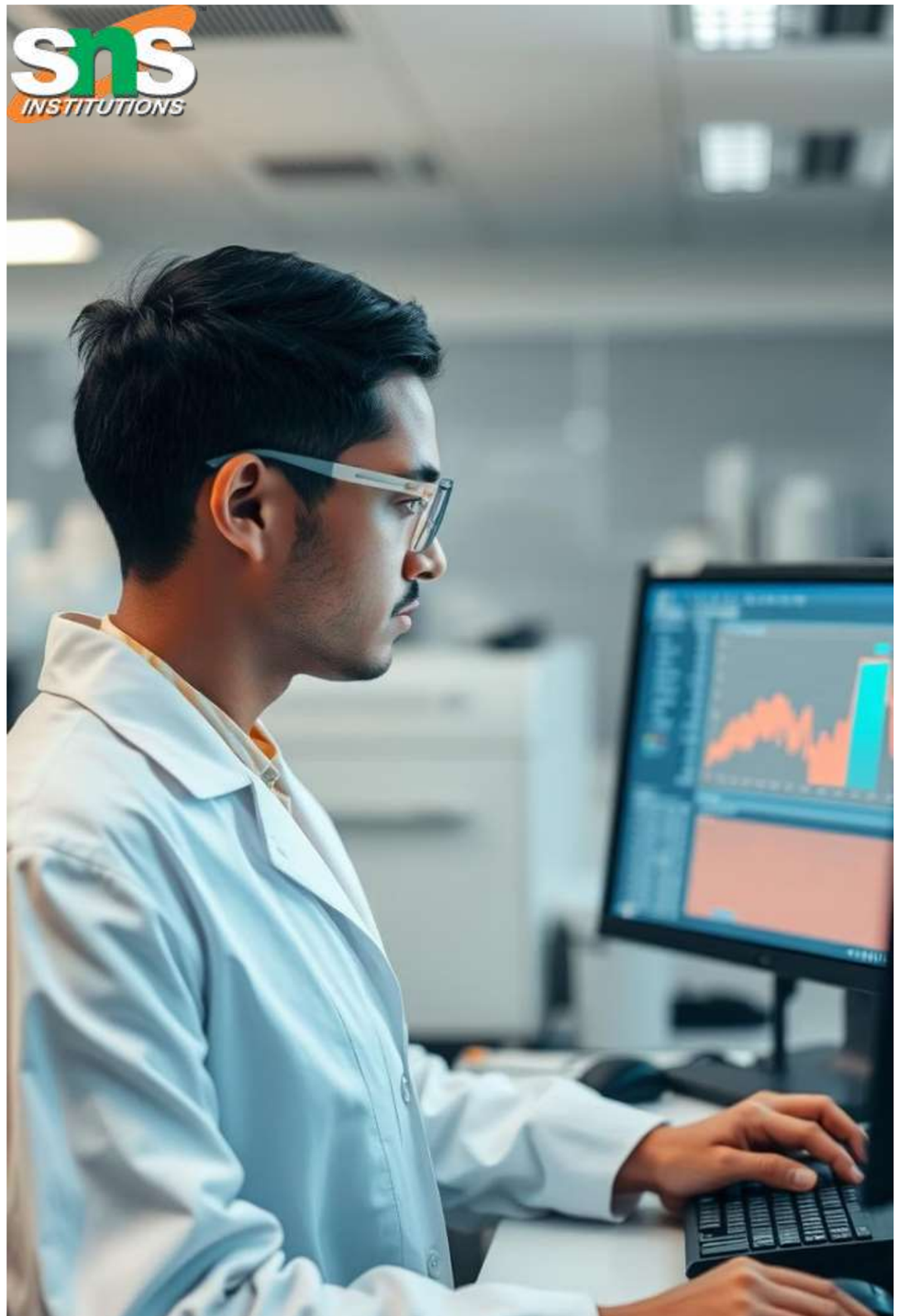
Good Laboratory Practices: General Provisions

Ensuring quality and integrity in non-clinical studies is essential. This presentation covers the general provisions of Good Laboratory Practices (GLP).

Presented by [Your Name/Organization] on [Date].



What Are Good Laboratory Practices (GLP)?

Quality System

Ensures uniformity, consistency, reliability, and integrity.

Non-Clinical Studies

Applied to health and environmental safety assessments.

International Standards

Developed by OECD and adopted by FDA and EPA.

Scope of GLP Regulations

Safety Studies

Supports submissions to regulatory authorities.

Applicable Areas

Pharmaceuticals, pesticides, food additives, medical devices.

Exclusions

Basic exploratory research is not covered.

Key Definitions in GLP

Test Article

The substance or product under study.

Control Article

Used as a comparison to the test article.

Test System

Animals, plants, microorganisms, or parts thereof.

Study Director & QAU

Study Director oversees conduct; QAU monitors compliance.

Responsibilities of Key Personnel

1 **Management**

Provide resources, training, and policies.

2 **Study Director**

Oversees study conduct and reporting.

3 **Principal Investigator**

Leads multi-site studies.

4 **Quality Assurance Unit**

Monitors and audits independently.

Facilities and Equipment

Facility Design

Proper size, construction, and location.

Separation to prevent contamination.

Equipment

Designed, maintained, and calibrated regularly.

Maintenance records kept up to date.

Test and Control Articles

Identification

Proper characterization and labeling of articles.

Storage

Procedures to maintain stability and prevent contamination.

Documentation

Records of receipt and usage must be maintained.

Standard Operating Procedures (SOPs)

1 **Written Procedures**

Cover all laboratory activities in detail.

2 **Regular Reviews**

Update SOPs periodically to maintain relevance.

3 **Ensure Data Quality**

Consistency and reliability of lab results.

Data Management and Record Keeping

Accurate Data

Complete and precise collection procedures.

Secure Storage

Data stored safely with easy retrieval.

Audit Trails

Track all data changes for transparency.

Compliance and Quality Assurance

1

QAU Inspections

Regular audits to ensure GLP adherence.

2

Reporting

Findings communicated to management and study director.

3

CAPA

Implement corrective and preventive actions promptly.

4

Data Integrity

Guarantees regulatory acceptance of results.