Clearlane CAPA

# Operational qualification (OQ) test script

**Document CL-OQ-CAPA · Version 1.1 · 4 November 2026 · Covers Clearlane CAPA 3.14.0 and later minor versions until superseded**

Run in a test Jira project with at least two test users. Record the app version (Manage apps) and your site before starting. Attach a screenshot to each test.

| | |
|---|---|
| **App version** | |
| **Site** | |
| **Executed by** | |
| **Date** | |
| **Approved by** | |

| Test | Steps | Expected result | Requirement | Result (pass / fail) | Tester, date |
|---|---|---|---|---|---|
| **OQ-01** Open a CAPA from a work item | On an existing work item, open the CAPA panel and start a CAPA with a severity. | A CAPA number is assigned, the step is Problem, and a target date is proposed from the severity. | ISO 13485 8.5.2 a) | | |
| **OQ-02** Containment | Record the immediate containment. | It is saved with the person and the date. | ISO 13485 8.5.2 a), c) | | |
| **OQ-03** Root cause guard | Enter “human error” or “training” as the only root cause. | The app warns that this is rarely a root cause and asks for the underlying cause. | ISO 13485 8.5.2 b) | | |
| **OQ-04** Action plan | Add a corrective action with owner, due date, effectiveness criterion and verification delay. Submit. | The plan waits for approval. | ISO 13485 8.5.2 d) | | |
| **OQ-05** Signed approval | A coordinator approves with the signing password. | The approval shows name, date and time, meaning and the fingerprint of the approved plan. | ISO 13485 8.5.2 d); 21 CFR 11.50, 11.70 | | |
| **OQ-06** Change after approval | Change the approved plan. | The approval is withdrawn and the plan must be approved again. | 21 CFR 11.70 | | |
| **OQ-07** Actions in Jira | Implement: create the action as a Jira work item. | A linked work item is created. Its Jira status is shown in the CAPA. | ISO 13485 8.5.2 d) | | |

| Test | Steps | Expected result | Requirement | Result (pass / fail) | Tester, date |
|---|---|---|---|---|---|
| **OQ-08**<br>Effectiveness check | Set the verification date in the past. | The CAPA shows the check as due and the owner receives Jira's daily reminder e-mail. | ISO 13485 8.5.2 f) | | |
| **OQ-09**<br>Not effective | Record the check as not effective. | The CAPA returns to root cause. The failed check stays in the record. | ISO 13485 8.5.2 f) | | |
| **OQ-10**<br>Signed closure | Record an effective check and close with the signing password. | The CAPA is closed. The evidence PDF contains the six steps, signatures, attachments and audit trail. | ISO 13485 8.5.2 f), 4.2.5 | | |
| **OQ-11**<br>Cancellation | Cancel a CAPA with a reason. | The CAPA is cancelled with its reason. Nothing is deleted. | ISO 13485 4.2.5 | | |
| **OQ-12**<br>Search | Search the register for overdue CAPAs, then use the CAPA fields in Jira search. | Both return the expected CAPAs. | ISO 13485 4.2.5 | | |

## Change history

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|---|---|
| **1.0** | 1.0 · 8 October 2026 · First issue |
| **1.1** | 1.1 · 4 November 2026 · Document number, version, covered app version, requirement for each test |

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