Pharmaceuticals / PH-08

Quality control laboratory and data integrity

Linking laboratory results to batches and maintaining an audit trail is an EU GMP inspection requirement.

A result must not change. If it does, the change must leave a trace.

When moving to EU GMP, laboratory data integrity is examined separately. The state reimburses half of the certification-related consultancy costs, but the laboratory process remains the company's own responsibility.

Conceptual architecture. No operating results are shown.

01 Sample	Batch · Time · Location
02 Test	Instrument · Result · Specification
03 Deviation	OOS · Investigation · Decision
04 Release	QA · Audit trail · Archive

At a glance

58 — Pharmaceutical manufacturers holding national GMP. [1]

$50,000 — Maximum reimbursable amount (50%) for foreign consultancy services on EU GMP / FDA GMP. [2]

55 — Countries to which Uzbek pharmaceutical products are exported. [1]

November 2026

01 Evidence and context

Who it is for

Head of QC	Results.
QA	Batch release.
IT	System validation.
Export	Buyer requirements.

Facts and global practice

Presidential meeting

All 58 manufacturers hold national GMP and must align with EU GMP; products are exported to 55 countries. [1]

yuz.uz

From 1 June 2026, 50% of the cost of foreign consultancy services for EU GMP, US FDA GMP and WHO prequalification is reimbursed, capped at $50,000. [2]

anhor.uz

Only 12% of companies hold an international GMP certificate. [3]

No statistics were found on Uzbek inspections related to data integrity.

02 Where the losses occur

Results in Excel

Spreadsheets have no audit trail.

Instrument data

Results are transcribed manually from instruments.

Sample traceability

Samples are not linked to batches.

Deviations

Out-of-specification investigations are on paper.

How the loss is calculated

Inspection observations	observations per inspection × corrective action cost per observation
Repeat testing	repeat tests per month × cost per test
Release delay	delay days per batch × delayed batches per month
Export	lost export market revenue per year

Illustrative calculations; establish the baseline, units and rates during the site assessment. Avoid counting the same loss twice.

03 Solution architecture

Sample, result and batch in one trail

The sample is linked to the batch, the result is entered from the instrument or via a form, every change is kept in the audit trail, and deviations are logged automatically.

01 Sample

Batch · Time · Location

02 Test

Instrument · Result · Specification

03 Deviation

OOS · Investigation · Decision

04 Release

QA · Audit trail · Archive

Modules

Sample and result log	With audit trail	Engineering capability
Deviation (OOS) log	Electronic	Engineering capability
Batch linkage (WMS)	Status	Commercially available
Full LIMS	Partner	In development

Each module has a readiness status. Third-party results are not a forecast for your site.

04 Implementation and measurement

01 Data integrity audit

Laboratory.

Output: Gaps.

02 Pilot

One test type.

Output: Audit trail.

03 Scale-up

All tests.

Output: Complete log.

04 Validation

With a partner.

Output: Inspection readiness.

What is measured

Manual transcription	Share	Audit
OOS cases	Count	Log
Result turnaround time	Days	System
Audit trail completeness	%	System

What is needed to start

- Head of QC
- List of tests
- List of instruments
- Validation requirements

05 Readiness checklist and next step

01 Are results stored in a system?	Yes / No / Unknown
02 Does every change leave a trace?	Yes / No / Unknown
03 Do instrument results arrive automatically?	Yes / No / Unknown
04 Are samples linked to batches?	Yes / No / Unknown
05 Is the OOS log electronic?	Yes / No / Unknown
06 Are user permissions restricted?	Yes / No / Unknown
07 Is the archive retention period defined?	Yes / No / Unknown
08 Has a reimbursement application been submitted?	Yes / No / Unknown
09 Has a consultant been selected?	Yes / No / Unknown
10 Is there a responsible person?	Yes / No / Unknown

What we do not promise

• Exact timeline and price without an audit

• GMP/GDP certification or inspection outcome

• Approving validation documents ourselves

• Unmeasured results

• Full LIMS (partner)

Laboratory audit

We review laboratory data integrity and identify inspection risks.

• Map of break points

• Pilot plan

• Implementation fee and monthly subscription

Scope, price and schedule are agreed after reviewing the site and its data.

06 Sources and scope

[1] Presidential videoconference: expanding production in the pharmaceutical industry. president.uz, 05.03.2026.

president.uz

[2] Decree of 05.03.2026 on incentives for the pharmaceutical sector: 2026 targets. yuz.uz, 2026.

yuz.uz

[3] “12% of pharmaceutical companies in Uzbekistan meet international standards.” anhor.uz.

anhor.uz

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