PHARMUNI DOWNLOADABLE GUIDE

# GMP or GLP?

## A Practical Decision Guide for Pharma Activities

Use this deck to choose the correct quality framework before writing procedures, assigning responsibilities, or preparing inspection evidence.

**10-step decision checklist**

**GMP • GLP • GCP boundaries**

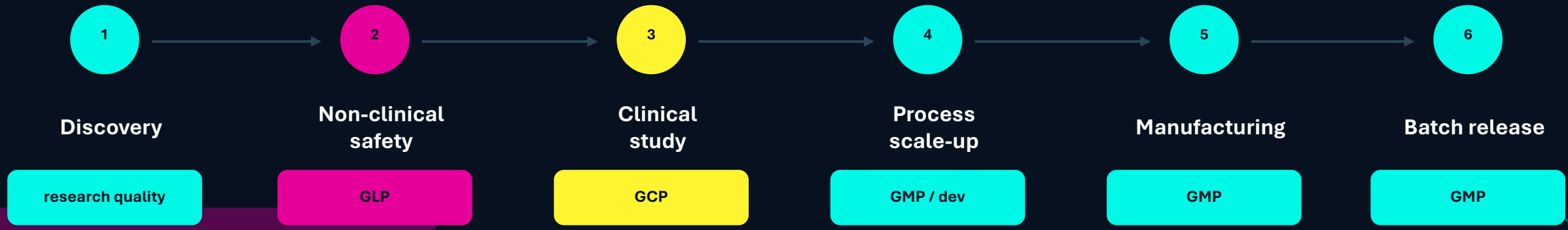
For pharma students, QA/QC teams, validation, regulatory affairs, and GMP learners

# The key problem: same lab, different purpose

A laboratory activity is not GMP or GLP because of the room, instrument, or analyst. The regulatory framework depends on the purpose of the activity and the data being generated.

**Simple rule**

First ask: Will the data support product release, product quality, or a non-clinical safety submission?



# One sentence difference

## GMP

Controls manufacturing and testing activities so each batch is consistently produced, controlled, and released.

**Product + batch quality**

**Purpose decides**

not the lab name

## GLP

Controls non-clinical safety studies so study data are reliable, traceable, and reconstructable.

**Study data integrity**

# Which framework applies to your activity?

**What is the data used for?**

## GMP

Batch release
or product quality

Manufacture, QC, validation, deviations, CAPA.

## GLP

Non-clinical
safety submission

Study plan, Study Director, raw data, QA unit, archive.

## GCP

Human subject
clinical evidence

Protocol, investigator, informed consent, clinical records.

# Use GMP when the activity controls product quality

## GMP

Good Manufacturing Practice applies when work affects the identity, strength, quality, or purity of a drug product.

**21 CFR 210/211 • EU GMP Vol. 4**

### Manufacturing

batch processing and packaging

### QC testing

release or stability decisions

### Validation

processes, cleaning, equipment

### QA systems

deviations, CAPA, changes

Practical test: If the record helps decide whether a batch can be used or released, think GMP first.

# Use GLP when the activity generates non-clinical safety data

### Study plan

approved design and amendments

### Study Director

single point of study control

### Raw data

traceable and reconstructable

### Archive

specimens, reports, records

## GLP

Good Laboratory Practice applies to non-clinical laboratory studies that support research or marketing applications.

**21 CFR 58 • OECD GLP**

Practical test: If the study supports non-clinical safety evidence, think GLP first.

# The 10-step decision checklist

01 Define the activity

02 Define the data use

03 Identify the product stage

04 List applicable laws

05 Assign owner

06 Choose records

07 Control changes

08 Check QA oversight

09 Plan archiving

10 Prepare inspection evidence

Tip: document the reason for framework selection before approving the procedure or study plan.

# Ten common pharma activities compared

| Activity | Main framework | Reason |
|---|---|---|
| Commercial tablet manufacturing | GMP | Controls batch production and release |
| Finished-product QC release test | GMP | Supports batch disposition |
| Stability testing for marketed product | GMP | Maintains product-quality evidence |
| Process validation campaign | GMP | Confirms manufacturing control |
| Equipment qualification | GMP | Supports controlled operations |
| Toxicology study for dossier | GLP | Supports non-clinical safety evidence |
| Mutagenicity study | GLP | Non-clinical safety endpoint |
| Bioanalytical method in GLP safety study | GLP | Part of a regulated study |
| Human clinical trial | GCP | Protects participants and clinical data |
| Early exploratory research | Research QMS | May not require formal GLP |

# What documentation should you expect?

## GMP evidence

- SOPs and batch records
- Specifications and QC results
- Deviation / CAPA records
- Change controls
- Validation and qualification files

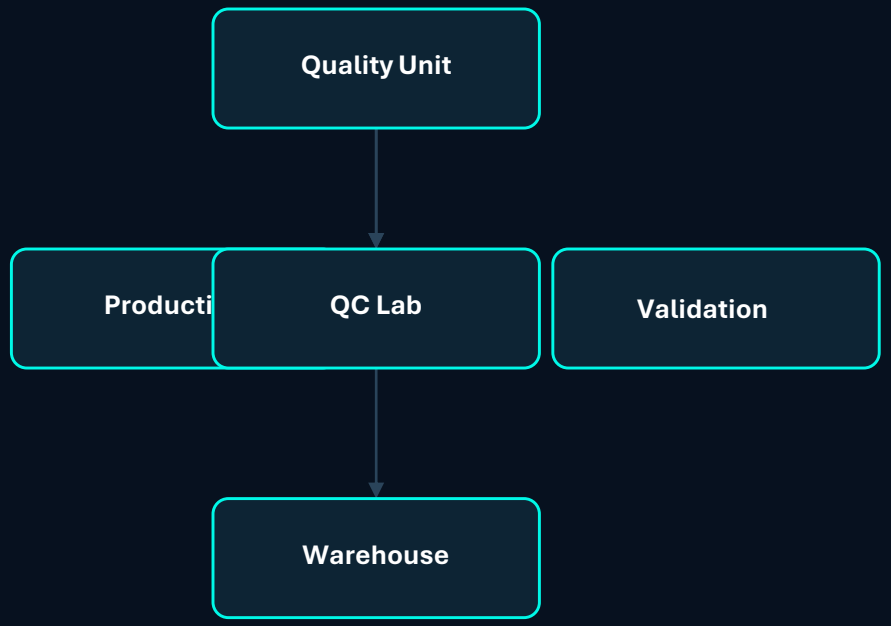
## GLP evidence

- Study plan and amendments
- Master schedule
- Raw data and specimens
- QA inspection records
- Final report and archives

Both systems require traceability, controlled records, and trained people — but the evidence package is different.

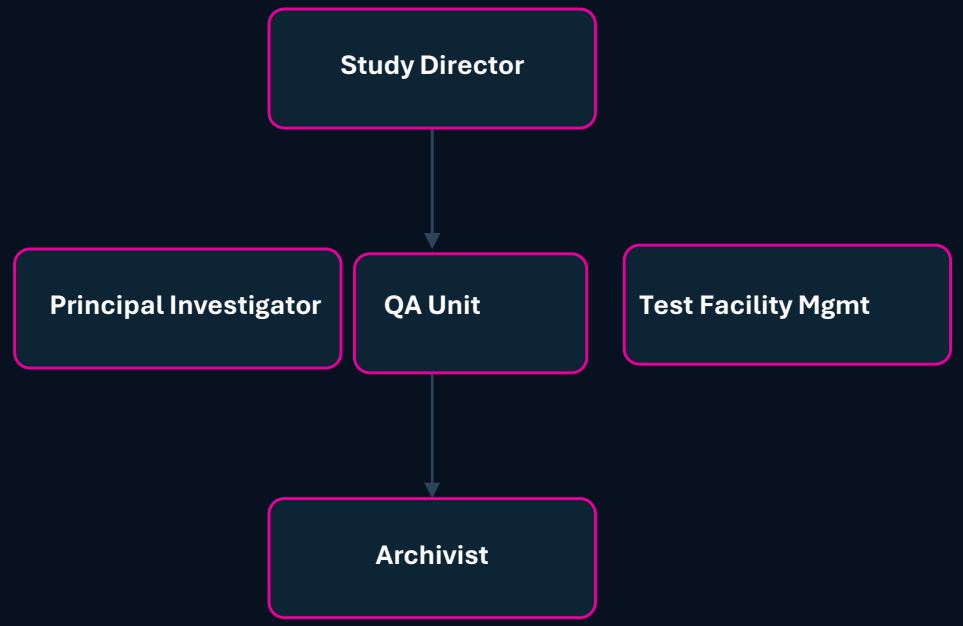
# Roles change with the framework

## GMP roles




GMP focus: independent quality decisions and batch control.

## GLP roles




GLP focus: study integrity from plan to archive.

# What inspectors usually look for

## GMP inspection focus

- ✓ Batch records match actual practice
- ✓ Deviations and CAPAs are justified
- ✓ Changes are assessed before use
- ✓ Equipment and processes are qualified
- ✓ Data integrity is preserved

**Evidence**

## GLP inspection focus

- ✓ Study plan is approved and followed
- ✓ Raw data reconstruct the study
- ✓ QA inspections are documented
- ✓ Test systems and specimens are controlled
- ✓ Reports and archives are complete

# Common mistakes to avoid

| Mistake | Correction |
| --- | --- |
| “All lab work is GLP.” | No. Routine batch-release testing is usually GMP. |
| “Method validation is always GLP.” | Only when it is part of a regulated GLP study. |
| “Same site means same framework.” | A site may host GMP and GLP work with separated controls. |
| “Documentation is the same.” | GMP batch evidence differs from GLP study evidence. |
| “GLP replaces GMP.” | They serve different lifecycle purposes. |

Use the activity purpose as your anchor. Then confirm the regulation, procedure, owner, and record set.

# Five-question knowledge check

| | | |
|---|---|---|
| 1 | A QC analyst tests a commercial batch for release. | GMP |
| 2 | A toxicology study supports a drug application. | GLP |
| 3 | A trial collects safety data from human subjects. | GCP |
| 4 | A cleaning validation run supports routine manufacturing. | GMP |
| 5 | An exploratory assay is used only for early discovery. | Research QMS |

Trainer tip: Ask learners to justify each answer using purpose, evidence, and responsible role.

# Sources and learning next steps

## Regulatory sources used

- FDA: Current Good Manufacturing Practice regulations, 21 CFR Parts 210 and 211
- eCFR: 21 CFR Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies
- OECD: GLP and Compliance Monitoring principles
- European Commission: EudraLex Volume 4, GMP guidelines
- FDA: Nonclinical laboratories inspected under GLP
- EMA: Good Laboratory Practice compliance overview

## Use this guide as a downloadable asset

Best placement in the article: after the section “Which Standard Applies to Your Activity?”

**Download the GMP vs GLP Decision Guide**

Suggested CTA: “Not sure whether GMP or GLP applies? Download the checklist and compare ten common pharma activities.”

Related Pharmuni learning: GMP Basics Career Path, QA/QC content, data integrity, validation, and regulatory affairs courses.