

E.1 Process owner

You own the work and the acceptable outcome. You are jointly accountable, with the quality unit, for every gate decision.

You own

- The bounded task definition (inventory D; GDR Section 1).
- The accuracy of the inventory row for your use.
- Review design and reviewer workload.
- Co-approval of every GDR (Section 7).

Do this

1. Describe the task as work: action, sources, output, user, downstream check. Not a vendor name. (6.4 row D)
2. Document the current process as the baseline and its known weaknesses. (Stage 1)
3. Choose the review method and test it; include the time available per output. (Rule 7)
4. For each decision, read GDR Sections 5 and 6 before approving: scope, conditions, residual risk, stop criteria, expiry. (7.5)
5. After approval, update the inventory row the same day using the mapping in 7.6.
6. Set the trigger event (AK) whenever something in 6.7 happens.

Your cells and sections

Inventory D, E, F, H, W, AD to AG, AK, AL • GDR Sections 1, 2, 6, 7

Never

- Set an authorized status before the GDR is signed.
- Let a pilot decision cover routine use, another site, or more authority.
- Accept "a reviewer is in the loop" as evidence of effective review.

E.2 Quality unit / quality owner

You decide whether the controls and evidence support the regulated use. Existing quality-unit approval duties do not change.

You own

- Approval of thresholds, the condition being authorized, the rubric, and the critical-failure mapping before testing (scoring sheet F9).
- The records and Part 11 determination.
- Co-approval of every GDR.
- Template adaptation and document control.

Do this

1. Before testing, approve F4 to F10 and B15. Keep F6 and F7 at 0. Set F8 from the consequence of failure. (8.4)
2. Check that someone independent of the evaluation owner confirmed the row 9 mapping. (8.5)
3. At the gate, read the verdict (D18), limiting factor (D21), holdout bound (B23), and all Breakdowns sections. (8.9, 8.10)
4. Confirm the Chapter 11 reconciliation checklist is attached to GDR Section 9.
5. Escalate any row counted in the inventory's "Excluded AI type in critical GxP" counter (T5).
6. Treat STOP OR CORRECT as an instruction to restrict live use now.

Your cells and sections

Scoring F4 to F10, B15 approval • Inventory R, S, AA, T5 review • GDR Sections 1 (records), 5, 6, 7

Never

- Approve thresholds or a mapping after holdout results are seen.
- Let a score offset a critical failure.
- Treat a human reviewer as making a critical function non-critical.

E.3 System owner, IT, security, and data owner

You define what the system may access and do, and you prove the limits are enforced technically.

You own

- The Authority Envelope (GDR Section 8) and its evidence.
- Security, privacy, and data-integrity disposition (GDR Section 4).
- Source boundary and classification (data owner).
- The configuration baseline under change control.

Do this

1. Complete all nine Authority Envelope elements with enforcing evidence. (7.5, Section 8)
2. Give each agent its own service identity with least privilege; deny prohibited actions technically and test them negatively.
3. Bind approvals to the reviewed record state; define stop, recovery, and out-of-hours contacts.
4. Complete GDR Section 4 and set inventory AC using the mapping in 7.5.
5. Record the system version (inventory M) and raise a trigger event for any model, prompt, configuration, source, integration, or permission change.
6. Data owner: define sources, document status, inclusion rules, and exclusions (inventory O, P; GDR Section 1).

Your cells and sections

Inventory J, K, M, O, P, Q, T, U, V, AB, AC • GDR Sections 1 (sources, enforcement), 4, 8

Never

- Rely on a prompt instruction as a prohibition.
- Let an agent run on the launching user's credentials.
- Expand permissions before a new GDR is signed.

E.4 Evaluation owner

You run the scoring sheet and produce the Stage 3 evidence. You do not confirm your own critical-failure mapping.

Do this, in order

1. Get the draft GDR ID; enter identity in B4 to B10. (8.3)
2. Select the condition being authorized in B15.
3. Enter the approved thresholds F4 to F10 and the approval reference F9. (8.4)
4. Set the row 9 mapping with the quality unit; fill Rubric D31:D36; arrange independent confirmation. (8.5)
5. Build the collection: baseline as **Current process**, challenge cases, strata, Tuning or Holdout for each case. (8.6)
6. Freeze: B11 date, B12 your name and role. Set B13 to Yes only after GDR Section 5 records the freeze and the confirmer.
7. Assign assessors; plan double scoring; record every case, including withdrawals.
8. If STOP OR CORRECT appears, stop testing and tell the process owner and quality unit the same day.
9. Complete GDR Section 5 from the table in 7.5, including tuning critical failures (B32) and the corrections made, and record the file hash. (5.3)

Your cells

Gate summary B4:B13, B15 · Case scoring rows 12 to 111 · Version log rows 9 to 12

Never

- Score holdout cases before the freeze.
- Change the design after results without a Version log entry.
- Use Breakdowns section 3 as the authorization figure; use B23.

E.5 Assessor

You score cases against the Rubric. Your job is accurate, consistent judgement, not a good average.

Before you start

- Read the Rubric anchors (8.8) and the expected finding for each case (column F).
- Take part in calibration on shared examples.

For every case

1. Score G to L: 0 to 2 for G, H, I, L; 0 or 1 for J and K. Correctly stopping or escalating scores 2 for decision appropriateness.
2. Set every flag N to S to Yes or No, including on Incomplete cases where the behaviour was observed. Never mark a case Incomplete to avoid a flag.
3. Record assessor status (U), completion (V), time to acceptable output (W), review time (AD), and the date scored (AG).
4. If you are the second assessor, score independently before seeing the first total; enter your total in AE.
5. Write scenario detail and the basis of any resolved disagreement in Notes (X). No protected content.

Remember

- Column T (critical failure) is calculated from the approved mapping; do not overwrite it.
- An unresolved disagreement blocks the verdict; resolve it against the Rubric.
- A fluent, well-cited output can still omit the decisive record: check the answer key, not the tone.

E.6 AI governance lead

You administer the toolkit and keep the inventory complete and current. You coordinate; local owners decide.

Set-up (once)

1. Confirm Excel version; quality-unit review; local document numbers. (5.1)
2. Replace the inventory sheet and structure password; protect the scoring sheet; decide GDR master protection.
3. Clear the example row and Use record B3; publish the identifier scheme.

Every week

- Read the row 5 counters; assign an owner and due date to every nonzero counter. (6.2)
- Chase red rows, especially blank or past next review dates.
- Keep the open-items list of accepted New entry gaps.

Every quarter

- Reconcile the inventory against procurement, access, integrations, and consumer-tool reports. (11.2)
- Confirm every authorized row has a signed GDR matching column AE.

Before every gate meeting

- Run the Chapter 11.1 checklist and attach it to GDR Section 9.

Never

- Become the substitute owner for a local use.
- Let the inventory become an annual spreadsheet: update on every trigger.