Atto Pharma
MANUFACTURING SIMPLIFIED

eBMR
Plant-driven.
IT-governed.
Nothing to install.

Control Stays with IT

Manufacturing and Quality run the electronic batch record; IT keeps access, security and validation in its hands, with less to run. Read how Atto Pharma eBMR® supports 21 CFR Part 11, EU GMP Annex 11 and a GAMP 5 approach to validation.



IT Head

access · security · validation

Development
load the BMR, train, rehearse

→

QA
OQ and PQ, approved promotion

→

Production
GMP batches, signed, audit-trailed

Three separate sites · releases qualified before they arrive · installation check on each site

Nothing to Install or Patch

No servers to run in the plant. Each release arrives already qualified, and an installation check (IQ) confirms every site serves exactly that release.

Access You Control

One role per person, the operations each is cleared for, two-step sign-in, and each company's records kept apart from every other company's.

Records You Can Defend

Electronic signatures with the signer's own password, a tamper-evident audit trail of every change with who, when and why, and ALCOA+ by design.

Validation Without a Project

A GAMP 5 approach: the platform is qualified with every release; the plant runs its own OQ and PQ on its own products. No custom code to validate.

Changes Under Control

Development, QA and production kept separate; products and master data promoted with approval; every release published and made default by a signed decision.

What Changes for IT

IT keeps	IT no longer carries
✓ Who gets access, and when	☐ Servers, patching and backups
✓ The security review of the vendor	☐ Custom code to maintain
✓ Signing the OQ with QA	☐ A validation project per product
✓ Who must use two-step sign-in	☐ Upgrade projects

For Your Security Review

- An IT & Security agent answers your team's questions, with sources
- Trust and Security Overview, security policies and the Application Security Whitepaper, under NDA
- Part 11 and Annex 11 controls, clause by clause, in the whitepaper

Read the Whitepaper

21 CFR Part 11, cGMP and GAMP 5

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What the system enforces, what stays the manufacturer's, and how it is validated.

Scan to Read the White Paper