LABLYTICA

LIFE SCIENCE

Talking Points

- Paperless document and archiving system
  - Setup
  - Scope

- Regulatory Inspections and Audits
  - Process
  - Discussions and findings

- Lessons Learned

Setup and Scope

- Documents are safe once signed

- Fully validated for regulatory use within GCP and GLP

- Compliant to CFR21 part 11 Electronic Records and Electronic Signatures (ER/ES)

- Electronic signatures are equivalent to wet-ink signatures

Setup and Scope

- Mirroring of paper archiving workflow

- Each document includes metadata with version history, dates and signatures

- Word, Excel and PDF documents can be archived

- No electronic metadata or instrument specific data is archived

Setup and Scope

- What is electronic archiving in OECD GLP?
  - A subset of an electronic dataset is migrated to a new location
  - The subset is deleted from its original location

- We do not "archive" in this sense, we keep the data in its current position in an un-editable form.

Regulatory Inspections and Audits

- Inform auditors and inspectors in advance that you have a paperless system

- Include an overview of the system in the opening presentation

- Fast-paced audits
  - All documents can be retrieved within seconds
  - Risk of going off track and jumping between audit points

- Most audits and inspections have no findings regarding the electronic documentation and archiving system

Regulatory Inspections and Audits

- Discussion 1: Is electronic archiving compliant to GLP?

  - Regulatory foundation for paperless archiving present in OECD GLP

    "**Any GLP-relevant data may be archived electronically. …** "
    Section 3.11. Archiving, OECD GLP No. 17 Advisory Document of the Working Party on Good Laboratory Practice Application of GLP Principles to Computerised Systems

Regulatory Inspections and Audits

- Discussion/Finding 2: Who is the Archivist?

  - No archivist named at test site for the electronic archiving system (2016)
  - Resolution:
    - Archivist from outside the GLP laboratory entered by name into Archiving SOP

  - IT system administrators need to be the archivist (2017)
  - Resolution:
    - IT system administrators appointed archivist and given basic GLP/GCP training.

  - No archivist named at test site for the electronic archiving system (2022)
  - Resolution:
    - Initial argument that IT system administrators are the Archivists
    - After long delay, it was agreed to write TSM as archivist into SOP

Regulatory Inspections and Audits

- Discussion/Finding 3: Everyone has access to archived documents?

  - Archived documents are accessible by staff after being archived
  - Resolution: No action taken

    "**Management might authorise read-only access on electronic records to a broader community.**" and "**Viewing electronic records without the possibility of alteration or deletion of the archived electronic record or replicating within another computerized system does not constitute "retrieval" of a record**."

    Sections 6.2 Access to the Archive and 7.7 Retrieval, OECD GLP No. 15 Establishment and Control of Archives that Operate in Compliance with the Principles of GLP

Regulatory Inspections and Audits

- Discussion/Finding 4: When is a document archived/un-archived?

  - Signing a document into a final, unchangeable version was considered insufficient to call it archived.

  - Resolution:
    - For projects, an "Archiving Statement" workflow and document was created, that specifies the date of archiving for all that project's documents and their version. Test Site specific documents are archived every year in a similar manner

Lessons Learned

- It is an additional computerized system

- Costs for administration and updates

- Training needed for staff

- Need to create an archiving and un-archiving process

- More explanation of system required

Lessons Learned

- Electronic archiving system has been accepted by inspectors and customers

- Archiving of a project takes about 60 minutes

- All documents are accessible within seconds

- If you can't find it, it is not there

- Over 9000 documents (about 55.000 pages) in the system after 7 years of use

Thank you for your attention

- QUESTIONS?