

# How to Prepare for an Inspection

While maintaining an active TMF process within your organization can help **establish a culture of inspection-readiness**, inspection preparation is a distinct process that readies your entire organization for a successful inspection. A best practice for inspection preparation is a standard operating procedure (SOP) that codifies the roles, procedures, and training your organization will enact in preparation for an announced inspection.

Below are key sections to include in your SOP, along with recommendations to help your organization prepare for an inspection.

## Roles and Responsibilities

Passing an inspection is a team effort, so it's important to call out some of the key roles that will play a part in the process.

- **Core inspection team.** Members are responsible for defining, reviewing, and implementing the procedures outlined in the SOP. The team should include the following roles, at a minimum:
  - **Team leader.** The team leader has the authority to coordinate and direct staff at all levels, and (ideally) has some project management experience.
  - **QA and regulatory team members.** Having discussions with these groups well in advance of an inspection will ensure you know whom to go to for documents outside of the TMF.
  - **Functional area contacts.** Involve these individuals in the development of the SOP as they will also act as liaisons for their respective departments during an inspection.
- **Interview candidates.** Identify primary interviewees and backups for each department. The interviewees and their backups should be trained at answering inspector questions, in case the primary candidate is unavailable:
  - **Study/program staff.** These individuals have insight into the specific scope of the inspection. Include CRO staff or any other study partners if necessary.
  - **Non-study staff.** Include individuals who can speak to non-study items, such as IT and security.
- **Ancillary support staff.** Include everyone who will support day-of inspection activities. They may require less intensive training than interview personnel but should still be prepared:
  - **Liaison/escort.** The escort accompanies the inspector throughout the day, provides a tour of the site, and facilitates all requests.
  - **Scribe.** The scribe will take notes on everything the inspectors say if recording the inspection is prohibited.
  - **Runner.** The runner will get inspectors anything they need that was not anticipated.

- **eTMF driver.** If you are utilizing an eTMF, ensure the eTMF driver is trained and comfortable navigating the system using the same level of access as the inspector.
- **TMF liaison.** For paper-based TMFs, outline a process for obtaining documents from the secure file area for the inspector's review. This may include providing copies to the inspectors as they may want to make notes or take the copies with them.
- **Others.** Include any roles that will engage with inspectors in any way on the day of inspection, e.g., security guard, receptionist, etc.

- Stakeholders and notification list.** Call out any roles to be notified throughout the process. Specify to what level they need to stay informed before, during, and after an inspection.

## Document Preparation

Typically, a large portion of a regulatory inspection will concern the documents created for and by the study. If you have already established a **culture of active TMF management**, this list will simply cover the specific types of documents and/or reports that inspectors will be reviewing.

- Study-related documents.** It is generally recommended that only final documents be made available, with no annotations.
- Charts and reports.** Depending on the type of study or inspection, you may be able to anticipate the type of information your inspectors will look for, such as data on contemporaneity of file submission. Create these charts and reports beforehand and be ready to explain the results to the inspectors if asked.
- 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.
- eTMF considerations:**
  - **eTMF access for inspectors.** If your organization uses an eTMF, restrict the inspector's access to only files needed for the inspection. This may require provisioning an inspector role or setting up specific permissions for that user. Include details on how these permissions will be validated before the inspection, and the plan for revoking access once the inspection has concluded.
  - **eTMF training materials.** Training inspectors to navigate the system should take no more than 15-20 minutes. Have this training ready even if you plan to have an eTMF driver. Training can take the form of a presentation, a demonstration, an instructional video, reference cards, etc.
  - **Work with your eTMF vendors.** Your eTMF vendor may have best practices or tips to help you organize documents more efficiently or present your processes in the best possible light.

## Communication Plan

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

- Timeline.** Outline who needs to be notified, when, and what level of detail they need. Items in the timeline may include:
  - **Arrival.** Who needs to be notified when an inspector arrives and through what means.
  - **Announcement.** How the inspection will be announced to the organization as a whole.
  - **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.
- Unannounced inspections.** 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 organization ready at a moment's notice.

## Training Content and Procedures

Everyone needs to know how to conduct themselves in the event of an inspection. This is especially true for team members who have never been through one before.

- Framing and attitude.** 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 calendar.** A calendar ensures that training and mock inspections occur in a timely fashion and that everyone completes the appropriate training for their role.
- Prepare and practice answers:**
  - **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.
  - **Storyboarding.** "Storyboarding" is the process of determining how to present information in a positive, collaborative light, and helps interview candidates practice their answers (and not overshare).
  - **Rapid fire.** 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 practice your response.
  - **Review and refine.** Allow individuals to hone their responses as needed without losing the key points.

### ☐ Responsibilities for ancillary support staff:

- **Security and reception.** Outline how security and reception staff should respond when an inspector arrives, as well as who should be notified and how to alert them. This is important if there is a time clock for the inspection that starts with the first interaction.
- **Scribes, runners, and escorts.** Select and train people who can perform these duties reliably. Make sure they know what areas and types of things are restricted.
- **eTMF driver or TMF liaison.** If you plan to have an eTMF driver or TMF liaison, make sure they practice and understand the level of access inspectors should have within the system.

### ☐ Mock inspections. Mock inspections serve an important purpose by gauging how prepared your organization is for an actual inspection:

- **Inspector role.** The person playing the role of the inspector is ideally someone who has experience as an auditor/inspector, and who is unfamiliar to the team, e.g., an external person or someone from another part of the organization.
- **Start from the first interaction.** Include any procedures that security or reception must follow when inspectors announce themselves.
- **Cover the entire SOP.** The mock inspection should cover everything contained in the SOP, including how the inspector is received, how ancillary staff fulfill their roles, the communication procedures throughout the day, and access to all necessary documents (both TMF and non-TMF).
- **Debrief.** Take the opportunity to use the observations and findings from the mock inspection and make changes as necessary.

## Day of Inspection Requirements

Be thoughtful about the physical needs of both the inspector and your preparation team so that they can all perform their jobs smoothly.

### ☐ Inspector's room. It's important that the inspector is comfortable while working with your team. This starts with the room used for the inspection:

- **Location.** 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.
- **Equipment.** Equip the room with anything the inspector may need, e.g., a computer with internet access, a phone, copier, etc.
- **Refreshments.** Indicate what type of refreshments are appropriate to provide. In some cases, you may need to be careful to avoid the appearance of bribery.
- **Welcome packet.** The welcome packet should include basic, non-study information, such as a site map, contact information for specific people, their roles, etc.

### ☐ Preparation team's room. Select a room for the preparation team that is adequately close to the inspectors' room and provides privacy.

*"Before anything else, preparation is the key to success."* -Alexander Graham Bell