

How to Successfully Navigate a Regulatory Inspection

The best preparation for a regulatory inspection starts with a strong **culture of inspection readiness** and a **well-documented SOP**. With these in place, the following tips will help your organization successfully navigate the day of inspection.

☐ Obtain inspection information

Get the inspector's full name, title, and contact information. Determine what will be inspected. Ask for the reason for the inspection, and the planned duration.

☐ Notify all stakeholders and affected personnel

Alert the team that preparation activities will take place and specify who should be involved.

☐ Consult the inspection preparation SOP and review training materials

Review your SOP to ensure documented procedures are followed. Check the training materials for accuracy and make any necessary changes.

☐ Review past inspection reports

Review any significant observations and corresponding responses. Ensure that findings from past inspections were addressed and recorded. Be prepared to answer related questions.

☐ Remind your team (and yourself) to stay calm

You have done everything you could to ensure the best possible outcome. Remind everyone that they are ready for this!

☐ Welcome and brief the inspector

Make sure the inspector's room is properly equipped with the necessary tools and/or refreshments. If there is a welcome packet, make sure to show it to the inspector and inform him or her of what is in it. Provide training on your TMF, but make sure that it lasts no longer than 15-20 minutes.

☐ **Assign a liaison and escort for the inspector**

Designate a point person or escort to field questions from the inspector or bring in applicable staff as needed. Although it is not necessary to chaperone the inspector at all times, inspectors should not be allowed to roam the site unattended.

☐ **Answers questions concisely**

All questions should be answered honestly and completely; do not volunteer information beyond the scope of the initial question.

☐ **Keep a general log of daily inspection progress**

Keep a record of what was reviewed, the personnel involved, and any deviations noted by inspectors.

☐ **Keep a record of requested documents**

If digital copies of documents from an eTMF are provided to the inspector, a log of those files should be sufficient. If paper copies were provided, keep physical copies of the documents for your own records.

☐ **Have a daily debrief with the inspector**

Ask the inspector to provide a summary of what they did that day, including any findings, and what is planned the next day. Provide a response to findings before the inspection ends (if possible). On the last day of the inspection, hold a final review meeting with the inspector.

☐ **Alert team members when the inspection is over**

Congratulate them on their teamwork and completion of the inspection.

☐ **Conduct a post-mortem**

Use a post-mortem review to identify any mishaps that occurred during the inspection, and if possible, how to avoid them in the future. Update the inspection preparation SOP if necessary.

*“Great things in business are never done by one person.
They’re done by a team of people” -Steve Jobs*