TMF MOCK INSPECTION & INTERNAL QUALITY REVIEW CHECKLIST

Preparing for a successful TMF inspection starts with knowing where you stand. This checklist is designed to guide teams through a comprehensive internal quality review or mock inspection, helping identify gaps before regulators do. From planning and record-level checks to system compliance and follow-up actions, use this tool to strengthen inspection readiness, ensure TMF completeness, and drive continuous improvement.

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☐ Planning the Review or Mock Inspection

- Define scope and objectives (e.g., focus on specific site, informed consent, or study closeout)
- Incorporate a risk-based, proportionate approach aligned with ICH E6(R3) to focus the review on high-priority areas and critical TMF components.
- Schedule review date(s) and notify relevant team members
- Select reviewers (internal QA, Clinical Ops, or external experts)
- Prepare tools (checklists, trackers, SOPs, training logs)
- Request any required record lists
- Request any TMF plans
- Clarify roles and expectations for reviewers and record owners

☐ Record-Level Review

For each record reviewed, confirm the following:

- Record is present and properly filed in the correct TMF section
- Final version only (no drafts or incomplete records)
- File name follows naming conventions (e.g., DocType_Study_Site_v1.0_Date)
- Correct version/template was used
- Required signatures are complete and dated
- Dates are logical (not missing, backdated, or future-dated)
- Electronic records show a clear audit trail (if applicable)
- Metadata fields (e.g., document date, author, site number) are complete and accurate
- No tracked changes or internal comments visible
- Confirming all pages are present
- Review any applicable blinded records, ensuring those required are present

☐ Process Review

- Review SOPs, TMF plans
- Review audit trail and other documents supporting TMF process
- QC reviews are documented and traceable
- Roles for document creation, review, approval, and filing are clearly assigned
- Training logs confirm that staff were trained on current SOPs
- CAPAs from previous reviews or inspections have been closed/resolved
- Checklists and trackers are up to date and consistently used

☐ System & Technology Compliance

- eTMF system is in use and actively maintained
- Compliance dashboards are monitored and acted upon
- Alerts and reminders are enabled for document approvals or overdue tasks
- Automation (e.g., audit trail tracking, overdue notifications) is functioning correctly
- Staff know how to access and navigate the eTMF

☐ Mock Inspection Simulation

- Reviewers act as inspectors and simulate real inspection questions
- Review TMF access controls and training, and test
- Ensure correct user permissions – read only for auditors/ inspectors
- Staff are interviewed to explain their roles and responsibilities related to TMF
- At least one real scenario is role-played (e.g., "Show me training documentation for Site 102")
- Common inspection findings (e.g., missing signatures, incorrect version control) are routinely reviewed
- Gaps are recorded with clear root causes

☐ After the Review

- Findings are documented with specific examples
- Each issue is assigned an owner and deadline for resolution
- Corrective actions are added to a CAPA tracker
- Lessons Learned Log is updated with what went wrong and how it was fixed
- Summary is shared with cross-functional teams for awareness and training
- SOPs or workflows are updated if needed
- eTMF access is revoked/disabled

☐ Continuous Improvement Actions

- Team debrief completed and feedback collected
- Refresher training provided based on identified gaps
- Future mock inspections scheduled (e.g., quarterly or by study phase)
- Improvements are monitored in follow-up reviews