CHECKLIST · FOR CRO QUALITY TEAMS

Sponsor Inspection Readiness Checklist

Use this checklist in the weeks leading up to a sponsor inspection to review your documentation, training, quality records, trial evidence, suppliers, facilities, and team readiness.

Inspection details

Sponsor: _____ **Study/Trial:** _____ **Inspection date:** _____

Sponsor requests received in advance

- [ ] Requested document and record lists have been reviewed.
- [ ] Requested employee/personnel information has been identified.
- [ ] Requested quality events, CAPAs, or trial records have been identified.
- [ ] Advance requests have an assigned owner.
- [ ] Requested records have been located and reviewed before submission.

Special requests / areas of focus: _____

1 Documentation & trial records

Controlled documents

- [ ] Applicable SOPs are current and approved.
- [ ] Required periodic reviews are complete.
- [ ] Trial-specific protocols and procedures are current.
- [ ] Required signatures and approvals are complete.
- [ ] Employees have access to current approved versions.
- [ ] Obsolete copies have been removed from work areas.
- [ ] Document histories can be retrieved if requested.

Document retrieval test

- [ ] Representative records have been selected for a retrieval drill.
- [ ] Employees know where authoritative records are maintained.
- [ ] Current versions can be identified without confusion.
- [ ] Requested evidence can be retrieved quickly.

Average document retrieval time: _____

Trial & supporting records

Confirm applicable records are complete and can be quickly retrieved:

- [ ] Raw data
- [ ] Instrument/equipment outputs
- [ ] Sample records
- [ ] Validation records
- [ ] Lab notebooks
- [ ] QC and control results
- [ ] Reagent/material records

INSPECTION-READINESS TIP

If documents, training records, CAPAs, change controls, and other quality evidence are managed in an eQMS, confirm that related records are correctly linked and easy to retrieve.

2 Follow the trail

Inspectors may start with one change, event, or record and follow the evidence wherever it leads. Before the inspection, follow those trails yourself.

Major changes since the last inspection

- [ ] Equipment
- [ ] SOPs or work instructions
- [ ] Subcontractors
- [ ] Facilities
- [ ] Processes or workflows
- [ ] Use of AI or other emerging technologies
- [ ] Protocols
- [ ] Suppliers
- [ ] Software or technology
- [ ] Key personnel or responsibilities
- [ ] Trial activities

Other: _____

For each significant change, confirm

- [ ] The change was appropriately documented and approved.
- [ ] Applicable risks were assessed.
- [ ] Required validation or qualification was completed.
- [ ] Procedures were created or updated as needed.
- [ ] Affected employees were trained.

3 Known gaps & quality metrics

Confirm current performance meets or exceeds your established benchmarks

- [ ] Training compliance
- [ ] Overdue CAPAs
- [ ] Open deviations / quality events
- [ ] CAPA effectiveness reviews
- [ ] Periodic review compliance
- [ ] Supplier qualification status
- [ ] Change control status

Other internal Quality KPIs: _____

_____

_____

For results outside of your established acceptable range

- [ ] The gap is documented.
- [ ] The cause is understood or being investigated.
- [ ] Applicable risk has been assessed.
- [ ] A remediation plan is documented.
- [ ] An owner and target date are assigned.
- [ ] Current status and rationale can be clearly explained.
- [ ] Supporting evidence is available.

INSPECTION-READINESS TIP

A known gap doesn't automatically mean your CRO isn't inspection-ready. Be prepared to demonstrate what happened, the associated risk, and how you're managing it.

4 Operations & people

Equipment & storage walkthrough

- [ ] Refrigerators, freezers, incubators, etc. are maintained.
- [ ] Temperature, maintenance, and equipment logs are complete.
- [ ] Qualification, validation, and calibration records are current.
- [ ] Reagents, chemicals, samples, etc. are properly labeled.
- [ ] No expired reagents or chemicals are present.
- [ ] Opening and expiration dates are documented.
- [ ] Materials and chemicals are appropriately stored.

Working environment walkthrough

- [ ] Employees are following PPE requirements.
- [ ] Required safety and laboratory practices are being followed.
- [ ] Work areas are orderly.
- [ ] Food and drink restrictions are being followed.
- [ ] Current procedures are accessible where needed.
- [ ] No obsolete or uncontrolled procedures are present.

Personnel & training

For employees assigned to the Sponsor's trial:

- [ ] Trial-specific training is current.
- [ ] Applicable SOP/procedure and protocol training is current.
- [ ] Required competency requirements have been met.
- [ ] Current job descriptions are available.
- [ ] CVs/qualification records are available.
- [ ] Applicable NDAs or agreements are available.
- [ ] Roles and responsibilities are clearly defined.

Employees understand

- [ ] Their responsibilities related to the trial.
- [ ] Which procedures govern their work.
- [ ] Where to find applicable procedures and records.
- [ ] Who to contact for Quality support.
- [ ] Who the appropriate SME is for questions outside their responsibilities.
- [ ] They should not guess if they don't know an answer.

5 Mock inspection

Before inspection day, conduct a mock inspection to make sure your preparation holds up in practice.

Have your mock inspector

- [ ] Ask: "What's changed since the last inspection?"
- [ ] Select an issue or CAPA and follow its history.
- [ ] Request records for employees assigned to the trial.
- [ ] Walk through the facility and inspect applicable equipment/storage areas.
- [ ] Test how quickly requested evidence can be retrieved.
- [ ] Request several records without advance warning.
- [ ] Select a recent change and follow its supporting evidence.
- [ ] Request trial-specific raw data or control results.
- [ ] Speak spontaneously with employees.

Final readiness check

Before telling leadership "We're ready," confirm

- [ ] Controlled documents and trial records are current and retrievable.
- [ ] Significant changes can be traced from end to end.
- [ ] Known gaps are documented and actively managed.
- [ ] Training and personnel records are current.
- [ ] Supplier and subcontractor oversight is current.
- [ ] Facility and operational walkthroughs are complete.
- [ ] Employees understand what to expect and how to respond.
- [ ] Mock inspection has been completed and identified issues are being appropriately managed.
- [ ] Sponsor requests received in advance are complete.
- [ ] Inspection-day roles are clear.

Inspection-day roles

Inspection host: _____

Quality representative: _____

Document coordinator: _____

Primary trial SME: _____

Backup SME: _____

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