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Stay Ahead of Pharmacovigilance Inspections

Strategic Tips for Success

Pill 3: The documents and gaps inspectors focus on

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Why is the PSMF a key inspection document?

The **PSMF provides an overview of the company's pharmacovigilance system** and may be requested, reviewed, and assessed by Competent Authorities during inspections.

- Location of the PSMF
- Code information (xEVMPD)
- Representation of the PV system
- Organization and knowledge of the content
- Format and language requirements
- QPPV, MAH, list of SOPs, and quality system

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What makes SOPs Inspection-Ready?

SOPs should describe the activities actually performed and be sufficiently clear for the process to be understood, followed and consistently reproduced.

- Description of activities performed
- Do not simply copy and paste legislation
- Easy to read and understand
- Provide sufficient detail to accurately reflect the real process

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What should inspectors see in PV training?

Training should be **structured, role-based, and supported by appopriate records**. Inspectors will assess both the overall training approach and the evidence demonstrating its implementation and effectiveness.

- Frequency
- Method
- Evaluation
- Training plan
- Training records
- Training on applicable SOPs
- Training levels defined according to job description
- Onboarding and training for new employees

What should PV agreements include?

PV agreements should clearly **define responsibilities and remain properly controlled throughout** their lifecycle, including the management and retention of obsolete versions

- Complete list of agreements, including obsolete versions
- Signed and dated agreements
- Clear identification of medicinal products covered
- Defined territories and scope of application
- Effective dates and validity perios
- Clearly documented responsibilities and obligations

What findings are commonly identified during inspections?

Common findings often highlight **weaknesses in areas such as resources, procedures, oversight, training, or quality systems**.

- Insufficient human resources
- Inadequate EU-QPPV training and qualifications
- Lack of PV training for MAH employees
- PV activities not adequately covered by written procedures
- Deficiencies in PSMF annexes or PV agreements

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- Strategic vision
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- Scientific precision
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Let’s build your regulatory strategy together!

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