Atto Pharma
MANUFACTURING SIMPLIFIED

ATTO QMS · CHANGE CONTROL, OOS RESULTS AND CAPA

Every quality event in its turn, by the right person. Checked, signed, on record.

Change controls, out-of-specification results and CAPA as electronic records, on their own or with the Atto Pharma eBMR and eLogbooks. Each step is taken by the role it belongs to, in its order, signed with the password; nothing closes while an action is open, and an open OOS holds the batch's QA release.

1 · Raise
Anyone with a QMS role, in their own department: permanent or temporary.

2 · Review
The head of department, then QA: risk assessment and the departments that concur.

3 · Approve
The QA Head, as major or minor, never the person who raised it.

4 · Act
The impact checklist and the actions, each done by its owner and verified by QA.

5 · Close
Post-implementation review, closure, then the effectiveness check.

THREE RECORDS, ONE QUALITY SYSTEM

Record	What Atto QMS keeps, step by step
Change control	Permanent or temporary; the head of department's review; QA's risk assessment and the departments that concur; approval by the QA Head; your impact checklist; customers or authorities told before or after, with their acknowledgement; the actions; post-implementation review, closure and the effectiveness check; a temporary change ends permanent or restored
OOS results	Logged by the QC analyst within the time you set (a reason if late); Phase IA for an obvious error; Phase IB with the checklist, the analyst's interview and a hypothesis plan approved by QA; retests by a second analyst, each result, the mean and the RSD against your limits; Phase II in the plant, Phase III, resampling only with the QA Head; the disposition by the QA Head; a review after closure
CAPA	Raised with its actions, owners and due dates; approved by the QA Head; each action done and verified by QA; completed, then checked for effectiveness (not effective: back in progress)
Your settings	**Departments, working days, numbering, days to close and extensions, categories and the impact checklist, OOS timelines, replicates and RSD limit: set by your QA Head, each change with its reason**

ON SCREEN

CC-P-2026-014 · Wider-angle spray nozzle on the coating pan

- Raised · Manufacturing — 2 Nov
- Head of department reviewed — 2 Nov
- QA review · Engineering concurs — 3 Nov
- Approved by the QA Head · minor — 3 Nov
- Actions: 2 of 3 done and verified — now
- Closure, effectiveness check — by 15 Dec

A change control: every step with who, when and its signature.

OOS-FP-2026-007 · Assay, finished product Retest

Retest	By	Result
1	Second analyst	99.1 %
2	Second analyst	98.8 %
3	Original analyst	99.4 %
Mean · RSD		**99.1 % · 0.30 %**

Limits 95.0–105.0 %; RSD within 2.0 % within

OOS retests: each result, the mean and the RSD checked against your limits.

Batch B26-0412 · QA release

Every step signed; reconciliation done.

QMS hold: OOS OOS-FP-2026-007 is open. The batch is released once the OOS is closed with its disposition.

With the eBMR: an open OOS on a batch holds its QA release. Made-up data.

CHECKED BY THE DATABASE, NOT BY A FORM

Electronic signatures
Each step signed with the password and its meaning (21 CFR Part 11); the second person always someone else.

In its order
Each step only by its role and only in its turn; nothing closes while an action is open.

Timelines
Due dates in working days from your settings; extensions by the QA Head, with a reason, a limited number of times.

Audit trail
Every step with the server's time, the signer's name and meaning, chained by hashes; records are never deleted.

On its own, or with the eBMR

Buy Atto QMS alone, or switch it on for your Atto Pharma eBMR or eLogbooks: the same people, signatures and batches. Priced per user a month. Built for 21 CFR Part 11 and EU GMP Annex 11.

Run your first change control in the 14-day pilot.

Sign up, choose Atto QMS, give your team their QMS roles.

dev.pharma-manufacturing.today
Sign up your company for the pilot