

# GVP Module III

## Revision 2

### **What has changed in pharmacovigilance inspections?**

Key regulatory updates, their practical implications, and what Marketing Authorisation Holders (MAHs) should consider reviewing.



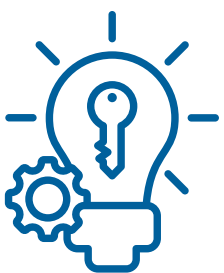
# PV Partners: Inspection Readiness Beyond the MAH

Pharmacovigilance activities may be outsourced, but the regulatory oversight of the PV system remains essential.

**Revision 2 clarifies the inspection framework applicable** to third parties performing PV activities on behalf of, or in conjunction with, an MAH, including further subcontracted parties.

What should MAHs review?

- Maintain an up-to-date overview of PV partners and relevant subcontracting arrangements.
- Ensure PV agreements clearly define responsibilities, access to records and inspection support.
- Verify that partners can provide the documentation and personnel needed during an inspection.



**Outsourcing PV activities does not remove the need for appropriate oversight and inspection preparedness.**

# Documentation Must Be Inspection-Ready

Access to accurate, complete and retrievable documentation is fundamental to an effective pharmacovigilance inspection.

**Revision 2 clarifies aspects of the timing for providing requested documents.** Organizations should ensure that responsibilities and document-retrieval processes are clearly defined.

Practical actions:

- Confirm that relevant PV records and procedures are current and version-controlled.
- Define who coordinates inspection requests and who provides the requested information.
- Test whether documentation held by external PV partners can be retrieved within the applicable timelines.
- Ensure that access to the Pharmacovigilance System Master File (PSMF) is managed in accordance with applicable requirements.



**Document availability should be part of routine PV operations, not an activity initiated only when an inspection is announced.**

# Inspection Planning: A Risk-Based Approach

A risk-based approach helps competent authorities prioritise inspections according to the characteristics and potential risks of a pharmacovigilance system.

The revised guidance reinforces the **importance of considering relevant risk factors when planning and prioritising inspections.**

What should organisations consider?

- Previous inspection findings and outstanding corrective and preventive actions (CAPAs).
- Significant changes to the PV system, processes or organisational structure.
- The complexity of outsourced activities and the oversight of PV partners.
- Signals of potential non-compliance or weaknesses in PV processes.



**Risk assessments should be meaningful, documented and supported by evidence of appropriate follow-up.**

# Remote Inspections: Is Your Organisation Ready?

**Revision 2 provides further clarification on remote inspections**, reflecting experience gained in their implementation.

Remote inspections require appropriate planning to ensure that the inspection objectives can be achieved and that relevant evidence can be assessed effectively.

Consider the following:

- Can inspectors securely access the relevant electronic systems and records?
- Are key personnel available for interviews and follow-up questions?
- Are procedures in place for sharing documentation securely and efficiently?
- Can potential technical issues be managed without compromising inspection activities?



**Remote inspection readiness depends on people, processes, systems and secure access to evidence.**

# Updated Regulatory References and Clarifications

**Revision 2 also updates and clarifies elements of the regulatory framework** governing pharmacovigilance inspections.

These updates are an opportunity to check whether internal documentation remains aligned with the current guidance.

What should be reviewed?

- SOPs and work instructions relating to inspection management.
- Inspection-readiness plans and supporting checklists.
- PV partner oversight procedures and relevant contractual arrangements.
- Training materials and references to applicable EU legislation.

Any changes to internal procedures should be based on a documented assessment of their applicability and impact.



**A targeted gap assessment can help identify where updates are necessary and prioritise implementation.**

# Is Your PV System Inspection-Ready?

Use the revised guidance as an opportunity to assess your current level of preparedness.  
Your inspection-readiness checklist

- ✓ Review your PV partner landscape and subcontracting arrangements.
- ✓ Verify access to relevant documentation, records and systems.
- ✓ Assess inspection risks and follow up on previous findings.
- ✓ Check your organisation's readiness for remote inspection activities.
- ✓ Identify and implement any necessary updates to SOPs and training.

**Inspection readiness is an ongoing process — not a last-minute exercise.**

# Your Trusted Partner

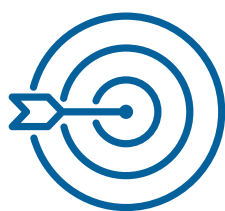
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