21 CFR PART 11 · SUBPARTS B, C

21 CFR Part 11 checklist for document control in Confluence

The key requirements for electronic records and signatures in Confluence: what to check, what Clearlane Controlled Documents provides, and what stays your part. Tick each line when your validation file holds the evidence.

REQUIREMENT	WHAT CLEARLANE CONTROLLED DOCUMENTS PROVIDES	YOUR PART	DONE
11.10(a) Validation	Supplier testing of every release (automated tests of the full workflow). OQ test scripts: clearlaneapps.com/solutions/quality.	Validate for your intended use (IQ/OQ/PQ), keep the validation file.	☐
11.10(b) Accurate and complete copies	Evidence file as PDF; register export as CSV; Confluence page export includes the control block.	Define how copies are provided to inspectors.	☐
11.10(c) Protection of records	Records kept in Atlassian's storage for your site; page history kept by Confluence.	Retention and backup of your Atlassian site. Export evidence files before uninstalling the app.	☐
11.10(d) Limiting access	Atlassian login and Confluence permissions; optional edit lock during approval.	Manage accounts and permissions.	☐
11.10(e) Audit trail	Time-stamped audit trail of lifecycle, signature and read events, visible to space administrators.	Review it as your procedures require.	☐
11.10(f) Operational checks	Enforced sequence: Draft, In review, Effective, Obsolete.	—	☐
11.10(g) Authority checks	Only the named approvers can sign; settings reserved to administrators.	Name the right people.	☐
11.10(i), (j) Training and accountability	Read-and-understood records per revision (Clearlane Read & Understood) support training records.	Training, written signature policy.	☐
11.50 Signature manifestation	Name, date and time, and meaning shown with each signature and in the evidence file.	—	☐
11.70 Signature and record linking	SHA-256 fingerprint of the signed content: an edit during review cancels the signatures; an edit after approval is flagged "Edited since approval", and the approved revision keeps its fingerprint.	—	☐
11.100 General requirements	Signatures tied to unique Atlassian accounts.	Verify identities; send the certification to FDA.	☐
11.200 Signature components	Two components: Atlassian login plus a personal signing password asked at each signature.	—	☐

REQUIREMENT	WHAT CLEARLANE CONTROLLED DOCUMENTS PROVIDES	YOUR PART	DONE
11.300 Password controls	Signing passwords stored hashed (scrypt); blocking after repeated failures.	Password policy, periodic review, loss procedure.	☐

Next step: run the OQ test script for Controlled Documents (operational qualification, step by step, with expected results) and add the filled-in supplier assessment to your supplier file. Both are free: **clearlaneapps.com/solutions/quality**. Questions in writing: **maxime@clearlaneapps.com**.

Clearlane apps are designed to help you meet these requirements. They are not certified: compliance comes from your validated system and your procedures. The OQ test scripts and the filled-in supplier assessment: clearlaneapps.com/solutions/quality.