Clearlane Controlled Documents

Operational qualification (OQ) test script

Document CL-OQ-CD · Version 1.1 · 4 November 2026 · Covers Clearlane Controlled Documents 4.0.0 and later minor versions until superseded

Run in a test Confluence space 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 Make a page a controlled document	Open a page, choose Controlled document, confirm.	The page gets a document number with the space prefix and the state Draft.	ISO 13485 4.2.4 e)		
OQ-02 Submit for approval	Name two approvers with their meaning (Reviewed, Approved) and submit.	State In review. Approvers see the document in My controlled documents.	21 CFR 11.10(f)		
OQ-03 Reject a wrong signing password	As an approver, sign with a wrong signing password several times.	Each attempt is refused. After repeated failures, signing is blocked for that person for a while.	21 CFR 11.200(a), 11.300		
OQ-04 Sign	Sign with the correct signing password.	The signature shows the full name, date and time, and meaning, with the SHA-256 fingerprint of the signed content.	21 CFR 11.50, 11.70		
OQ-05 Edit during approval	Change the page text while an approval is open.	Signatures already collected are voided and the approvers are asked to sign again.	21 CFR 11.70, 11.10(f)		
OQ-06 Become effective	All approvers sign the unchanged content.	State Effective, with the effective date and the next review date.	21 CFR 11.10(f)		
OQ-07 Edit an effective document	Change the text of the effective page.	The document is flagged Changed since approval, with a link to the approved version and a comparison.	21 CFR 11.70		

Test	Steps	Expected result	Requirement	Result (pass / fail)	Tester, date
OQ-08 Read and understood	Ask a group to confirm reading. A member confirms. Then publish a new revision.	The confirmation is recorded with date and time. After the new revision, confirmation is requested again.	ISO 13485 6.2 e)		
OQ-09 Periodic review	Set a review date in the past.	The register shows the review as overdue and a reminder comment is posted on the page.	ISO 13485 4.2.4 b)		
OQ-10 Evidence file	Download the evidence file.	The PDF lists signatures (name, date and time, meaning, fingerprint), revisions, read confirmations and audit events.	21 CFR 11.10(b)		
OQ-11 Audit trail access	Open the space audit trail as a space administrator, then as a regular user.	The administrator sees the events of the tests above with date, time and person. The regular user cannot open it.	21 CFR 11.10(d), (e)		
OQ-12 Obsolete	Make the document obsolete.	State Obsolete. The document stays in the register with its history.	21 CFR 11.10(f); ISO 13485 4.2.4 h)		

Change history

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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