Clearlane Tests

Operational qualification (OQ) test script

Document CL-OQ-TESTS · Version 1.1 · 4 November 2026 · Covers Clearlane Tests 2.12.0 and later minor versions until superseded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. A test Jira project (key shown as KEY) with Clearlane Tests installed and its subscription active; four Story work items S1–S4 (the only stories of the project), one Task E1 for evidence, a version "1.0" and a "Bug" work item type. User A: project administrator (Browse projects, Edit work items, Administer projects). User B: tester (Browse projects, Edit work items, Create work items). Jira language set to English. Run the tests in order: each one uses the data of the previous ones. Times are shown in your time zone on screen and in UTC in the PDF.

App version	
Site	
Executed by	
Date	
Approved by	

Test	Steps	Expected result	Requirement	Result (pass / fail)	Tester, date
OQ-01 Set up electronic signatures	As user A, open "Clearlane Tests" in the project sidebar, tab "Settings". Under "Project settings", choose "Every run and the closure" for "Electronic signatures", "Bug" for "Type of the bugs created from a failed step", select "Story" in "Requirement types (coverage)", click "Save", then "History of changes". Then, as user A and as user B, in "My signing password", type a 5-character password in "New signing password" and click "Set my signing password"; then type a password of at least 8 characters and click it again.	"Settings saved" is shown, and the history of changes lists the change with user A's name, date and time. The 5-character password is refused with "The password is too short."; the valid one gives "Signing password saved" and "Your signing password is set."	21 CFR 11.200, 11.300		
OQ-02 Create a test case linked to a requirement	As user A, tab "Test cases", click "New test case". Enter a "Title" and three steps, each with "Action", "Test data" and "Expected result" (button "Add a step"). In "Covers (requirements)", search and select S1. Click "Save". Change the "Expected result" of step 2 and click "Save" again. In "Versions", click "View" on version 1.	"KEY-T1 created" is shown; the case shows "Version 1", the "Covers" card lists S1 with its summary, and "History" shows "Created" with user A's name, date and time. After the change: "Saved · version 2"; "Versions" lists versions 1 and 2 with author and date, "View" shows the original steps of version 1, and "History" shows "Version 2: steps".	IEC 62304 5.7.1 (traceability)		
OQ-03 Import test cases from CSV and archive one	Prepare a CSV file with the header "Summary,Action,Expected result,Requirement" and three rows: "Login works,Open the sign-in page,The form is shown,[S3 key]", ",Enter valid credentials,The home page is shown," and "Logout works,Click Sign out,The sign-	Before importing: "Format recognised: generic CSV · 2 cases · 3 steps". After: "2 cases imported"; "Login works" has 2 steps and covers S3. After archiving: "[case key] archived"; the case leaves the list and is listed under "Archived", opens with "Archived: out of the	IEC 62304 5.7.1		

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	in page is shown,". As user A, tab "Test cases", click "Import CSV", choose the file in "CSV file" and click "Import 2 cases". Open "Logout works", set "Status" to "Obsolete", click "Save", then "Archive". In the case list, click "Archived".	library and of the limit of cases, kept with its history." and its "History" shows "Archived".			
OQ-04 Work item panel	As user A, open story S2 in Jira and open the "Clearlane Tests" panel. Click "+ New test case", enter a "Title" and, in "Steps", two lines: "Open the order page = › The order is listed" and "Click Pay = › Order confirmed"; click "Save". Click "Link a case", type KEY-T1 and click "Link a case"; then click "Unlink" next to KEY-T1.	Before: "Coverage" shows "Not covered" and "No test case covers this work item yet." After saving: "[case key] created"; the case is listed with "Not run", the panel shows "1 test case" and coverage "Not run". Linking gives "KEY-T1 linked" and lists it; "Unlink" gives "KEY-T1 unlinked" and removes it. Clicking the new case opens it in Tests with S2 under "Covers" and 2 steps.	IEC 62304 5.1.1 c)		
OQ-05 Create a campaign and assign runs	As user A, tab "Campaigns", click "New campaign". Enter a "Title", choose "1.0" in "Version", a "Due date" and E1 in "Jira work item for evidence"; click "Save". Click "Add cases", tick KEY-T1, the case created from S2 and "Login works", choose user B in "Search people" and click "Add 3 cases". Then, as user B, open "Clearlane Tests" from the Jira Apps menu.	"KEY-C1 created"; the header shows KEY-C1 · 1.0 and the due date. After adding: "3 cases added"; three runs, each "Not run", with user B as "Assignee", and "Runs" = 3. User B sees the three runs under "Runs assigned to you" with the campaign and due date. The campaign "History" (button "Open") shows "Created" and "3 cases added" with user A's name.	IEC 62304 5.7.5		
OQ-06 Execute: pass, fail with a note, bug in one click	As user B, open KEY-C1 and click the KEY-T1 run; click "Pass" on steps 1 and 2 within a second while watching the status at the top of the run, wait 2 seconds, then click "Pass" on step 3. Click "Next" to the run of the case created from S2: click "Pass" on step 1 and at once "Back to KEY-C1", then open that run again. Click "Fail" on step 2, type a note in the comment box under step 2 and click outside it. Click "+ Create a bug", keep the suggested "Summary" and the type "Bug", click "Create a bug". Open the new bug in Jira.	KEY-T1: after steps 1 and 2, "Saving…", then "Saved" about 1.5 s after the last click; step 3 (the final result) is saved at once: "Saved", result "Passed", "Executed by [user B] · [date, time]". Second run: the campaign page opens only once step 1 is saved, and the run opened again shows step 1 "Pass" and "In progress"; "Fail" on step 2 is saved at once ("Saved" with no wait). Result "Failed", "[bug key] created and linked", and the "Bugs" card lists the bug with "Step 2". In Jira the bug's description starts "Found by Clearlane Tests: [case key] (version 1) in campaign KEY-C1." and gives the steps to reproduce, the expected result of step 2 and "Actual:" with the note; the bug is linked to S2 and its "Clearlane Tests" panel shows "Found by" "KEY-C1 · [case key] · step 2". The campaign shows 1 "Passed", 1 "Failed", 1 "Not run" and "Pass rate" 50%.	IEC 62304 5.7.2, 9.1		
OQ-07 Coverage of requirements (traceability)	As user A, tab "Coverage": keep the test project in "Requirements in project", check that only "Story" is selected in "Work item types" (taken from the project settings), keep "Latest result" in "Results", click "Show coverage". Click the "Not covered" counter, then click it again. Click "Export CSV". In Jira issue search, run the JQL query testCoverage = failed.	"4 requirements" and "75% covered"; S1 "Passed" (KEY-T1), S2 "Failed" (its case), S3 "Not run" ("Login works"), S4 "Not covered" with no case; each case key is coloured by its result and opens the case. The "Not covered" counter filters the table to S4. The file KEY-coverage.csv has the columns Requirement, Summary, Type, Jira status, Coverage, Test cases, each case key followed by its result. The JQL query returns S2.	IEC 62304 5.1.1 c), 5.7.4		
OQ-08 Sign a run: wrong password and lock-out	As user A, open the KEY-T1 run of KEY-C1. As user B, open the same run; in "Sign this run", type a wrong password in "Current signing password" and click "Sign this run"; repeat with wrong passwords until the message changes, then try the correct password. Wait for the lock-out period (default 15 minutes, "Lock-out (minutes)" in "Site settings (Jira administrators)") and sign with the correct password.	User A sees "Only the person who recorded the result signs it." and no password field. User B: wrong passwords 1 to 4 give "Wrong signing password."; the 5th (default "Attempts before lock-out") gives "Signing is locked for a few minutes after too many attempts.", and the correct password is refused with the same message while locked. After the lock-out: "Run signed"; the card shows "Signed by [user B] on [date, time]", the statement "I executed KEY-T1 (version	21 CFR 11.300		

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		2) in campaign KEY-C1, and the recorded results are a true record of that execution." and "SHA-256" followed by 64 hexadecimal characters; the campaign shows "✓ Signed" on the run and its "History" shows "KEY-T1 signed".			
OQ-09 Signed closure of a campaign	As user A, open KEY-C1, click "Close campaign", type the correct password and click "Close campaign". Then, as user B, sign the failed run as in test 8. As user A, click "Close campaign", type a wrong password and confirm; then type the correct password and confirm. Note the SHA-256 value shown.	The first attempt is refused with "Some executed runs are not signed yet." (the campaign also shows "1 executed run is not signed yet: each executor signs before the campaign is closed."). The box shows "Closing freezes every result of this campaign. Runs not executed are reported as not run." and the statement "I approve the results of campaign KEY-C1 (3 runs: …) and close it." with the counts. Wrong password: "Wrong signing password." and the campaign stays "Open". Correct password: "KEY-C1 closed", status "Closed", "Closed by [user A] on [date, time]", the statement, "Closure signature valid: the results match what was signed." and "SHA-256" followed by 64 hexadecimal characters; "History" shows "Closed and signed".	21 CFR 11.50, 11.70; IEC 62304 5.8.1		
OQ-10 Results frozen after closure; reopening	As user B, open the failed run of KEY-C1 and try to change a step result. As user A, click "Reopen", type "abc" and click "Reopen"; then type a reason of at least 5 characters and click "Reopen". As user B, set step 2 of that run to "Pass" and sign the run again; as user A, close the campaign again with the signing password.	While closed: the run shows "This campaign is closed: results are frozen.", its result buttons are disabled, and "+ Create a bug", "Link an existing bug", "Attach files", "Add cases", "Edit" and "Close campaign" are not offered; user B has no "Reopen". "abc" is refused with "Give a reason (at least 5 characters).."; the reason gives "KEY-C1 reopened" and "History" shows "Reopened: [reason]". After the change the run is "Passed", its signature is gone ("This project signs every executed run.") and "History" shows "[case key]: Failed → Passed", "[case key]: recorded results changed: step 2: Failed → Passed" and "[case key]: signature voided (results changed)". The new closure shows a SHA-256 value different from the one noted in test 9.	21 CFR 11.10(e); IEC 62304 5.7.3		
OQ-11 PDF report, audit trail and archive	As user A, open KEY-C1, click "PDF report" and open the downloaded file KEY-C1-report.pdf; compare it with the campaign page and its "History" (button "Open"). Then click "Archive", go back to "Campaigns", click "Archived", open KEY-C1 and click "PDF report" again.	The PDF "Test campaign report" shows KEY-C1 and its title; Status, Version 1.0, Due, Created and Closed (date, time UTC, name), Evidence work item E1; "Summary"; "Requirement coverage (in this campaign)"; "Results" (Case, Title, Ver., Result, Executed by, Date (UTC), Bugs, Signed); "Electronic signatures" (Subject, Name, Date (UTC), Statement, SHA-256 fingerprint, "Results identical to those signed.") for the closure and each signed run, with the closure fingerprint shown on screen; "Execution records" with each step's action, data, expected result, result and comment ("Not run." for the run not executed); "Audit trail" with every History event, including the reopening reason, the changed step result and the voided signature; "Generated [date] by [user A] · Clearlane Tests" and "Page x of y" on every page. After archiving: "KEY-C1 archived"; the campaign is listed only under "Archived", opens with "Archived: out of the campaign list and of the limit of campaigns, kept with its report." and its PDF report can still be generated.	IEC 62304 5.7.5; 21 CFR 11.10(e)		

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OQ-12 Access follows Jira permissions	As user A, open KEY-T1 from “Clearlane Tests” (Jira Apps menu) and copy the browser address. Remove user B’s “Browse projects” permission on the test project (for example by removing B from the project role). As user B, open “Clearlane Tests” from the Apps menu, then open the copied address. As user A, create a campaign KEY-C2, click “Add cases”, tick KEY-T1, choose user B in “Search people” and click “Add 1 case”. Give B the permission back afterwards.	User B does not see the project under “Projects with tests” nor any of its runs under “Runs assigned to you”; the copied address shows “Not found, or in a project you cannot see.” and no test data. Assigning user B is refused with “This person cannot see the project: choose someone who can.”	21 CFR 11.10(d)		

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

Template provided by Clearlane to support your validation. Adapt it to your intended use and procedures. clearlaneapps.com/validation/