
بسم الله الرحمن الرحيم

SUPERVISED CLINICAL LABS PRACTICES

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SUPERVISED CLINICAL LABS PRACTICES

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

RESOURCES

Management
Personal
Buildings & Equipment

MANAGEMENT

Overall responsibility for GLP implementation

Resources

Management is responsible for providing resources and demonstrating that these are suitable for the task

- **Personal**
  - **Study Director** → single point of study control
  - **Quality Assurance** → ensure management of GLP compliance
  - **Archivist** → manages archives
  - **Study personal** → perform study according to instructions
- **Facilities / Equipment**

MANAGEMENT

- **Has responsibility for promoting:**
  - Good science
  - Good organization

Good Science

- Experimental design
- Based on known scientific principles
- Knowledge of experimental variables / bias
- Interpretation of results
- Results become part of accepted scientific knowledge

Good Organization

- Planning of studies and resource allocation
- Adequate physical facilities
- Sufficient qualified staff - recruitment
- Definition of staff responsibilities

Good Organization

- Staff training
- Ensuring proper conduct of studies
- Good record keeping & organized achieves
- Implementation of verification procedures for study conduct and results

Good Organization

- All these organizational aspects are covered by

GLP

- **GLP is about ensuring good organization of studies**

Resources

Planning / Resources Allocation

- Management responsibility
- Sufficient physical resources and personals

MASTER SCHEDULE

MASTER SCHEDULE

- All studies should be included
- Keep up-dated & have a change control procedure
- Include actions such as protocol review and report preparation
- Have only one official schedule

MASTER SCHEDULE

- Define the system in an SOP
- Decide who should maintain this document
- Archive – as necessary
- Distribute to those who need it

Resources

Master Schedule

Test item : ....

STUDY INFORMATION				DATES						...
Study N°	*Study Director*	*Title*	*Location*	*Protocol Review*	*Start Date*	*End In-Vivo*	*Draft Report Audit*	*Final Report Review*	*Archive*	*Comments*

PERSONAL

Organization shown in standard documents

- Organization chart, reporting relationship
- Curriculum vitae
- Training records
- Job descriptions

Organization Chart

- Should give a good idea of how the organization operates
- Keep it simple
- Add functional responsibilities only if this helps to explain the organization

Resources

Curriculum vitae

- For all personals
- In standard format
- Up-to-Date / archived
- Contains:
  - Qualifications/educations/diplomas
  - Professional experience

Training Records

- **Past**
  - Induction to the job
  - Competence of personal regarding SOPs
  - External courses / internal courses
  - Attendance at congress/seminars may be included
- **Future**
  - Training for each member of staff
- **Up-to-Date and archived**

Job Description

- Clearly define day-to-day responsibilities and tasks
- Make it clear who reports to whom
- Describe delegation of tasks
- Must be up-to-date
- Standard format
- Best signed by “n” and “n+1”

Job Description

- Department/group
- Name, position, level
- Name, position of the direct supervisor
- Position summary
- Tasks and responsibilities
- Work relationships
- Approval signatures and dates

FACILITIES

BUILDINGS & EQUIPMENT

BUILDINGS

- Suitability and Adequate for the study
- Maintenance
- Documentation including site plans

BUILDINGS : Factors to consider

- **Experimental**
  - Test systems
  - Study types
  - Number of studies
- **Staff**
  - Safety and comfort of staff
  - Possible impact on study from staff
- **Operational**
  - Access / security
  - Cleaning
  - Storage
  - Utilities and maintenance
  - Waste disposal

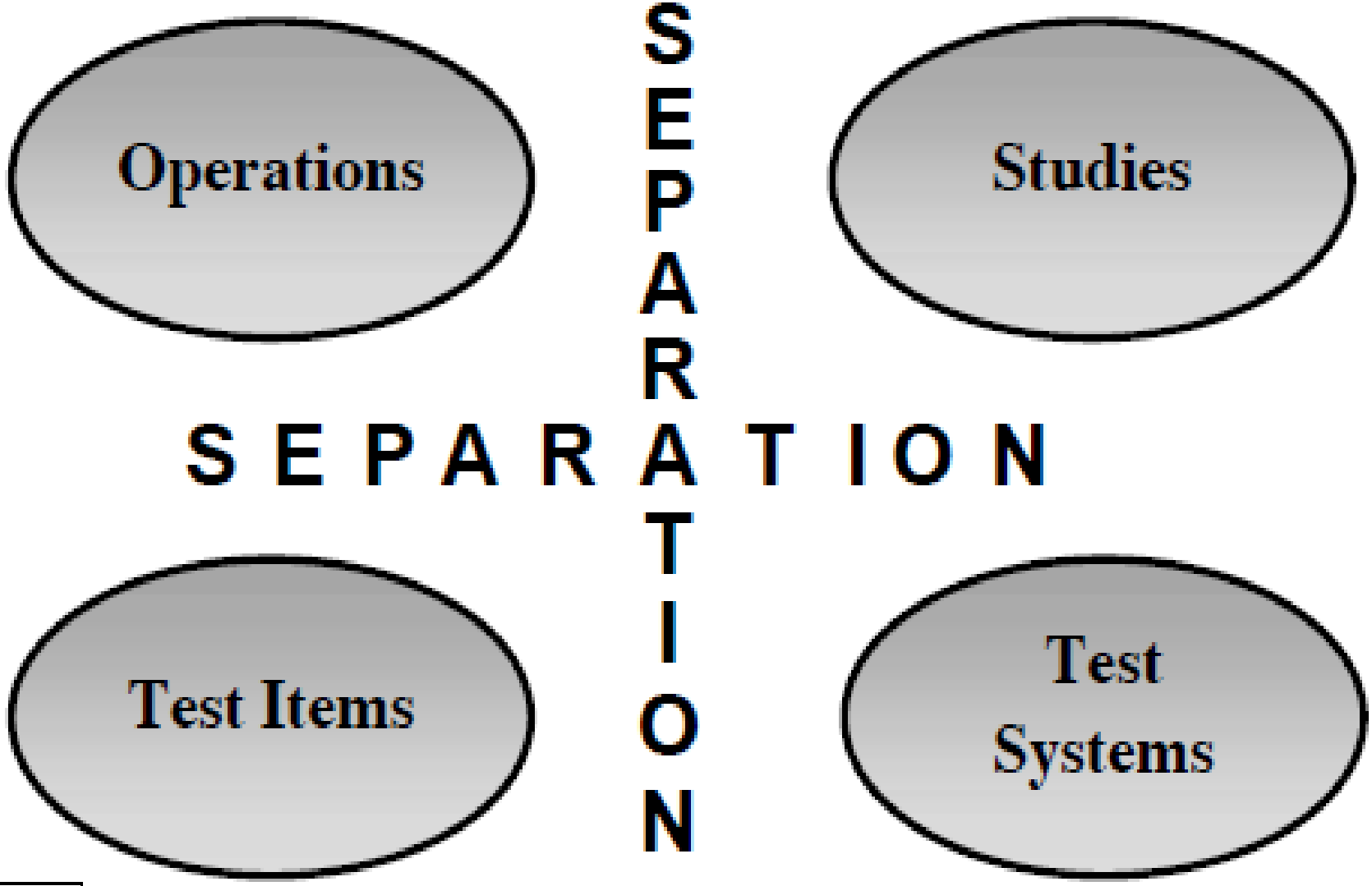
BUILDINGS : Suitable / Adequate for study

- Size, Construction, Location
- Minimize disturbances
- Separation between activities

BUILDINGS : Adequate Separation

- **Physical separation**
  - Rooms
  - Cabinets / isolates
  - Air systems and filters
- **Separation by organization**
  - Defined work areas
  - One-ways systems
  - Different activities in same areas at different times
  - Cleaning between activities
  - Separate staff

Resources


Operations
Studies
SEPARATION
SEPARATION
Test Items
Test Systems

BUILDINGS : Examples

Two examples :

- Dose mixing unit
- Animal facilities

Dose Mixing Unit

Deals with test and control items and their :

- Receipt
- Storage
- Dispensing
- Weighing
- Mixing
- Dispatch

Dose Mixing Unit

- **Size**
  - Accommodates all activities (including paperwork) without risk of mix-ups or cross contamination
  - Sufficient working area, separate storage and waste disposal
- **Construction**
  - Materials allow for easy cleaning
  - Air flow / filters protect test items & personnel

Dose Mixing Unit

LOCATION – Separate areas for :

- Storage of test materials under different conditions
- Storage of control materials
- Handling volatile materials
- Weighing areas
- Mixing different dose forms (e.g. diet & liquid)
- Storage of prepared dose
- Cleaning equipment
- Offices – rest rooms / changing rooms

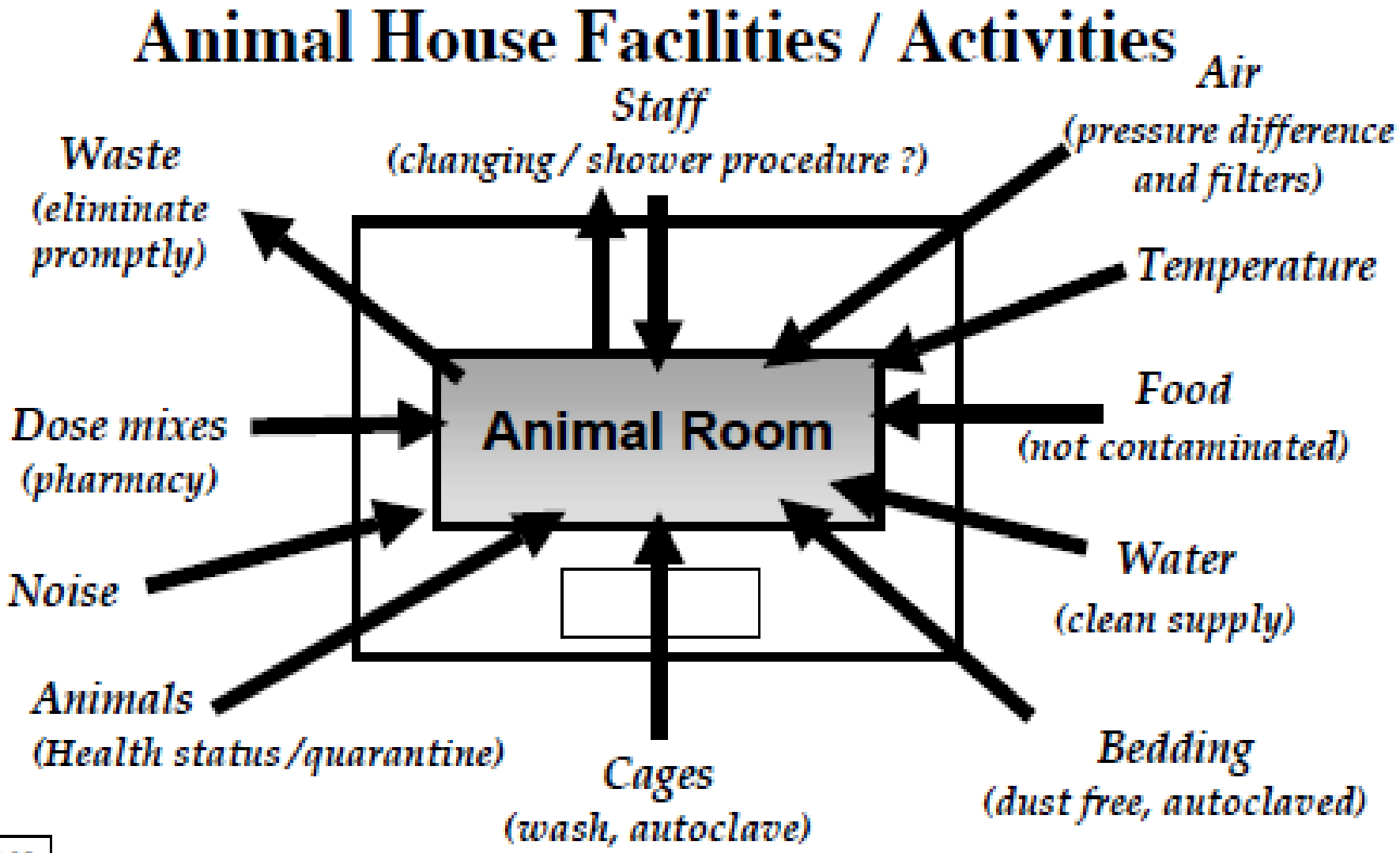
Animal House Facilities

- Design should :

  Reduced risk of test system :

  - being affected by environmental variables
  - encountering disease
  - Encountering other test articles

- Separate activities where possible, use barriers


Animal House Facilities / Activities
Staff
(changing / shower procedure ?)
Air
(pressure difference and filters)
Waste
(eliminate promptly)
Temperature
Animal Room
Food
(not contaminated)
Dose mixes
(pharmacy)
Water
(clean supply)
Noise
Animals
(Health status /quarantine)
Cages
(wash, autoclave)
Bedding
(dust free, autoclaved)

Animal House Facilities

- *Separation*
  - *Species*
  - *Studies*
  - *Quarantine*
  - *Changing rooms*
  - *Receipt of material*

Resources

Animal House Facilities

- *Separation*
  - *Storage*
    - *bedding*
    - *Diet*
    - *Dose mixes*
    - *cages*
  - *Necropsy*
  - *Laboratory techniques*
  - *Waste disposal*

Animal House Facilities

- *Environmental factors controlled and/or measured*
  - Temperature / humidity
  - Air flow
  - Light (intensity and duration)
  - Noise
- *Cleaning*
  - Smooth flat surfaces, walls, doors, ceilings
  - No gaps, cracks, holes

Animal House Facilities

- Even if facilities are not “State of the Art” :
  - Minimize staff entry into building
  - Restrict entry into animals rooms
  - Organize work flow (e.g. use of corridors clean / dirty at different times)
  - Require staff to adopt dress procedures
  - Clean between studies

EQUIPMENTS

- Suitability
- Calibration

EQUIPMENTS : Suitability

- The scientist's responsibility
- Some times requires proof of suitability
- May need formal equipment qualification

EQUIPMENTS : Calibration

- Need proof of standard working conditions
- Calibration usually requires use of standards
- If feasible, link :
    - “secondary – working” standards to …
    - … “primary” standards to…
    - …”national / international” standards
- Fix frequency of calibration in SOP
- Respect calibration frequency

BUILDINGS and EQUIPMENT

- Maintenance
- Documentation

BUILDINGS / EQUIPMENTS : Maintenance

- Preventive maintenance
- Curative maintenance (fix it when it breaks)
- Back-up equipment / procedures
- Contracts with external service organizations
- Alarms

BUILDINGS / EQUIPMENT : Service Plan

Plan title												
YEAR	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
Check Airflow alarms	D	D	D	D	d	d	d	d	d	d	d	d
Check Air Intakes	D	D	D	D	d	d	d	d	d	d	d	d
Check lane working	D	D	D	D	d	d	d	d	d	d	d	d
Check drive belts	M	M	M	m	m	m	m	m	m	m	m	m
Lubricate fans			X			x			x			x
Record Air Flows					x						x	
Strip lane		X										

MAINTENANCE : Service /Report / Label

INSTRUMENT NO. _____

DATE OF LAST SERVICE _____

NEXT SERVICE DUE _____

NAME OF SERVICE PROVIDER _____

Signature / date _____

MAINTENANCE : Fault Action Report

BUILDING NO./DEPARTMENT/ROOM		*EQUIPMENT I.D.*
DESCRIPTION OF FAULT	*Signature*	*Date*
IMMEDIATE ACTION TAKEN	*Signature*	*Date*
ACTION BY SERVICE PROVIDER	*Signature*	*Date*
INSTRUMENT OK FOR USE	*Signature*	*Date*

BUILDINGS / EQUIPMENTS : Documentation

- Have SOPs for :
  - Use of building / equipment
  - All maintenance actions including outside contractors
- Keep record of :
  - Use - logbook
  - Qualification calibration / checks
  - Maintenance service plan
  - Fault action report

COMPUTERISED SYSTEMS

Should be:

- Developed
- Validated
- Operated
- Maintained

In compliance with the principles of GLP

COMPUTERIZED SYSTEMS : Responsibilities

- Management – must ensure suitability for intended purposes
- Study Director – must be aware of the involvement of such systems in studies and ensure that they are GLP compliant
- Personnel – must ensure that they use the systems following instructions
- QAU – must monitor use and GLP compliance

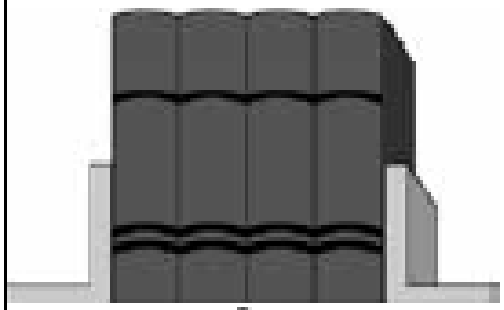
COMPUTERIZED SYSTEMS

- Training : documented on the job / external
- Facilities : physical location, backup
- Equipment : Hard ware & Soft ware, their communications
- Maintenance & Disaster recovery
- Security – physical, software
- Validation to ensure that systems are suitable for their intended use
- Documentation should cover policies, description of systems, source code and SOPs

COMPUTERIZED SYSTEMS

- Data
  - Raw data should be defined
  - System design provide an audit trail capability
  - There should be provision for long term retention of data
- Maintenance logs and calibration records are required to verify the validity of raw data or to permit study reconstruction. These should be archived
- Electronic data should be stored with the same level of access control, indexing and expedient retrieval as for other type of data.

Documentation for Buildings / Equipment

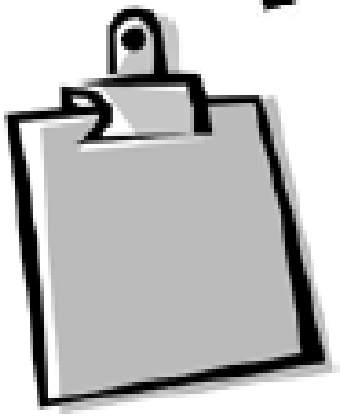


SOPs

Qualification report

Logbook

Service reports



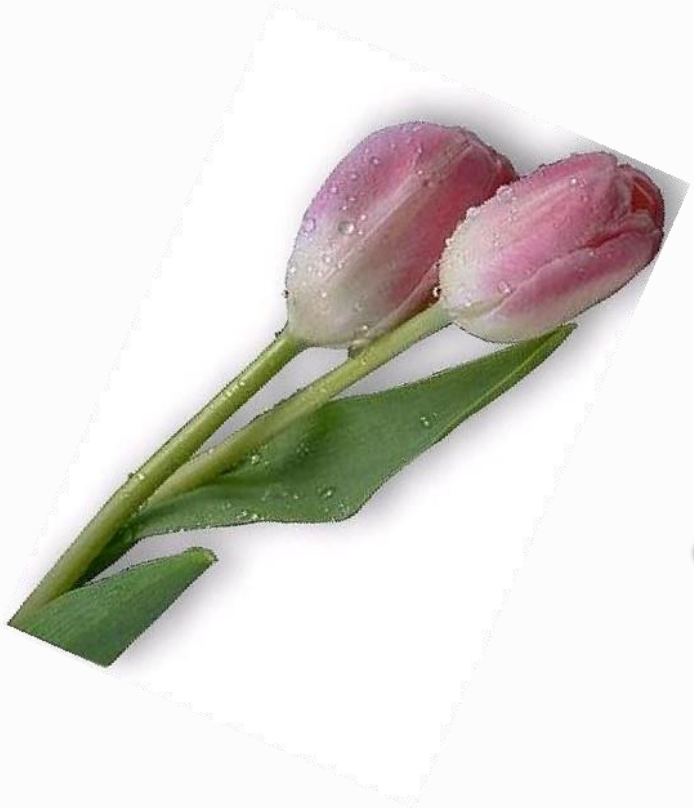
Fault action report

Compliance with GLP requires that:

- 1. The tests should be conducted by qualified personnel.
- 2. Each study should have a Study Director responsible for the overall conduct of the tests.
- 3. The laboratory study and the accompanying data should be audited by a Quality Assurance Unit.
- 4.All laboratory activities must be performed in accordance with written and filed management-approved Standard Operating Procedures (SOPs). SOPs should cover policies, administration, equipment operation, technical operation, and analytical methods.
- 5. All control and test articles and reagents must be identified, characterized, and labeled with information regarding source, purity, stability, concentration, storage conditions, and expiration date.
- 6. The equipment must be maintained, calibrated, and must be designed to meet analytical requirements.

Application of the Principles of GLP

- The primary purpose of **GLP** is to ensure uniformity, consistency, and reliability of safety tests (nonclinical) for pharmaceuticals, agrochemicals, aroma and color food/feed additives, cosmetics, detergents, novel foods, nutritional supplements for livestock, and other chemicals. **Establishment of GLP is mandatory to evaluate safety or toxicity of products intended to undergo clinical trials.**



Thank You...