



# 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*



- 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



- **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 **sponsors 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)

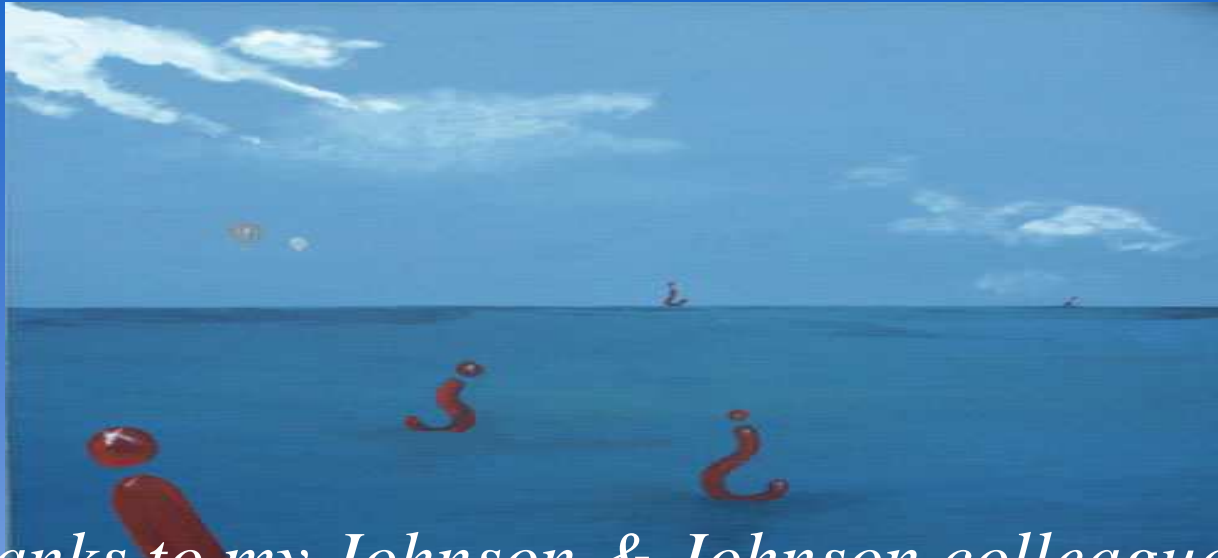


# *Common Responsibility of Health Authority and Pharma Industry*



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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