

Stay Ahead of Pharmacovigilance Inspections

Strategic Tips for Success

**Pill 1: What happens
before the inspection**



What is the purpose of a PV inspection?

A pharmacovigilance (PV) inspection is conducted to assess whether the **Marketing Authorization Holder (MAH) complies with pharmacovigilance obligations established under EU legislation**. It also aims to identify any non-compliances that could compromise patient safety or pose a risk to public health.

- Assess compliance with EU PV obligations
- Identify non-compliances
- Help protect public health
- Review the MAH's PV system



How is a Pharmacovigilance inspection usually notified?

The inspection process may begin with an **inspection notification and a request from the competent authority for the Pharmacovigilance System Master File (PSMF)**. When requested, the PSMF must be submitted within **7 calendar days**.

- Receipt of the inspection notification
- Request for the PSMF
- 7 calendar days for submission
- Review by the Agency



What information is normally provided?

When a PV inspection is notified, the company is typically informed of the **inspection team, the purpose and scope of the inspection, and how it will be conducted.**

- Names of the inspectors
- Inspectors' roles and positions
- Inspection agenda
- Date and duration
- Purpose of the inspection



What should happen before the inspection starts?

Preparation should begin as soon as the inspection is anticipated. The inspection agenda should be reviewed internally, and roles and responsibilities should be clearly assigned.

- Review the agenda with the EU-QPPV
- Establish an inspection team
- Ensure all members are available
- Appoint a team leader from the PV unit
- Create an inspection checklist



What logistical preparation is expected?

Inspection readiness also includes operational preparation. The company should prepare the inspection area and ensure that documentation can be retrieved, reviewed and provided efficiently during the visit.

- Inspection room ready for use
- Telephone connection
- Projector
- Internet connection
- Clean and organized space
- Back-up room for documentation preparation



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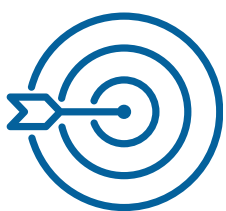
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