

# 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



# Your Trusted Partner

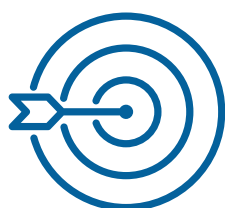
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