GLP Requirements For Radiation Dosimetry

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What is GLP?

GLP = Good Laboratory Practice

- A quality standard promulgated by the FDA in 1978.
- Codified in 21 CFR Part 58
- Instituted by the FDA following cases of animal test fraud by pharmaceutical and industrial manufacturers.
- GLP applies to **nonclinical (animal)** studies
  - ✓ Safety including **toxicologic and pharmacologic** studies in animals before being introduced in man.
  - ✓ **Animal Rule** studies.

Why GLPs?

GLP = Good Laboratory Practice

To help the FDA ensure
that the products that it regulates are:

“Safe and efficacious

for its intended use”

by testing in animals before introduction in man.

Overarching GLP Principles

GLP = Good Laboratory Practice

- GLP doesn't conflict but enhances good science.
- Management is in control.
- If it wasn't documented, then it didn't happen.
- Documentation: Write it , do it, record it.
- Continuous Quality Improvement
- GLP is a **mindset**.
- GLP is a **PITA** !!!

Requirements for GLPs

GLP = Good Laboratory Practice

GLP studies require adequate and permanent documentation of everything involved in an experimental test:

- **Management** plans, reviews, oversees and approves everything
- **Staff** Qualifications
- **Valid Study Design**
- **Well-controlled environment:** laboratory, vivarium
- Standard Operating Procedures **(SOPs)**
- **Controlled** collection and retention of **study data.**
- **Equipment** calibration, validation and maintenance
- **QAU** (Quality Assurance Unit)

Equipment Validation

GLP = Good Laboratory Practice

- Procedures are very specific to the FDA.
- Covered within GLP Regulations (21 CFR 58) and FDA Guidance Documents.

Validation of MicroStar Reader

Landauer MicroStar Inlight Dosimeter

- Functional Requirements Specifications (FRS):
  How you intend to use the equipment which drives tests showing it meets these requirements.

- Master Validation Plan
  Test Scripts: Test procedures to compare actual with expected results

  - ✓ **Equipment qualifications:** documenting what it is, model numbers, all specs.
  - ✓ **Instrument physical environment,** physical and virtual security
  - ✓ **Installation Qualification (IQ):** Set up and software installation by the numbers

Validation of MicroStar Reader

Landauer MicroStar Inlight Dosimeter

- ✓ **Operational Qualification (OQ):** Functional Requirements testing using Traceability Matrix
  - Assess Barcode Scanner and Data Operations
  - Verify calibration function
  - Verify Standard Measurements And Reading Dots Function
  - Assess Data Operations: Database Backup/Restore/Reset
  - Data archive to flash drive
  - Data Integrity and Management
- ✓ **Performance Qualification (PQ):** Performed by user
  - Assessing Accuracy and Reproducibility of Dot Dosimeter Readings

➢ Validation Report: Provides results of executed tests, any deviations and corrective actions. Reviewed and signed/approved by management.

Calibration and Standardization Methodologies in Medical Physics

GLP = Good Laboratory Practice

- Annual, monthly and daily QA calibration methodologies are performed, particularly on clinical instruments e.g. LINAC, Theratron, to ensure patients receive the correct doses to the planned fields.

- Methods are outlined in Task Groups within published articles in the journal Medical Physics, e.g. Task Group 142, Quality Assurance of Medical Accelerators.

Calibration and Standardization Methodologies in Medical Physics

Task Group 142 report:

Quality assurance of medical accelerators

Medical Physics / Volume 36 / Issue 9 / TASK GROUP REPORT

Differences Between Medical Physics QA and GLP

- Task Group articles tell ***what to do*** through Task Group articles for calibration, verification and QA.
- **GLP provides:**
  - ✓ ***What to do***, ***Where to do it***, ***How to do it , Who can do it ,*** and ***When to do it*** by using detailed SOPs, training records, validation documentation, schedules, and management control
  - ✓ ***Independent QA*** to check your work!
- Advantage: better standardization, accuracy, reproducibility.