Responsibilities of Test Facility Management & Sponsor

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Responsibilities of management & sponsor

• Responsible people
• Quality Assurance
• Test facility, supplies, test item, computerized systems
• SOP’s
• Performance of a study

OECD 1: OECD Principles of Good Laboratory Practice
OECD 11: The Role and Responsibilities of the Sponsor
OECD 13: Organisation and Management of Multi-Site Studies
OECD 15: Archives
Management

• Definition: Test Facility Management means the person(s) who has the **authority** and formal **responsibility** for the **organisation** and **functioning** of the test facility according to GLP

• What does this mean?
  - Identification of management
  - Job descriptions
  - SOP on the organisation of the test facility
  - Sufficient number of qualified personnel, Master Schedule, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study
Personnel

- Record of the **qualifications, training, experience** and **job description**
- Personnel clearly **understand their functions**

**What does this mean?**
- CV, Basic Training Plan
- SOPs and SOP training
- Development plan and ongoing training
Study Director

- Designate a Study Director **for each study**
- **Replacement** of a Study Director
- Study Director **workload**

- What does this mean?
  - Study request form, kept in raw data
  - Development Plan & ongoing training
  - Described in SOPs (incl. replacement) and documented in raw data
Principal Investigator

- Multi-site study: designation of a Principal Investigator
- Replacement done according to established procedures, and documented

- What does this mean?
  - Same principles as for Study Director request form, basic and on-going training, documented replacement
Quality Assurance

- **Quality Assurance Program**

- What does this mean?
  - Independent reporting structure
  - Approved document appointing QA and listing responsibilities
  - Access to Master Schedule
  - QA audits reported to management
    - Inspection reports (study specific, system, CRO)
    - Overview reporting of observations and trending with trend analysis
  - Open communication
  - Proactive handling, Innovative solutions, Risk Management
Test facility supplies meet requirements appropriate to their use in a study

What does this mean?

Reagents, materials, animals, food, equipment, ...

- as much as possible from ISO certified companies
- vendor audits performed by QA
- equipment: validated, calibrated and quality controlled
Test and reference item

- Test and reference items are appropriately characterized

- What does this mean?
  - Certificate of analysis available before the start of the study
    - identity with batch No.
    - purity
    - stability
    - storage conditions
    - ...
Computerized systems are suitable for their intended purpose and validated, operated and maintained in accordance with GLP.

What does this mean?
- IT department with internal preclinical IT team
- Validation methodology described in policy and SOPs
- Master Validation Plan
- Validation file for all computerised systems and defined change control
- QA audits
SOPs

- Appropriate and technically valid SOPs established and followed
- Approve original and revised SOPs
- Maintain historical file of SOPs

- What does this mean?
  - SOP management System
  - Procedure on how to manage SOPs
  - Defined responsibilities for SOP owners
Performance of a study

- Documented approval of study plan
- Multi-site study: **clear lines of communication** between SD, PI, QA and study personnel

- What does this mean?
  - Study plan is signed by SD, management signs as sponsor rep (described in SOP)
  - Procedure on study plan distribution and documented evidence
  - Multi-site: Described in procedures and study plan
  - Multi-site: Documented communication
Archives

- Individual identified as responsible for management of the archive
- Records and materials should be archived
- Out of business: the archive should be transferred

- What does this mean?
  - Archivist appointed, responsibilities described in job description
  - Paper, material and electronic archiving described in SOPs
  - Controlled access
  - Described in study plan and reflected in the report
  - Discussed and audited during CRO evaluation
  - Described in SOP (checked during CRO evaluation)
Sponsor responsibilities

• Definition: Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study

• Ensure that the test facility is able to conduct the study in compliance with GLP and that it is aware that the study is to be performed under GLP

• What does this mean?
  – Before the start of a study
    • Preselection visits and Audits by QA/Sponsor scientists
  – Ongoing follow-up
    • QA audits and Study monitor visits
  – GLP requirement described in contract & study plan
**Sponsor responsibilities**

- Provision of **chemical safety information**
- **Characterization** of the **test item**, carried out either by the contracted test facility or by the sponsor
- Submission of data to regulatory authorities:
  - **Study Director = scientific validity of a study**
  - **Sponsor = make the decision, based on the outcome of the study**
- **What does this mean?**
  - Safety information is provided before the start of the study
  - Certificate of analysis is provided and is part of the final report
  - Sponsor’s decision to submit final report to HA
Sponsor responsibilities

- Materials and records are retained and maintained under conditions that ensure their integrity and continued access. If records and materials transferred into the sponsor's possession = storage in GLP archives.

- What does this mean?
  - Study plan specifies how long data are being stored.
  - Archiving can be done internally or externally (part of CRO evaluation).
Common Responsibility of Health Authority and Pharma Industry

Opportunity in front of us to step up together to come up with one global set of GLP Principles which in turn can lead to one global submission file.

It is firmly hoped that Health Authorities and Industry, hand in hand, can actually optimize their interaction to the overall benefit of human health.
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