

Stay Ahead of Pharmacovigilance Inspections

Strategic Tips for Success

**Pill 2: How to manage
the inspection itself**



What does good behaviour during an inspection look like?

During the inspection, **teams are expected to remain professional, transparent, and well organised.** Effective communication is a key component of inspection readiness.

- Be courteous and professional
- Respond honestly
- Do not argue with inspector
- Do not raise your voice
- Stay calm, structured, and in control



How should questions be answered?

Answers should be **clear, concise, and limited to what inspectors actually ask**. If the answer is not known, it is appropriate to say so, verify the information, and follow up with a response.

- Only one person should answer each question
- Respond clearly
- Keep answers concise
- Answer only what was asked
- Do not guess. If you are unsure, say you will verify the information and follow up.



How should the team stay aligned during the inspection?

Inspection management requires **continuous internal coordination** throughout the day. **Availability and regular alignment** are key to avoiding confusion and ensure consistent responses.

- Ensure the inspection team is fully available
- Ensure participants are available when required
- Inform company members who may become involved
- Take notes during the inspection
- Summarize key points internally at the end of each day



How should visits to company areas be handled?

If inspectors request to visit specific areas, the company should maintain oversight and ensure that **inspectors are accompanied at all times**.

- Do not leave inspectors unattended
- Accompany inspectors to relevant areas, such as the archive, PV area and/or IT/server areas
- Maintain order, cleanliness and inspection readiness in all visited areas



How should documentation be managed?

Documents should be **available, controlled, and easy to trace**. Inspection success depends heavily on the quality, accuracy, and effective management of documentation.

- Provide copies of documents upon request
- Ensure documents are complete, current and approved
- before sharing
- Maintain version control and traceability for all documents provided

Do not provide original documents or copies intended to be taken outside the company unless formally authorised



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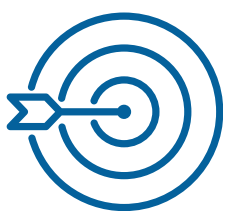
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