How to Prepare for an Inspection and Establish a Culture of Readiness

Preparing for a regulatory inspection can be daunting – but it doesn't have to be. The stress of an inspection can be lessened by building inspection-readiness practices into daily operations. This can be paired with a strong preparation process that readies your entire organisation for a successful inspection. This approach will ensure inspections run smoothly with little disruption to day-to-day operations.

Roles and Responsibilities

Passing an inspection is a team effort, so it's important to call out some of the key roles. The core team is responsible for defining, reviewing, and implementing procedures outlined in the standard operating procedure (SOP). This codifies the roles, procedures, and training your organisation will enact ahead of an announced inspection.

Essential team members include:

- A leader with the authority to coordinate and direct staff at all levels, and with strong project management skills
- Quality assurance and regulatory team members who are well prepared to provide documents outside of the TMF
- Functional area contacts involved in the development of the SOP. These individuals will also act as liaisons for their respective departments during an inspection

Team Expectations

Both study staff and non-study staff will need to be ready to be interviewed on inspection day. Organisations should identify primary interviewees and backups for each department.

Equally important is the ancillary support staff who will support with logistics on the day. This team may require less intensive training than interview personnel but should still be prepared. Consider who the inspector will meet on the day, as well as specialised staff you may need to call on. This could include an eTMF driver or a TMF liaison.

Leadership endorsement is essential to build and maintain an inspection-ready culture. Ongoing and consistent communication from executives is critical in making sure that everyone is aware of the benefits of incorporating inspection-readiness practices into daily operations. Make it a practice to gather feedback from internal and external study teams. This can be done during study planning, training sessions, or pre-defined times throughout the study.

Involving all stakeholders regularly in the process will increase trust, improve collaboration, and maintain high-quality documentation practices throughout the study.

Document Preparation

Inspection-readiness begins and ends with your TMF. A well-developed TMF plan includes the roles and responsibilities of internal and external partners across the study, document content requirements, instructions for inspections, and the type and frequency of quality checks. It is a living document that should be reviewed and updated on a regular basis to ensure the TMF is fully leveraged to enable a constant state of inspection-readiness for your organisation.

An active TMF operating model ensures a constant state of inspection-readiness. Incorporate active TMF management practices into daily operations by submitting or creating all TMF documents in a timely and contemporaneous manner. Apply quality control checks to ensure they are accurate and complete. Each action should be traceable and auditable for inspectors to review.

Before a planned inspection, the following list is a good starting point for the documents that inspectors will be reviewing.

- Study-related documents – preferably final versions without annotations
- Charts and reports – you may be able to anticipate the type of information your inspectors will look for, such as data on contemporaneousness of file submission; create these charts and reports beforehand and be ready to explain the results
- Previous findings – it's likely that inspectors will want to see the resolution plan for past issues; include complete responses and documentation about corrective and preventive actions (CAPA) taken
- Non-study-related documents – the inspector may want to review non-TMF-related materials such as company SOPs, IT system security, validation documentation, etc.

If your organisation uses an eTMF, you will need to consider the inspector's access to these files. Restrict the inspector's access to files only needed for the inspection. Include details on how these permissions will be validated before the inspection, and the plan for revoking access once the inspection has concluded.

Training inspectors to navigate an eTMF should take no more than 15-20 minutes. Have this training ready even if you plan to have an eTMF driver present for the duration of the inspection. Your eTMF vendor may have best practices or tips to help you organise documents more efficiently or present your processes in the best possible light.

Communication Plans

All key stakeholders should be aware of preparation activities and their role as soon as an inspection is announced.

Establish and monitor key performance indicators to drive inspection-readiness and inform proactive decision-making. Design reports to help identify issues before they become problems, and use KPIs to assess TMF timeliness, quality, and completeness. Checking these on a regularly scheduled basis will enable your organisation to identify and resolve issues proactively, before an inspection occurs.

Unannounced inspections are a critical reason for having an SOP in place and all staff trained. Be clear on what absolutely must happen if inspectors show up unannounced. Start with the communication procedure and include who is responsible for getting the inspectors settled and the organisation ready at a moment's notice.

Planned inspections can be more defined in their set-up, with organisations able to plan every step of the way. The following timeline serves as a guide for the day of inspection with who should be involved and when.

- Arrival – who needs to be notified when an inspector arrives and through what means
- Announcement – how the inspection will be announced to the entire organisation
- Core inspection team – what information is needed by the core inspection team while the inspection is being conducted and who is responsible for delivering that information
- Liaisons and ancillary staff – how liaisons will communicate with the inspectors, their departments, and the core inspection team
- Post-inspection – similar to arrival communications, identify who should be notified upon the departure of inspectors
- Inspection results – how inspection results will be communicated and to whom

Training Content and Procedures

Everyone needs to know how to conduct themselves in the event of an inspection. Position inspections as a normal, important activity that requires everyone's collaboration to be successful. Even small things like renaming the "inspection war room" to the "inspection preparation room" can help reduce tension.

Training should include regulations, the company's processes, and information about the construct of the TMF. All new team members should receive this training as part of their onboarding process.

Just as a "fire drill" helps everyone in a building to prepare for an emergency, conducting internal audits and mock inspections ensures your organisation is ready for an inspection. Leverage these activities to identify areas where processes and/or performance can be enhanced or improved.

Compose answers to anticipated questions; the core inspection team should come up with questions inspectors are likely to ask and how these questions should be answered. Determine how to present information in a positive, collaborative light, and help interview candidates practise their answers (without oversharing).

Inspectors are sometimes said to shoot rapid-fire questions to see how prepared you are, and as a way to measure awareness and transparency. Anticipate what these questions might be and practise your response. Allow individuals to hone their responses as needed without losing the key points.

Mock inspections serve an important purpose by gauging how prepared your organisation is for an actual inspection. The person playing the role of the inspector is ideally someone who has experience as an auditor/inspector, and ideally is unfamiliar to the team. Start from the first interaction and include any procedures that security or reception must follow when inspectors announce themselves.

A mock inspection should cover everything contained in the SOP, including how the inspector is received, how ancillary staff fulfil their roles, the communication procedures throughout the day, and access to all necessary documents. Take the opportunity to use the observations and findings from the mock inspection and make changes as necessary.

Day of Inspection Checklist

Be thoughtful about the physical needs of both the inspector and your preparation team so that they can all perform their jobs smoothly. It's important that the inspector is comfortable while working with your team.

Inspectors should be given their own working space. Do not put inspectors in a room where confidential materials may be visible. Make sure restrooms are conveniently accessible. Equip the room with anything the inspector may need; consider a computer with internet access and a phone, and be prepared to source anything else the inspector may need.

Indicate what type of refreshments are appropriate to provide. In some cases, you may need to be careful to avoid the appearance of bribery. Provide a welcome packet which includes basic, non-study information, such as a site map and contact information for specific people and their roles.

Don't forget about your internal team; select a room for the preparation team that is adequately close to the inspectors' room and provides privacy.

Plan for Change

Remember, an ounce of prevention is worth a pound of cure. Be prepared to modify any step in this plan to accommodate any necessary regulatory changes in a timely manner. It is better to incorporate changes when needed rather than risk citation for failure to comply during an inspection – planned or otherwise.

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