Quality Assurance

Responsibilities

Quality Assurance

GLP :

A quality system

- for laboratories that undertake non-clinical safety studies

Quality Assurance

GLP : Defines conditions under which studies are :

- Planned
- Performed
- Recorded
- Reported
- Archived
- Monitored

Quality Assurance

GLP requires a Quality Assurance Unit

- Independent monitoring to ensure compliance with:
  - Study protocol
  - SOPs

Quality Assurance

GLP requires a Quality Assurance Unit

- Pre-arranged programme of audits of:
  - Facilities
  - Systems
  - Equipment
  - Methods
  - QC procedures
  - Documentation
  - Reports

Quality Assurance

GLP requires a Quality Assurance Unit

- Audit must be conducted by a competent person:
  - Designated by Trial Facility Management
  - Independent of work being audited
  - Audits by external experts are permitted

Quality Assurance

GLP requires a Quality Assurance Unit

- Audit results must be recorded
- Reports of audits must contain all findings
- Audit reports may contain corrective actions

Quality Assurance

GLP requires a Quality Assurance Unit

- Study Directors and Trial Facility Managers must respond to the audits
- Corrective actions should be tracked to ensure implementation

Quality Assurance

GLP requires a Quality Assurance Unit

- QA issues an audit statement which:
  - Identifies the activity audited
  - Indicates the dates reports sent to SD and management

Quality Assurance

QA Programme /Personnel

- Documented
- Independent
- Familiar with studies
- Report to management
- Master schedule

Quality Assurance

QA Responsibilities (from OECD)

- Review study plans
- Review SOPs

Quality Assurance

QA Responsibilities (others)

- Consultation and Advice
- Training
- Inspection / Audit

Quality Assurance

QA Responsibilities (from OECD)

3 TYPES

- Study-based
- Facility / System-based
- Process-based

Quality Assurance

QA Responsibilities (from OECD)

- Study-based
  - Protocol (study plan)
  - In-life
  - Report

Quality Assurance

QA Responsibilities (from OECD)

Facility / Systems-based

- Installations / equipment / metrology
- Support services
- Computer systems
- Personnel training / documentation
- etc...

Quality Assurance

QA Responsibilities (from OECD)

Process-based

- Process which occur frequently – examples
    - Slide preparation
    - Reading Ames tests

Quality Assurance

QA Responsibilities (others)

- SOPs
- Suppliers
- Sub-Contractors

Quality Assurance

QA Involvement in Studies

- Planning (MSS, Inspection Plan)
- Protocol review
- Study Specific inspections (critical phases)
- Facility / System inspections / Audits
- Final report / Raw data
- Q.A. Statement

Quality Assurance

QA Typical Inspection Report

Header				
phase audited	QA Comments		Responses/Corrective action planned	
	Signature	Date	Signature	Date

Quality Assurance

QA Statement

- Dates of inspections
- Dates findings to Study Director & Management

Plus

- Phases audited
- Any exceptions
- Sign only if GLP compliance statement from Study Director is considered justifiable and all corrective actions completed