Steadeye

Vision system validation checklist

For camera counting and inspection stations that produce GMP records. Part A is what to verify before you buy, Part B the tests that prove it during qualification. Take it into a vendor meeting and ask for each point to be demonstrated on the running system.

A Technical controls to verify before purchase

- [ ] **Unique identity for every action**
  Personal accounts, optionally from your directory service. No shared line logins.
- [ ] **Computer-generated audit trail**
  Creation, change and deletion with time stamp and user, independent of the operator, not switchable off without trace.
- [ ] **Records protected for the retention period**
  Closed batches immutable; a change made directly in the database is detectable.
- [ ] **Electronic signatures with meaning**
  Credentials re-entered at signing; who, when and why, bound to the record.
- [ ] **Copies for an inspector**
  Human-readable report with evidence images and identities, plus an audit trail export.
- [ ] **Trustworthy time**
  One documented time source and time zone; operators cannot move the clock.
- [ ] **Documentation to validate against**
  Functional specification, requirements traceability matrix, IQ/OQ/PQ protocols, build identity of the delivered version.
- [ ] **Evidence image per result**
  The frame the decision was based on is stored with the result, not just the number.
- [ ] **Model traceability**
  The active model version and its checksum are recorded with every result it produced.

B Challenge tests for the OQ

- [ ] **Exact quantity**
  Known-good tray counts correctly and passes.
- [ ] **Known shortfall**
  Missing units are reported, recorded per camera and sent to the line.
- [ ] **Deliberate extra unit**
  Overcount is its own verdict, not silently accepted.
- [ ] **Nothing to inspect**
  Empty station is documented and kept out of the totals.
- [ ] **Partly covered tray**
  Behaviour is defined and documented.
- [ ] **Edit a closed batch**
  Attempt is refused and the attempt is visible.
- [ ] **Change a setting mid-run**
  Audit trail shows old and new value, user and time.
- [ ] **Export and verify the trail**
  Chain verification runs outside the application.
- [ ] **Role permissions**
  Enforced server-side; a leaver loses access; lockout after failed logins.
- [ ] **Triggered from PLC or API**
  Result lands in the same record with correct attribution; connection drop handled.

- [ ] **Damaged and edge-case units**
  Chipped, broken and borderline units; the class limits are documented.
- [ ] **Power loss during capture**
  Nothing is silently lost; incomplete work is marked.

C The detection model under change control

- [ ] **Validated version fixed**
  Which model version is part of the validated state is written down.
- [ ] **Checksum in the IQ**
  Model checksum recorded at installation and carried in every batch record.
- [ ] **Revalidation triggers agreed**
  What a retrained model requires: risk assessment, new version recorded, performance evidence for the affected product.
- [ ] **Training data ownership**
  Where images and datasets live, who may label, and whether anything leaves the site.

D Keeping the validated state

- [ ] **Change control**
  Software, model, camera and lighting changes assessed, not swapped quietly.
- [ ] **Periodic review**
  System still matches its documentation; trail findings and access reviewed.
- [ ] **Restore tested**
  The restore is executed, not just the backup.
- [ ] **Training records**
  Operators trained on the current version; manual under document control.

This checklist is a practical aid, not legal advice, and it does not replace your validation plan or your SOPs. Your QA and validation lead decide what applies to your process. Steadeye ships IQ, OQ and PQ protocol templates plus a requirements traceability matrix with the station, on a GAMP 5 category 4 approach.