

Checklists and Templates: Facility Audit Help or Hindrance?

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Abstract

Utilizing an Audit Template or Checklist to conduct a facility inspection has pros and cons. This poster will explore completing quality assurance work with a checklist in hand and suggest other tools and methods of inspection that may provide greater flexibility through a less restrictive approach.

Content on checklists or report templates may be written to achieve consistency between different audit staff members or to ensure that guideline or regulatory requirements are thoroughly addressed. At some point, multi-page, step-by-step templates may be cumbersome and repetitive and lead to a loss of the big picture. Further, checklists may constrain the ability of experienced auditors to fully apply their skills.

This poster will contrast the value of checklists and the limitations they may impose. It will compare the use of checklists and templates with a variety of other methods or strategies for successfully completing a facility inspection. Suggestions of how to employ audit tools to effectively meet inspection objectives will be provided.

Audit Checklist Pros and Cons

Pros

- Provides consistency among various auditors
- Identifies specific foci for sponsor-directed inspections
- Assures review of guideline or regulatory requirements
- Jogs the memory of the auditor to check topics or discuss issues which may have gone unnoticed
- Prioritizes inspection format and increases efficiency

Cons

- Some checklists are too specific, hindering a higher level review of the facility and its capacity
- Others are too broad, and attention to critical details may be inadequate
- Cumbersome or lengthy templates require additional training or preparation time prior to the audit and wasted time on-site while capturing all required content
- Reduction in application/utilization of auditor's skills to deduce risk
- Reduced flexibility in audit format; impediment to the experienced auditor
- Higher cost for audit in exchange for unremarkable supplemental information reported in assessment

Risk-Based Audits

Definition: Inspections that rely on a sliding scale where greater review priority is placed on documents and processes which, if not effective, will result in a direct negative impact on the quality and integrity of the study (examples below)

Some Risk

Record Keeping / Documentation

- Training records errors
- Data recording practice SOP unclear or incomplete

Organization Chart

- Unavailable or not recently updated
- Disorganized

Higher Risk

Facility Archives

- Secure but with no fire protection
- Sign-out procedures have no time limit

Equipment Calibration Records

- Routine maintenance is not SOP defined
- Records are not easily accessible (in another department)

Highest Risk

Study Director / Investigator

- Lacks sufficient qualifications
- Workload too great
- Lack of data/records review

Data Collection System & Instruments

- Weak or no validation
- No calibration & maintenance records

Management

- QA is not independent and has limited influence
- Deliverable delays imply poor allocation of resources as scheduled

Quality Indicators

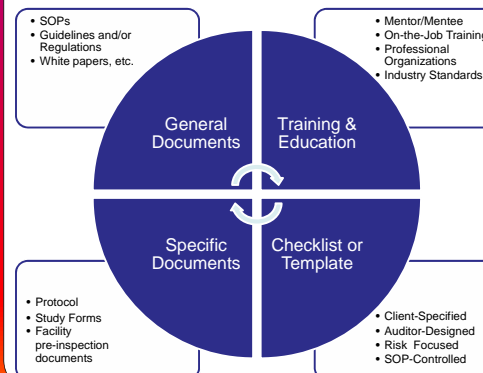
Definition: Documents, processes, or issues that are targeted for review in order to assess general regulatory diligence, experience, and capabilities in an organization.

Some Examples:

- Organization chart in a small organization (implies an understanding of QA's function)
- "SOP on SOPs" (document management, review processes, management involvement, training records)
- Test article and sample chain of custody processes (labelling, elapsed time tracking, storage procedures, shipping, archive)
- Validation Master Plan (level of understanding, attention to detail, IT expertise)
- Analytical Method Validation SOP (regulatory diligence, currency with industry and regulatory expectations)
- QA Audit Report distribution and tracking (effectiveness of QA, response and review process, timeliness of process)

A Balanced Audit Approach

Identify the audit objective and scope:



Avoid a Checklist When:

- Checklists should not serve as the primary basis on which an audit is conducted. Without critical thinking, preparation, and experience, the depth of a checklist-controlled-audit will not be sufficient to accomplish the scope intended.
- Requalification Audits may not require an extensive, holistic checklist; instead, scrutinize areas or processes known from past experience to complicate studies or cause confusion.
- If a sponsor-directed audit involves a facility of scope larger than services required (i.e. sponsor conducting animal trial hiring a lab with capacity for human and animal studies), use audit time wisely and inspect only areas critical to the sponsor's study.
- Particularly in a large comprehensive facility, deficiencies may go unnoticed while completing an audit template. Begin with Quality Indicators to identify facility's level of compliance. As deficiencies are observed, explore more deeply where attention is apparently needed.

A Checklist is Useful When:

- Auditors qualified through training, sufficient audit preparation, and experience may consider customized audit checklists a handy tool.
- Approximately two-thirds of the way through the audit, consider if the investigation has consisted of appropriate Quality Indicators. Consult a checklist as a double check of missed areas or inspection topics.
- Use a checklist prior to an audit to assist with establishing the audit scope and objectives; determined by the type of inspection or audit conducted (Mock FDA, Facility Qualification or Phase Inspection) or by sponsor's direction.
- A complete checklist is essential for initial facility qualification inspections during which a comprehensive exploration of a facility's capabilities and level of compliance is being assessed for the first time.

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