How to overcome a Veterinary Pharmacovigilance inspection

Pharmacovigilance veterinary inspections are conducted to ensure that Marketing Authorisation Holders (MAHs) comply with legal and regulatory requirements related to the safety and efficacy of veterinary medicinal products.

The following Legal Framework is to be taken into consideration:

- Regulation (EU) 2019/6
- Commission Implementing Regulation (EU) 2021/1281
- Veterinary Good Pharmacovigilance Practices (VGVP) Module: Controls and pharmacovigilance Inspections

What to Expect During a Veterinary Pharmacovigilance Inspection

Veterinary pharmacovigilance inspections involve a detail review of the company pharmacovigilance procedures, systems, personnel and facilities in place; in order to determine their compliance with regulatory pharmacovigilance obligations.

A veterinary pharmacovigilance inspection typically comprises the following phases:

1. Notification

During this initial phase, the MAH is notified of the upcoming inspection. This notification includes preliminary details such as the scope, objectives, and planned date of the inspection.

A response to this notification is also requested to accept the inspection and to confirm the availability during the inspection of personnel involved in pharmacovigilance tasks. The documentation requested in this notification is to be provided within a maximum of seven (7) calendar days.

Although the majority of inspections will be announced, it may be possible to receive unannounced inspections or announced with at short notice (e.g. when the announcement could compromise the objectives of the inspection or when the inspection is conducted in a short timeframe due to urgent safety reasons).

2. Agenda

An agenda is provided, outlining the specific timeline, areas of focus and key activities that will occur during the inspection.

This stage allows the MAH to prepare the appropriate documentation. It is recommended to:

- Prepare a brief presentation for each session. These presentations should provide a clear overview of the relevant processes, systems, and key data pertinent to the topic of the session.
- Identify the necessary personnel who need to be present for each session of the inspection. These personnel should be able to provide detailed explanations or answer any questions the inspectors may have.

3. Inspection

The core phase, which involves a thorough review of the pharmacovigilance systems, processes, and documentation. Inspectors will examine records, interview staff, and observe procedures to assess compliance with regulatory requirements.

The scope of the inspections may include the following elements, among others:

- Collection, reporting, and recording of suspected adverse events
- Continuous benefit-risk balance monitoring
- Roles and responsibilities of the Qualified Person Responsible for Pharmacovigilance (QPPV) and of the MAH
- Content and maintenance of the Pharmacovigilance System Master File (PSMF)

- Quality management system. Standard operating procedures. Audits. Deviations management. Corrective and Preventive Action (CAPA) plan
- Training
- Document management system
- Contracts and agreements
- Communication in accordance with Veterinary Good Pharmacovigilance Practices

5. Initial report and CAPA plan

Following the inspection, inspectors issue an initial report highlighting the findings, including any identified deficiencies or areas of non-compliance. The MAH is then expected to develop and submit a CAPA plan outlining how they will address the findings.

6. Final report, follow-up phase and Inspection completion

Once the CAPA plan has been reviewed, a final report including the information provided in the CAPA plan is issued.

During this phase, the implementation of the agreed measures from the CAPA plan is verified, ensuring all corrective and preventive actions are effectively conducted. The process is considered final after the submission of the last piece of evidence.