الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Mid-annual PV Inspection Report 2026

1st Jan 2026 until 30st Jun 2026

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1. Introduction

Between January 1 and June 30, 2026, the National Pharmacovigilance Center (NPC) at the Saudi Food & Drug Authority (SFDA) conducted a total of 24 pharmacovigilance inspections targeting Marketing Authorization Holders (MAHs) across various regions in the Kingdom. Types of Inspections Conducted: 9 Routine Inspections, 4 For-Cause Inspections, and 11 Re-Inspections.

The report examines the types of inspections performed and the inspection findings, including an analysis of the specific topics where the inspection team found the highest number of findings. The purpose of these inspections was to evaluate the MAHs' compliance with existing Saudi pharmacovigilance regulations and guidelines. The MAHs were selected for inspection using a risk-based methodology, which follows the guidance in GVP Module III. This methodology considers factors such as:

- Product-specific risks (e.g., new active substances or new biological products)
- The complexity of the pharmacovigilance system
- The complexity and size of the organizations involved in the pharmacovigilance system, including service providers and the number of products
- The compliance and inspection history of an organization
- The reporting rate of the MAHs

The inspection types used by the inspection team are listed in Appendix I. The definitions for critical, major, and minor inspection findings are included in Appendix II.

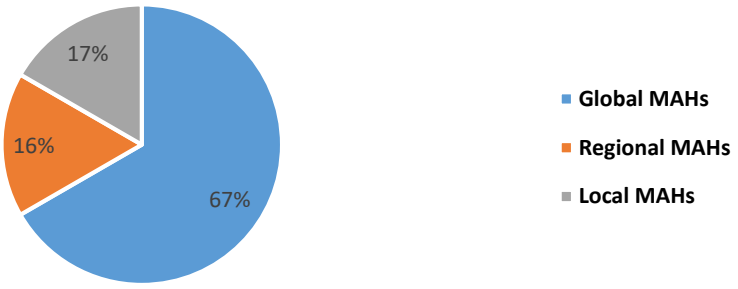
2. Overview

During the reported period, the NPC inspection team conducted a total of 24 pharmacovigilance inspections, classified as follows:

- 9 Routine Pharmacovigilance Inspection.
- 4 Pharmacovigilance Inspection (For cause).
- 11 Pharmacovigilance Re-inspection.

3. Inspection Results of Routine and for cause inspections

Figure 1- MAHs Classification, no=13



As shown in Figure 1, out of the 24 pharmacovigilance inspections conducted by the National Pharmacovigilance Center (NPC) between January 1 and June 30, 2026, 8 were conducted for global MAHs, 2 for a regional MAH, and 3 targeted local pharmaceutical companies. This distribution reflects the NPC's ongoing efforts to monitor compliance across all levels of the pharmaceutical sector.

Inspection Results:

A total of 152 inspection findings were identified across the inspected MAHs during the reporting period .These findings were categorized based on their severity as follows:

- 13 Critical findings.
- 91 Major Findings.
- 48 Minor findings.

Figure 2- Inspection Results for Semi Annaul 2026

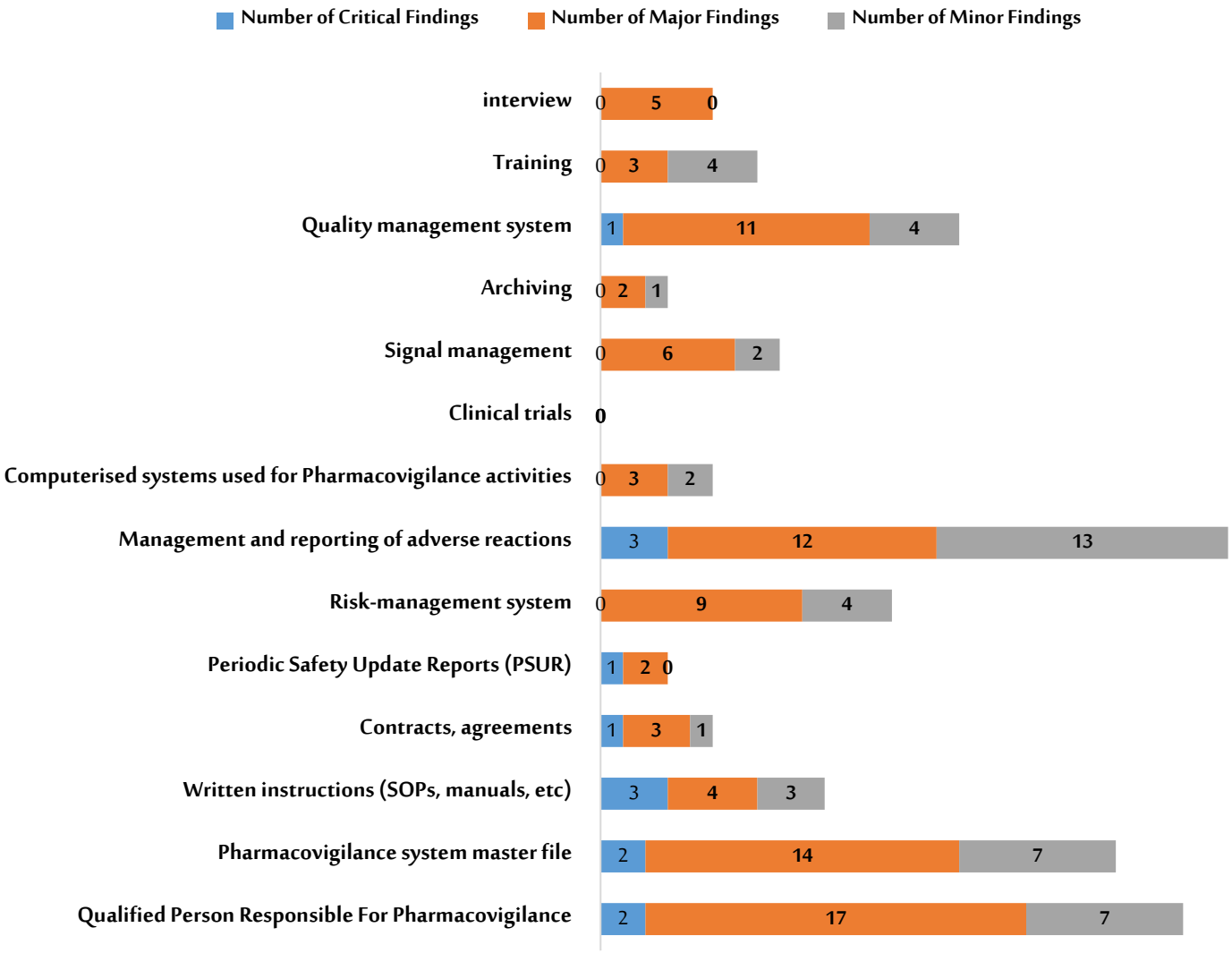


Table 1: Inspection Findings by Topic area and severity

Topic Areas	Critical Findings	Major Findings	Minor Findings
Qualified Person Responsible For Pharmacovigilance	2	17	7
Pharmacovigilance system master file	2	14	7
Written instructions (SOPs, manuals)	3	4	3
Contracts, agreements	1	3	1
Periodic Safety Update Reports (PSUR)	1	2	0
Risk-management system	0	9	4
Management and reporting of adverse reactions	3	12	13
Computerized systems used for Pharmacovigilance activities	0	3	2
Clinical trials	0	0	0
Signal management	0	6	2
Archiving	0	2	1
Quality management system	1	11	4
Training	0	3	4
Interview	0	5	0

The table above summarizes the distribution of critical, major, and minor findings identified during pharmacovigilance inspections conducted by the NPC inspection team across the different pharmacovigilance system areas. The highest proportion of findings was related to the management and reporting of adverse reactions accounting for 18.4% of the total observations. This was followed by findings related to the Qualified Person Responsible for Pharmacovigilance (QPPV) which represented 17.1% and deficiencies associated with the Pharmacovigilance System Master File (PSMF) constituting 15.1% of the total observations.

Common Areas of Findings:

I. Management and reporting of adverse reactions.

This area represented for the highest proportion of finding, representing 18.4 % of all findings during inspections.

Figure 3 - Management and reporting of adverse reactions, no=28

II. Qualified person responsible for pharmacovigilance (QPPV).

This area represented 17.1 % of all inspection findings, making it the second most common area of non-compliance.

Figure 4- Qualified Person Responsible For Pharmacovigilance, no=26

III. Pharmacovigilance system master file (PSMF)

This area represented 15.1 % of all inspection findings.

Figure 5 - Pharmacovigilance system master file, no=23

The majority of the findings were concentrated in the areas of Management and Reporting of Adverse Reactions, Qualified Person Responsible for Pharmacovigilance (QPPV), and the Pharmacovigilance System Master File (PSMF). The observed findings were mainly associated with the following factors:

1. **Incomplete Implementation of the Pharmacovigilance System**

- Inadequate implementation of pharmacovigilance procedures at the local level.
- Insufficient oversight of pharmacovigilance activities
- Weak documentation and traceability of pharmacovigilance processes

2. **Deficiencies in Pharmacovigilance Governance**

- Limited oversight and involvement of the local QPPV in pharmacovigilance activities
- Inadequate maintenance of pharmacovigilance documentation, including the PSMF
- Inconsistent implementation of Saudi GVP requirements across pharmacovigilance activities

3. **Weaknesses in Safety Data Management**

- Deficiencies in adverse drug reaction reporting and case management processes.
- Limited mechanisms to ensure timely reporting, reconciliation, and follow-up of safety information.

- Insufficient monitoring of pharmacovigilance performance and compliance.

4. Re-Inspection Outcomes

Out of the 11 re-inspections conducted during the reporting period (January 1—June 30, 2026), the majority of Marketing Authorization Holders (MAHs) demonstrated satisfactory progress in addressing the findings identified during the previous inspections.

- 10 MAHs successfully implemented the required Corrective and Preventive Actions (CAPAs) and were considered compliant based on the re-inspection outcomes.
- One MAH did not demonstrate adequate progress in implementing the required CAPAs and the identified deficiencies remained unresolved. Consequently, the MAH will be scheduled for a Second re- inspection to verify the implementation and effectiveness of the required corrective actions.

Among the 11 re-inspections conducted during the reporting period, 10 MAHs successfully addressed the previously identified findings and were considered compliant. One MAH did not demonstrate adequate progress in implementing the required Corrective and Preventive Actions (CAPAs) and has been scheduled for a second re-inspection to verify the implementation and effectiveness of the required corrective actions.

To further support regulatory compliance, the NPC organized a series of workshops in 2026 for QPPVs and their deputies. These workshops focused on strengthening the understanding and implementation of Saudi GVP requirements, addressing common deficiencies identified during inspections, and providing clarification on key regulatory expectations.

5. Trend analysis and root causes of increased findings in 2026.

- Compared with the findings reported in the 2025 Mid-Annual Report, the total number of inspection findings increased from 87 to 152, representing an increase of approximately 75%. The observed trend suggests that recurring compliance gaps remain across key pharmacovigilance system areas. The increase in findings may be attributed to the following factors:
- **Inadequate implementation of Saudi GVP requirements:** Although pharmacovigilance systems were generally established, several MAHs demonstrated gaps in the implementation of key Saudi GVP

requirements, including inconsistencies between documented procedures and actual practices, resulting in recurring inspection findings.

- **Inadequate fulfillment of QPPV responsibilities:** several inspections identified limited involvement of the QPPV in local pharmacovigilance activities, maintaining compliance, and ensuring effective communication with the global pharmacovigilance function.
- **Deficiencies in adverse reaction management and reporting:** Recurring findings were identified in adverse reaction management and reporting processes, including case management, timely reporting and follow-up activities indicating weaknesses in pharmacovigilance practices
- **Deficiencies in Pharmacovigilance System Master File (PSMF) management:** Several MAHs maintained incomplete or outdated PSMFs that did not fully reflect their implemented pharmacovigilance systems or current Saudi GVP requirements.

6. Summary

During the reporting period, the inspection team carried out a total of 24 pharmacovigilance inspections, comprising 9 routine inspections, 4 for-cause inspections, and 11 re-inspections. Among these, 13 inspections targeted Marketing Authorization Holders (MAHs), including 8 global MAHs, 3 local MAHs, and 2 regional MAH. A total of 152 findings were identified across all inspections conducted during the reporting period, including 13 critical, 91 major, and 48 minor findings. The predominance of major findings indicates that, although pharmacovigilance systems are generally established, significant gaps remain in their implementation and compliance with regulatory requirements.

The highest proportion of findings was related to the management and reporting of adverse reactions accounting for 18.4% of the total observations. This was followed by findings related to the Qualified Person Responsible for Pharmacovigilance (QPPV) which represented 17.1% and deficiencies associated with the Pharmacovigilance System Master File (PSMF) constituting 15.1% of the total observations.

Compared with the previous mid-annual report, the number of inspection findings increased. This trend may reflect ongoing challenges in the implementation of the updated Saudi GVP requirements, including incomplete alignment of local SOPs with current regulatory expectations, inconsistent implementation of pharmacovigilance processes, and insufficient definition of local pharmacovigilance roles and responsibilities.

Appendix I: Inspection definitions

**excerpt from page 100-105 of the Guideline on Good Pharmacovigilance Practices (GVP) (Version 3.1, January2023).*

Routine inspections

Routine pharmacovigilance inspections are inspections scheduled in advance as part of inspection programs. There is no specific trigger to initiate these inspections, although a risk-based approach to optimize supervisory activities should be implemented. These inspections are usually system inspections but one or more specific products may be selected as examples to verify the implementation of the system and to provide practical evidence of its functioning and compliance. Particular concerns, e.g. raised by assessors, may also be included in the scope of a routine inspection, in order to investigate the specific issues.

'For cause' inspections

For-cause pharmacovigilance inspections are undertaken when a trigger is recognized, and an inspection is considered an appropriate way to examine the issues. For-cause inspections are more likely to focus on specific pharmacovigilance processes or to include an examination of identified compliance issues and their impact for a specific product. However, full system inspections may also be performed resulting from a trigger.

Pre- authorization inspections

Pre-authorization pharmacovigilance inspections are inspections performed before a marketing authorization is granted. These inspections are conducted with the intent of examining the existing or proposed pharmacovigilance system as it has been described by the applicant in support of the marketing authorization application. Pre-authorization inspections are not mandatory, but may be requested in specific circumstances. Principles and procedures for requesting pre-authorization inspections should be developed to avoid performing unnecessary inspections which may delay the granting of a marketing authorization.

Announced and unannounced inspections.

It is anticipated that the majority of inspections will be announced i.e. notified in advance to the inspected party, to ensure the availability of relevant individuals for the inspection. However, on occasion, it may be appropriate to conduct unannounced inspections or to announce an inspection 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).

Remote inspections

These are pharmacovigilance inspections performed by inspectors remote from the premises of the marketing authorization holder or firms employed by the marketing authorization holder. Communication mechanisms such as the internet or telephone may be used in the conduct of the inspection. This approach may also be taken where there are logistical challenges to an on-site inspection during exceptional circumstances (e.g. a pandemic outbreak or travel restrictions). Such approaches are taken at the discretion of the inspectors and in agreement with the body commissioning the inspection. The logistical aspects of the remote inspection should be considered following liaison with the marketing authorization holder.

Re-inspections

A re-inspection may be conducted on a routine basis as part of a routine inspection program. Risk factors will be assessed in order to priorities re-inspections. Early re-inspection may take place where significant non-compliance has been identified and where it is necessary to verify actions taken to address findings and to evaluate ongoing compliance with the obligations, including evaluation of changes in the pharmacovigilance system. Early re-inspection may also be appropriate when it is known from a previous inspection that the inspected party had failed to implement appropriately corrective and preventive actions in response to an earlier inspection.

Appendix II: Inspection finding definitions

**excerpt from page 127-128 of the Guideline on Good Pharmacovigilance Practices (GVP) (Version 3.1, January2023).*

Critical deficiency

Is a fundamental weakness in one or more pharmacovigilance processes or practices that adversely affects the whole pharmacovigilance system and/or the rights, safety or well-being of patients, or that poses a potential risk to public health and/or represents a serious violation of applicable regulatory requirements.

Major deficiency

Is a significant weakness in one or more pharmacovigilance processes or practices, or a fundamental weakness in part of one or more pharmacovigilance processes or practices that is detrimental to the whole process and/or could potentially adversely affect the rights, safety or well-being of patients and/or could potentially pose a risk to public health and/or represents a violation of applicable regulatory requirements which is however not considered serious.

Minor deficiency

Is a weakness in the part of one or more pharmacovigilance processes or practices that is not expected to adversely affect the whole pharmacovigilance system or process and/or the rights, safety or well-being of patients. Deficiencies are classified by the assessed risk level and may vary depending on the nature of medicine. In some circumstances, an otherwise major deficiency may be categorized as critical. A deficiency reported after a previous inspection and not corrected may be given higher classification

Appendix III: Categorization of finding

Table 2: Topics and sub-topics of inspection findings

Topic area	Sub-topic of reported findings
Qualified Person Responsible For Pharmacovigilance	Qualifications
	Job description
	System oversight
	Back-up process and delegation
Pharmacovigilance system master file	Organizational structure
	Pharmacovigilance system
	Maintenance and submission
Written instructions (SOPs, manuals, etc.)	Procedures
	Manuals
	Process for SOP training
Contracts, agreements	Contracts
	Agreements
Periodic Safety Update Reports (PSUR)	PSUR scheduling
	Format and content
	Quality control of PSURs
	Timeliness of submission
	Assessment report comments
Risk-management system	Risk-management plan format and content
	Compliance with risk minimization measures which are beyond routine Pharmacovigilance
Management and reporting of adverse reactions	Data collection methods
	Assessments of seriousness, causality and expectedness
	Medical review
	Quality control process
	Submissions and follow up processes
	Literature screening

Computerized systems used for Pharmacovigilance activities	Backup and disaster recovery process
Clinical trials	Adverse event reporting from clinical trials
	Consistency between the Investigator's Brochure and SPC when marketed products are used in CT
Signal management	Dataset used for conducting signal detection (inclusion of information from all relevant sources)
	Periodicity of data review
	Signal validation process
Archiving	Archiving facilities
Quality management system	Quality system and compliance management
	Facilities and equipment for pharmacovigilance
	Audit (internal- and external) and Corrective and Preventive Actions process
Training	Available trainings
	Evaluation of training
	Maintenance of training records
Interview	MAH employees interview

Appendix V: Abbreviations

ADR	Adverse Drug Reaction
AE	Adverse Event
aRMM	Additional Risk Minimisation Measure
CAPA	Corrective and Preventative Action
GVP	Good Pharmacovigilance Practice
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
NPC	National Pharmacovigilance Center
PSMF	Pharmacovigilance System Master File
PSSF	Pharmacovigilance Sub-System File
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person responsible for Pharmacovigilance
RMP	Risk Management Plan
SFDA	Saudi Food & Drug Authority
SOP	Standard Operation Procedures