

Stay Ahead of Pharmacovigilance Inspections

Strategic Tips for Success

Pill 4: What happens after the inspection



What should happen immediately following the inspection?

Once the inspection is completed, **the company should address any open points with inspectors and align internally on next steps.** The post-inspection phase is critical for translating observations into concrete actions and ensuring effective follow-up.

- Clarify any open questions during the closing meeting
- Agree on the timeline for delivery of the inspection report
- Conduct an internal post-inspection review meeting
- Document key observations, findings, and pending actions



What is expected upon receipt of the inspection report?

The final report **should be reviewed carefully** to understand the observations raised and prepare an appropriate response. This stage requires a structured assessment, clear ownership, and effective internal coordination.

- Review the final report in detail
- Identify observations and non-compliances
- Align internally on the response approach
- Prioritize actions according to impact



How should corrective actions be prepared?

Inspection findings should **lead to clear responses and corrective actions**. The objective is not only to answer the authority, but also to strengthen the pharmacovigilance system.

- Prepare responses to inspection findings
- Define corrective actions and remediation measures
- Establish implementation timelines
- Assign clear responsibilities for execution and follow-up



What does effective CAPA follow-up involve?

Corrective and preventive actions should be followed through over time. Effective follow-up ensures that commitments are implemented, actions are verified, and improvements are sustained.

- Track CAPA implementation progress
- Monitor progress against established timelines
- Verify completion and effectiveness of agreed actions
- Maintain documented evidence of follow-up activities



How can companies build long-term inspection readiness?

Inspection readiness should **not depend on a single inspection cycle**. It is built through ongoing preparation, strong oversight, robust documentation, and continuous training

- Be proactive rather than reactive
- Conduct routine mock inspections and readiness assessments
- Empower the EU-QPPV
- Maintain traceability of processes and decisions
- Invest in communication skills and stress management
- Build and sustain a quality-driven culture over time



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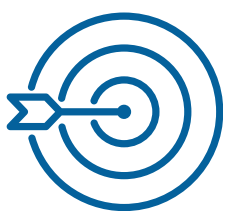
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