ISO 13485 §8.5.2 · ISO 9001 §10.2 · 21 CFR 820 (QMSR)

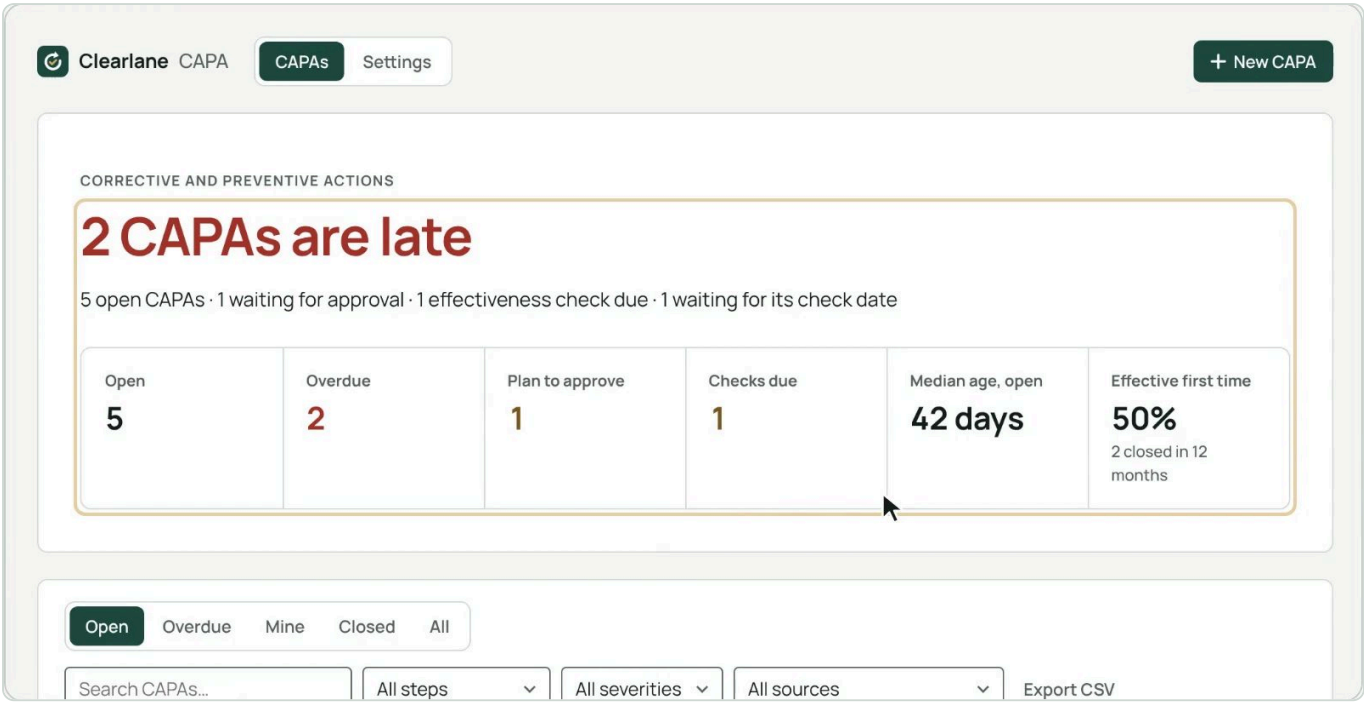
A CAPA in Jira, from nonconformity to signed closure

One nonconformity followed step by step, with screenshots of the real app (demo data). No meeting needed: read it at your own pace, then try it on your own Jira site.

Step 1

See where you stand

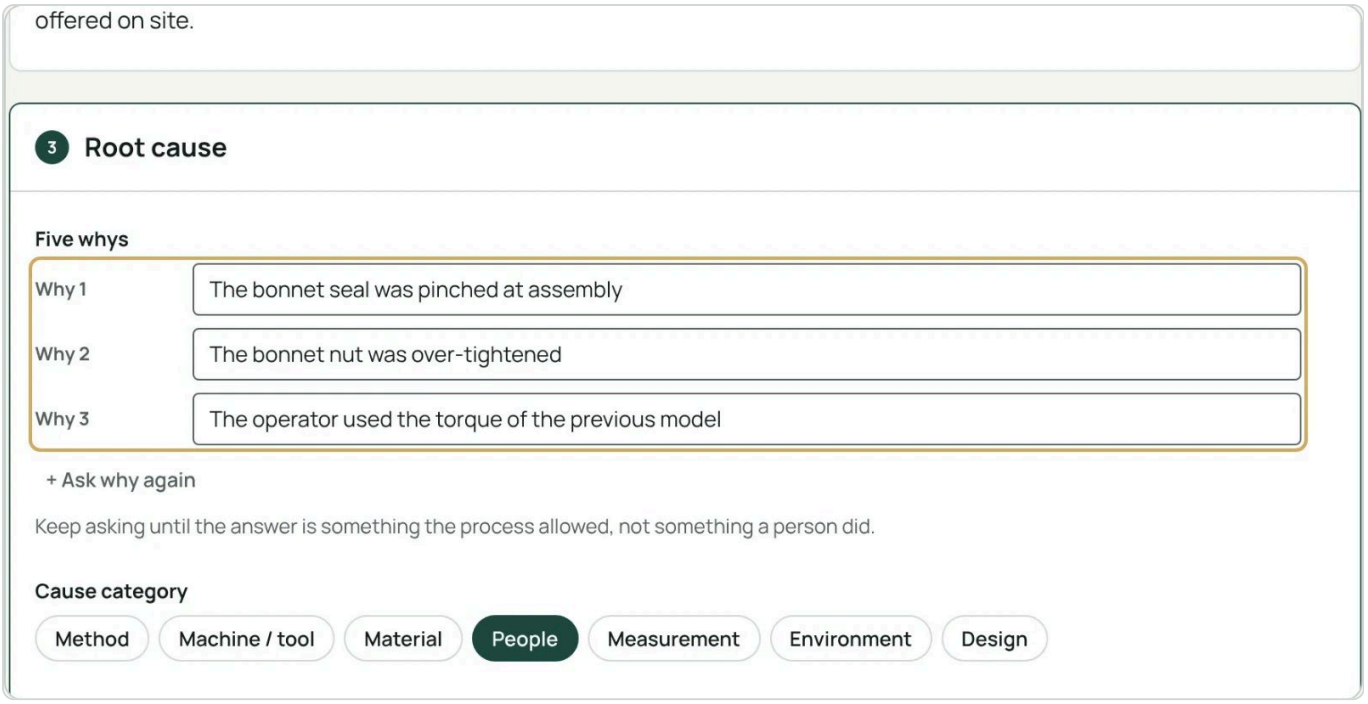
The CAPA register shows what is open, overdue, waiting for approval or due for an effectiveness check. Any Jira work item, such as a complaint, an audit finding or a nonconformity, becomes a CAPA.



Step 2

Find the real root cause

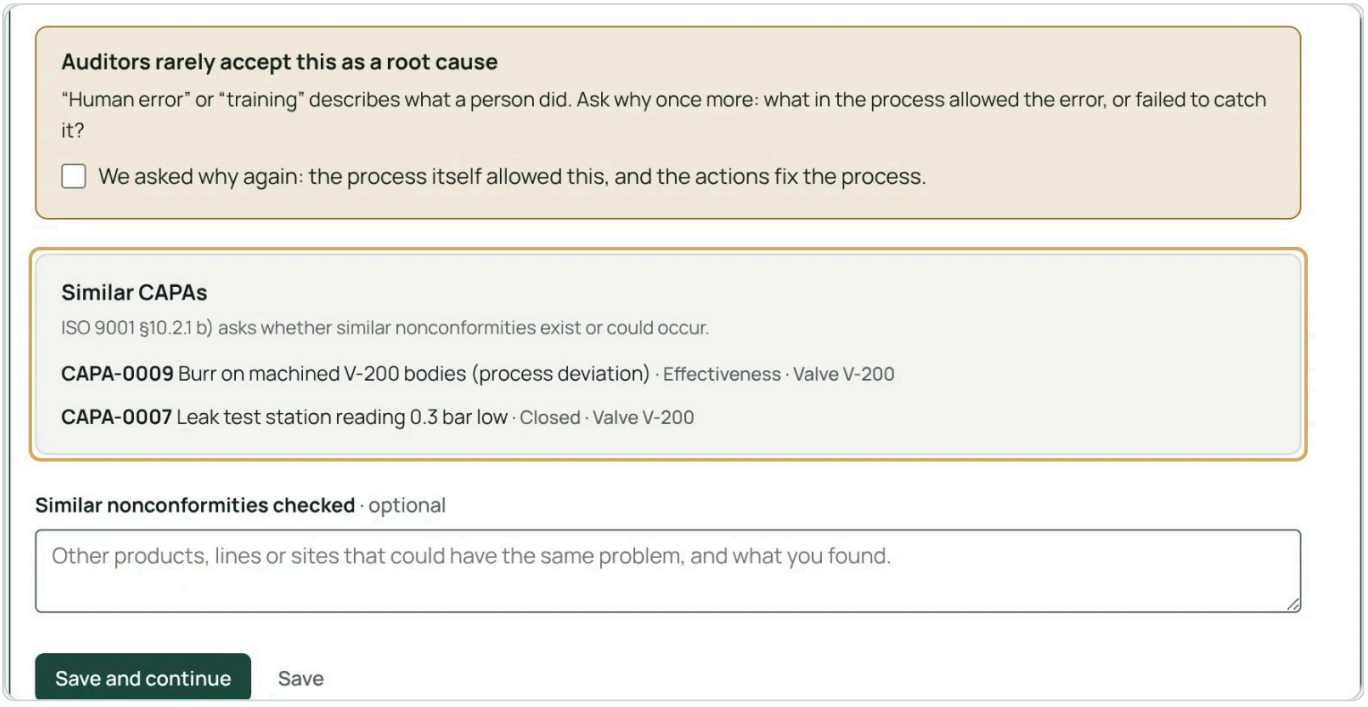
Guided five whys and cause categories. When the answer reads like “human error” or “training”, the app asks you to look once more at what the process allowed.



Step 3

Check for similar problems

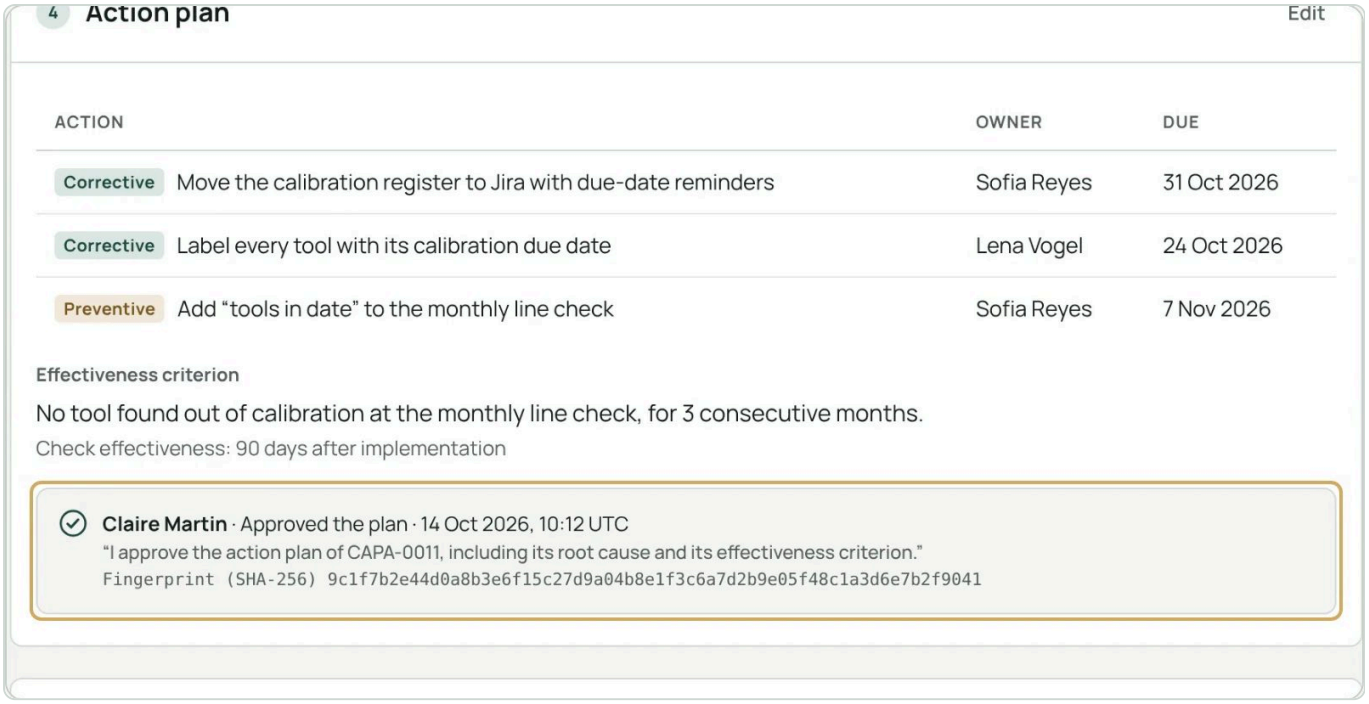
While you analyse the root cause, CAPAs on the same product or process, or with the same kind of cause, are listed, so you can check whether similar nonconformities exist or could occur.



Step 4

Approve the plan with a signature

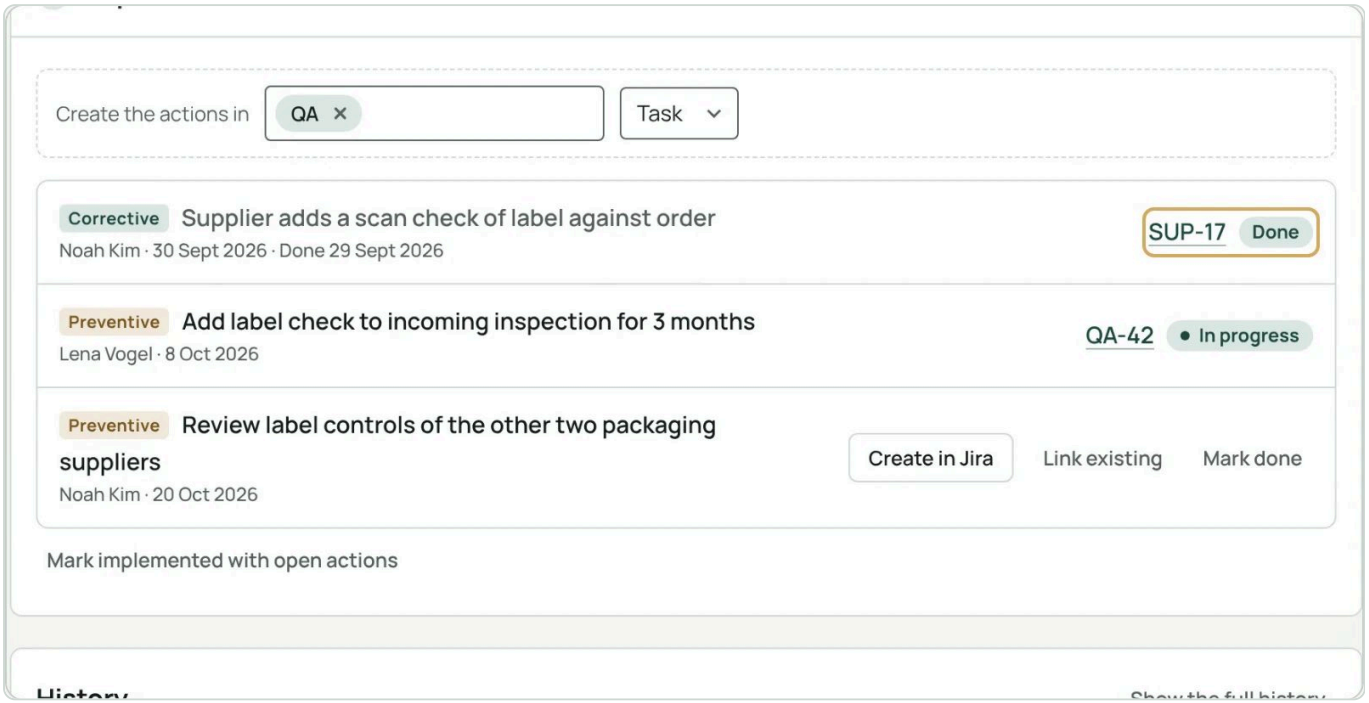
A coordinator approves the plan with an electronic signature: name, date, meaning, a statement shown before signing, a personal signing password and a SHA-256 fingerprint of what was signed.



Step 5

Run the actions in Jira

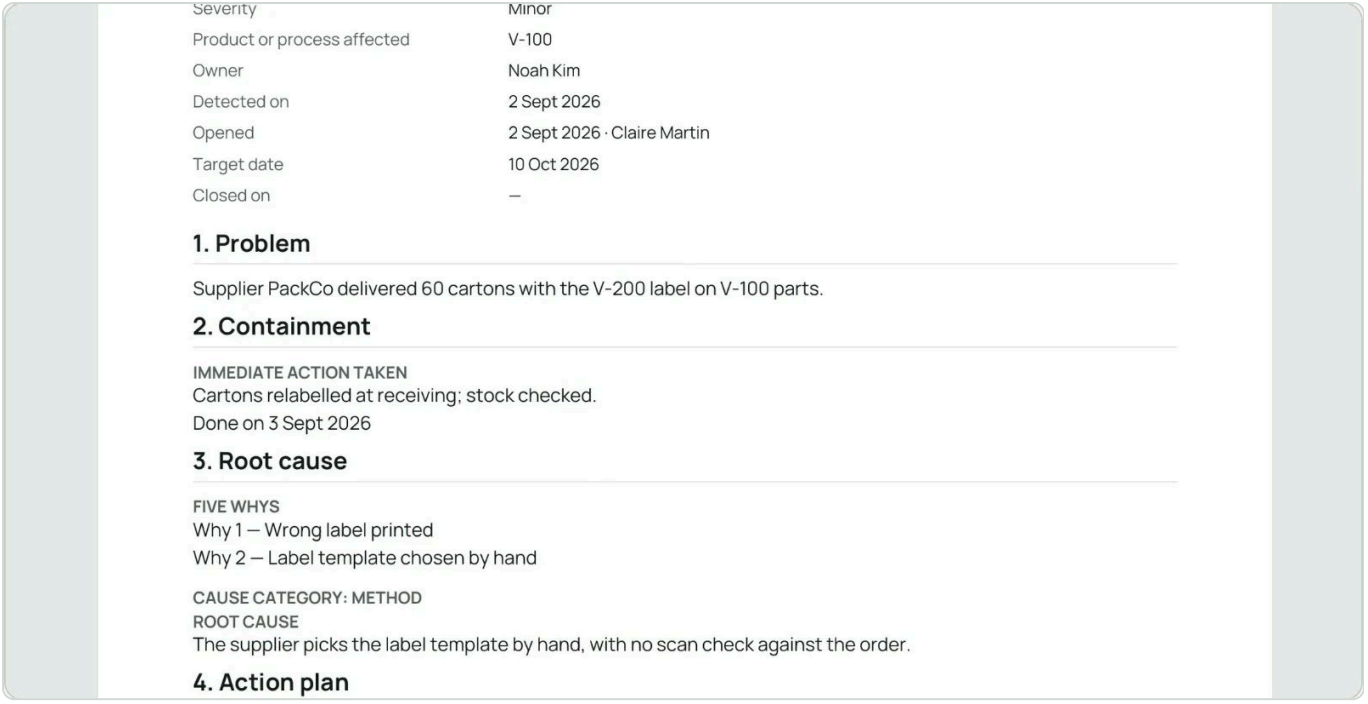
Each action becomes a Jira work item linked to the CAPA, and its status comes back on its own. The CAPA then waits for its check date and reminds the owner. Not effective? It goes back to the root cause, and the failed check stays on record.



Step 6

Hand the auditor one file

A PDF evidence file per CAPA: the six steps, signatures, attachments and the audit trail. Nothing is deleted.



Severity Minor
Product or process affected V-100
Owner Noah Kim
Detected on 2 Sept 2026
Opened 2 Sept 2026 · Claire Martin
Target date 10 Oct 2026
Closed on —

1. Problem

Supplier PackCo delivered 60 cartons with the V-200 label on V-100 parts.

2. Containment

IMMEDIATE ACTION TAKEN
Cartons relabelled at receiving; stock checked.
Done on 3 Sept 2026

3. Root cause

FIVE WHYS
Why 1 — Wrong label printed
Why 2 — Label template chosen by hand

CAUSE CATEGORY: METHOD
ROOT CAUSE
The supplier picks the label template by hand, with no scan check against the order.

4. Action plan

Try it on your own site: Clearlane CAPA has a free trial on the Atlassian Marketplace. Want this walkthrough written for your own process? Write to **maxime@clearlaneapps.com**. The OQ test script and the supplier assessment: **clearlaneapps.com/solutions/quality**.