When to audit data?
  - In-progress inspections
  - Data audits
  - Final/Phase report audits
  - Facility inspections
- Start with:
  - Protocol/changes
  - Methods
  - Standard Operating Procedures (SOPs)
- QA training and system access

Auditing e-Notebooks

- Check any notes/files that may be included in the e-notebook.
- Check completeness of the notebook; no blanks.
- Confirm protocol requirements met and documented. Deviations should be documented.
- Confirm method and SOP requirements met and documented. Deviations should be documented.
- Check the audit trail.
  - Confirm direct entry
    - If not, is there an indication that the data was transcribed?
    - Check for the original raw data; confirm e-notebook matches the original raw data.

Auditing Sample Tracking

- Sample logs used for tracking:
  - Receipt
  - Storage location
  - Preparation for analysis
  - Shipping
  - Disposal

Auditing Temperature Data

- Dataloggers
  - Data downloaded per SOP?
  - Electronic records are kept?
  - Data summary reflects original data?
- Temperature Monitoring System
  - Review data for equipment used during study conduct.
  - Storage per protocol?
- Typically, temperature records are considered facility data; however, it supports study conduct and must be retained.
  - For storage stability studies, make sure to include temperature data in the study file for the duration of the study, for each storage unit used.

Auditing Equipment Logs

- Check that maintenance is being performed per the SOP.
- Maintenance activities should be entered on the day they were performed.
  - Maintenance performed by an external party may not have been entered on the same day.
    - In this case, check the maintenance date entered is supported by the documentation received.
    - This documentation must be maintained.
- Non-routine maintenance entries should include all the required information per the GLPs.
- For maintenance captured in an electronic system, check the audit trail.

Auditing Reagent & Solution Records

- Reagents
  - Check correct expiration date assigned.
  - Check non-expired reagents are used.
- Solutions
  - Check correct components used.
  - Check correct amount used.
  - Check components are not expired.
  - Check correct expiration date assigned.

Auditing Analytical Data

- Sample and standard preparation
- Instrument set-up
- Acceptance criteria
- Robots
- Audit trail

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Auditing Spreadsheets

- Software that writes data to a LIMS or spreadsheet.
  - The electronic data is the original data.
  - The software and process need to be validated.
  - If data is written to a spreadsheet:
    - The spreadsheet must be printed, initialed/dated by the person performing the activity.
    - Check that the information on the printout matches that of the electronic file.
    - The file save date should match the date of the activity and date on the printout.
- A spreadsheet is often used to perform calculations on the data generated.
  - Validation is helpful, to avoid having to do full QC/QA on the file.

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