Pharmaceuticals / PH-04

Moving to EU GMP: the electronic batch record

58 manufacturers hold national GMP certification and now need to align with EU GMP. Plants worldwide are moving their batch records to electronic form.

A paper batch record is the inspector's first question.

At a presidential meeting it was stated that all 58 manufacturers hold national GMP certification and now need to meet EU GMP requirements. From 1 June, 50% of the cost of obtaining EU GMP certification will be reimbursed. Internationally, the electronic batch record (eBR) is the main tool for this transition.

Conceptual architecture. No operating results are shown.

01 Materials	Receipt · Quarantine · Approval
02 Weighing	Scale · Recipe · Signature
03 Execution	Steps · Deviations · Time
04 Release	QA review · Audit trail · Archive

At a glance

58 — Enterprises that directly manufacture medicines; all hold national GMP certification. [1]

50% — Share of EU GMP certification costs to be reimbursed (from 1 June). [1]

12% — Share of enterprises with international GMP certification, according to Anhor. [2]

November 2026

01 Evidence and context

Who it is for

CEO	Exports and certification.
Quality Director (QA)	Batch release.
Production	Execution.
IT	Validation.

Facts and global practice

Presidential meeting

More than 300 pharmaceutical enterprises, of which 58 directly manufacture medicines; all hold national GMP certification; they now need to align with EU GMP. [1]

Presidential meeting

From 1 June, 50% of the costs of obtaining EU GMP certification will be reimbursed from the Trade Promotion Fund. [1]

anhor.uz

Only 12% of enterprises hold international GMP certification. [2]

Siemens; Reliamag

Siemens Opcenter Execution Pharma and Körber PAS-X offer electronic batch recording and a review-by-exception approach (reviewing only deviations). [3]

Körber

Statement by a Körber representative: PAS-X EBR has improved product and process quality by up to 98% at many customers. [4]

The Körber figure is a vendor claim. Large eBR systems are expensive and take a long time to implement; smaller plants need a phased approach.

02 Where the losses occur

Manual records

Weighing results and calculations are written by hand.

Signatures

Signatures and their time sequence cannot be verified.

Review

QA reads every page, so batch release is delayed.

Audit trail

There is no change history.

How the loss is calculated

Release delay	release delay (days) × batch value × daily cost of capital (annual rate ÷ 365)
Deviations	review hours × QA hourly cost
Rejected batch	batch value
Inspection	preparation cost

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

03 Solution architecture

Phased eBR

Phase one: electronic records and audit trail for weighing, materials and batches. Where a full MES/eBR system is required, it is delivered with a partner vendor.

01 Materials

Receipt · Quarantine · Approval

02 Weighing

Scale · Recipe · Signature

03 Execution

Steps · Deviations · Time

04 Release

QA review · Audit trail · Archive

Modules

Materials and quarantine (WMS)	GMP statuses	Commercially available
Weighing and dispensing record	Scale integration	Engineering capability
Deviation log and audit trail	Electronic	Engineering capability
Full eBR/MES	Partner	In development

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

04 Implementation and measurement

01 GMP gap audit

Paper records and systems.

Output: Gap map.

02 Materials and weighing

One product.

Output: Electronic record.

03 Deviations

With QA.

Output: Review by exception.

04 Validation

With a partner.

Output: Inspection readiness.

What is measured

Batch release time	Days	System
Deviations	Count	Log
Manual entries	Share	Audit
Audit trail completeness	%	System

What is needed to start

- QA Director
- Sample batch record
- List of scales
- Validation requirements

05 Readiness checklist and next step

01 Is the batch record electronic?	Yes / No / Unknown
02 Are weighing results transferred automatically from the scale?	Yes / No / Unknown
03 Is there an audit trail for every change?	Yes / No / Unknown
04 Are electronic signatures used?	Yes / No / Unknown
05 Does QA review only deviations?	Yes / No / Unknown
06 Is material quarantine managed in the system?	Yes / No / Unknown
07 Is batch release time (in days) recorded?	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 designated responsible person?	Yes / No / Unknown

What we do not promise

• Fixed timeline and price without an audit

• GMP/GDP certification or inspection outcome

• Approval of validation documents by us

• Unmeasured results

• Full eBR/MES (partner)

GMP gap audit

We review the batch record and materials processes and identify where they fall short of EU GMP.

• Map of breakpoints

• 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 video conference: expanding production in the pharmaceutical industry. president.uz, 05.03.2026.

president.uz

[2] «12% of pharmaceutical enterprises in Uzbekistan meet international standards». anhor.uz.

anhor.uz

[3] Siemens Xcelerator: «Review by Exception» (Opcenter Execution Pharma). xcelerator.siemens.com. Reliamag: «Best MES for Pharmaceutical Manufacturing 2026: an independent comparison». 2026.

xcelerator.siemens.com

[4] Körber: «Boosting efficiency and productivity with Electronic Batch Recording». koerber.com.

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Prepared from the cited sources. Vendor statements and reported sector figures are attributed, not independently verified here. No performance, certification or regulatory outcome is guaranteed. Check the current official rules before making decisions.

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