

Commercial/Outsourced Archiving

FIMEA Annual GLP Seminar
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Outsourcing in GLP

- Introduction
- Outsourced/Commercial Archiving in GLP:
 - A) Printed material, wet material, tissue blocks, slides etc
 - B) Electronic archiving: electronically produced records



Outsourcing of archives in GLP

Introduction

Outsourcing or commercial services =

Not produced nor provided by the test facility/test site

Usually commercial services; may serve many different clients!

Apply especially to small test facilities/test sites: lack of suitable space and/or resources

→ Archiving outsourced

→ ***General requirement: outsourced archive should comply with GLP-Principles!***

Outsourcing of archives in GLP

Outsourcing of Archiving – Contract Archives

Advisory Document: Establishment and control of archives that operate in compliance with the principles of GLP, No 15

Chapter 10.: Contract Archive Services: ...”the use of contract archive facilities is not precluded.”

→ Confirmation of compliance with GLP:

→ Responsibility of test facility/site management

→ are subject to audits by QA!



Outsourcing of archives in GLP

Outsourced/commercial archiving services – what to expect?

- documents describing the commercial archive and services
- Possible references; other GLP-facilities using it?
 - Existing quality systems, e.g accreditation
 - ISO standard 11799
 - ISO/TC 46/SC 11
 - ISO 16175 (digital archiving)
- Compliance to national legislation requirements
 - Finland: National Archives orders and administrative regulations

Outsourcing of archives in GLP

General requirements for outsourced/commercial archives

- **Contracts/agreements:** what is archived, duration, removal etc
- **Rights and responsibilities:** appointed archivist, who is allowed to make a loan, who has right to dispose material and how etc. → documentation must be found; contract, SOP
- **Access** to contract archive: who, when and how? Must be controlled and traceable: log book for entries
- General **facilities and environment;** environmental control, structure, conditions of storage, separation of archive spaces (if serves many clients); log books, indexes of archived materials
- **Training of personnel,** resources, contact persons, **SOP's**
- Distance; **transportation** issues, **responsibilities,** chain of custody, data integrity during transportation, transportation conditions



Outsourcing of archives in GLP

Electronic archiving:

- *Management responsibility of IT-systems? Responsibility of test facility/site management*
→ Co-operation between IT and archivist
- SOP's, contract, archivist, controlling of environment – defined area!
- transferring of electronic data: in which formats and how, what kind of data is archived
 - CD vs. electronical transfer
- how transfer is controlled? Confirmation of data integrity → validation of archiving
 - protection of data from any changes
- access to transferred data, data retrieval, long-term retention
- Transferring of data to another form; validation, data integrity, documentation

Outsourcing of archives in GLP

General management issues

- Subject for internal QA audits
- Communication between contract archive and test facility/test site
- Plans for transfer/move/closing of operation of the archive
→ Documentation (SOP, risk assessment, contract..)
- Plans for crisis and disaster recovery (fire, flood..): documentation; contract, SOP, risk assessment/evaluation
- How sponsor is informed and by whom in case of emergency etc?
Contract, SOP?
- Disposal of archived material? Rights and responsibilities?
→ contract, SOP



*Thank you for your attention!
Any questions?*

