

Validation Protocol Pack — IQ / OQ / PQ

Template generated 2026-08-09 · Customer-executed · Complete the header, execute each step, record evidence, and route for approval per your SOPs

How to use this pack. Aliquora is not delivered pre-validated. These protocols are templates for your organization to execute in your own environment: record the actual result and evidence for each step, mark pass/fail, document deviations, and obtain the sign-offs your quality system requires.

Validation header

Organization / site	
System under validation	Aliquora LIMS — production URL: _____
Application version / build	
Validation lead	
Protocol period	

IQ — Installation Qualification

Confirms the system is delivered and configured as ordered.

ID	STEP	EXPECTED RESULT	PASS / FAIL	ACTUAL RESULT / EVIDENCE	INITIALS / DATE
IQ-01	Confirm the production URL loads over HTTPS and presents a valid TLS certificate.	Site loads over HTTPS; certificate is valid and not expired.	☐ Pass ☐ Fail		
IQ-02	Confirm your organization (tenant) exists and is named correctly.	Organization record is present with the agreed name and plan.	☐ Pass ☐ Fail		
IQ-03	Confirm the subscription plan and enabled features match the order.	Plan and feature flags match the signed order/quote.	☐ Pass ☐ Fail		

ID	STEP	EXPECTED RESULT	PASS / FAIL	ACTUAL RESULT / EVIDENCE	INITIALS / DATE
IQ-04	Confirm administrator and initial user accounts are created with the correct roles.	Each account exists with the intended role; no unexpected accounts.	☐ Pass ☐ Fail		
IQ-05	Record the application version / build identifier shown in the product.	A version/build identifier is recorded for this validation baseline.	☐ Pass ☐ Fail		
IQ-06	Confirm supported browsers/devices for your users can reach and render the application.	Each in-scope browser/device loads the application without error.	☐ Pass ☐ Fail		

IQ approval

ROLE	NAME	SIGNATURE	DATE
Executed by			
Reviewed by (QA)			
Approved by			

OQ — Operational Qualification

Confirms the controls operate as specified: access, authority, spec evaluation, locking, signatures, witnessing, exports, and isolation.

ID	STEP	EXPECTED RESULT	PASS / FAIL	ACTUAL RESULT / EVIDENCE	INITIALS / DATE
OQ-01	Log in with a valid account; then attempt login with an incorrect password repeatedly.	Valid login succeeds; repeated failures trigger account lockout.	☐ Pass ☐ Fail		
OQ-02	As a read-only user, attempt an action reserved for a higher role.	Action is blocked; authority check is enforced server-side.	☐ Pass ☐ Fail		
OQ-03	Create a material type, a test definition with spec limits, and a sample with tests.	Records are created and retrievable with the entered values.	☐ Pass ☐ Fail		
OQ-04	Enter a result within spec, then a result outside the spec limit.	In-spec result is accepted; out-of-spec result is automatically flagged.	☐ Pass ☐ Fail		
OQ-05	Verify a result, then attempt to edit it without unlocking.	Edit is blocked (locked record returns a conflict).	☐ Pass ☐ Fail		
OQ-06	As an administrator, unlock the verified result (password re-auth + reason), then review the audit trail.	Unlock requires password and a reason; an audit entry records who, when, and why.	☐ Pass ☐ Fail		
OQ-07	Apply an electronic signature; confirm the password prompt and signature meaning.	Signing requires re-authentication and captures signer, timestamp, and meaning.	☐ Pass ☐ Fail		
OQ-08	Change the signed record and re-open the signatures list.	Signature verification flags the record as changed (tamper-evident).	☐ Pass ☐ Fail		
OQ-09	Generate a Certificate of Analysis (PDF) and export samples/results/audit log to CSV.	PDF and CSV exports are produced; export is recorded in the audit trail.	☐ Pass ☐ Fail		
OQ-10	Log in as a user from a different organization (or confirm scoping in test data).	No data from another organization is visible (tenant isolation).	☐ Pass ☐ Fail		
OQ-11	Sign an ELN notebook entry with password re-authentication.	Entry becomes signed and locked; a content hash is recorded with the signature.	☐ Pass ☐ Fail		

ID	STEP	EXPECTED RESULT	PASS / FAIL	ACTUAL RESULT / EVIDENCE	INITIALS / DATE
OQ-12	As the signer, attempt to witness your own entry; then witness it as a second user.	Self-witnessing is refused; a different user's witness moves the entry to witnessed.	☐ Pass ☐ Fail		
OQ-13	Amend the signed entry with a documented reason.	Signatures are cleared, the signed version is preserved in the entry history, and the audit trail records the reason.	☐ Pass ☐ Fail		
OQ-14	Dispense from a controlled inventory item without a witness; then with a second person's credentials.	The un-witnessed dispense is refused; the witnessed dispense is recorded with the witness named on the ledger.	☐ Pass ☐ Fail		

OQ approval

ROLE	NAME	SIGNATURE	DATE
Executed by			
Reviewed by (QA)			
Approved by			

PQ — Performance Qualification

Confirms the system performs your laboratory's real workflow reliably.

ID	STEP	EXPECTED RESULT	PASS / FAIL	ACTUAL RESULT / EVIDENCE	INITIALS / DATE
PQ-01	Run one full real workflow end to end: receive, prepare, enter results, review, approve, report.	The sample progresses through every status and produces a correct COA.	☐ Pass ☐ Fail		
PQ-02	Have each role perform its routine daily tasks for a defined trial period.	Each role can complete its tasks; no permission gaps or blockers found.	☐ Pass ☐ Fail		
PQ-03	Import a representative batch of results from your instrument export.	Results map to the correct samples/tests; mismatches are flagged for review.	☐ Pass ☐ Fail		
PQ-04	Reconcile a day of records against the audit trail and any parallel records.	Records and audit trail agree; no unexplained discrepancies.	☐ Pass ☐ Fail		
PQ-05	Confirm reports/COAs meet your reporting SOP (content, layout, sign-off).	Reports satisfy the laboratory's reporting requirements.	☐ Pass ☐ Fail		

PQ approval

ROLE	NAME	SIGNATURE	DATE
Executed by			
Reviewed by (QA)			
Approved by			

Deviation log

#	STEP ID	DESCRIPTION OF DEVIATION	RESOLUTION / IMPACT	INITIALS / DATE
1				
2				

#	STEP ID	DESCRIPTION OF DEVIATION	RESOLUTION / IMPACT	INITIALS / DATE
3				
4				
5				
6				