الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pharmacovigilance Inspections Report 1st Jan 2025 to 31st Dec 2025

Contents

1 Introduction

Between 1 January 2025 and 31 December 2025, the National Pharmacovigilance Center (NPC) within the Saudi Food and Drug Authority (SFDA) conducted 26 inspections of Marketing Authorization Holders (MAHs). These inspections aimed to assess compliance with applicable pharmacovigilance regulations and guidelines in Saudi Arabia. MAHs were selected using a risk-based methodology aligned with the principles of GVP Module III, taking into account:

(i) product-specific risks (e.g., new active substances or new biological products),
(ii) the complexity of the pharmacovigilance system,
(iii) the complexity and size of the organization(s) involved in the pharmacovigilance system (including service providers and the number of products),
(iv) an organization's compliance and inspection history,
(v) the MAH reporting rate.

This report summarizes the outcomes of 12 routine inspections and 14 for-cause inspections conducted during the reporting period, including the inspection types applied and the findings identified. The areas associated with the highest concentration of findings across the inspections are also highlighted. The inspection types used by the inspection team are provided in Appendix I, and the definitions of critical, major, and minor findings are provided in Appendix II.

2 Overview of Inspection Department activities

In 2025, of the 26 inspections planned and conducted, one routine inspection and two re-inspections were postponed and rescheduled to a later date due to unforeseen circumstances that affected the MAHs' ability to undergo the inspection as planned. In addition, 14 inspections were triggered by the NPC departments based on the performance of the MAHs. Among the for-cause inspections, two were emergency trigger inspections, and one of these inspections was referred to the legal department to initiate the necessary action against the MAH, considering the MAH's compliance history as reflected in SFDA inspection data.

Across the 26 routine and for-cause inspections, the inspected entities comprised 15 global MAHs, 4 regional MAHs, and 7 local MAHs. Furthermore, 7 MAHs were inspected through local distributors, as presented in Figures 1 and 2.

Figure 1 - The distrubution of inspections conducted by type during 2024

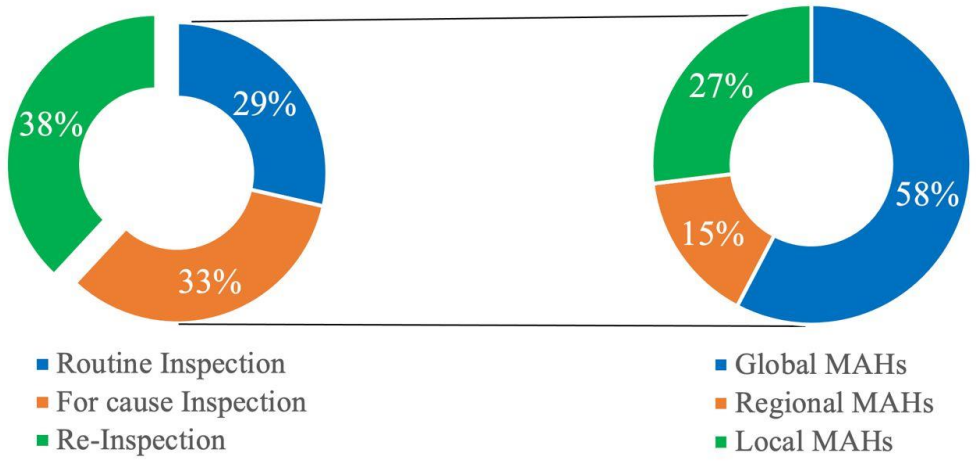
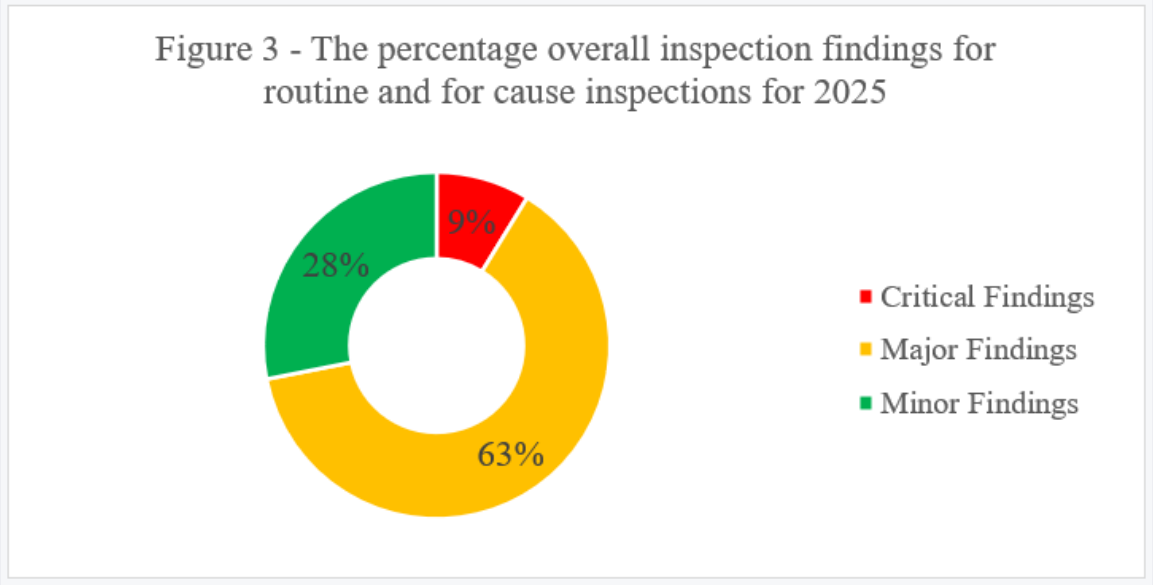


Figure 2 - The distrubution of the third party inspections conducted by type during 2025

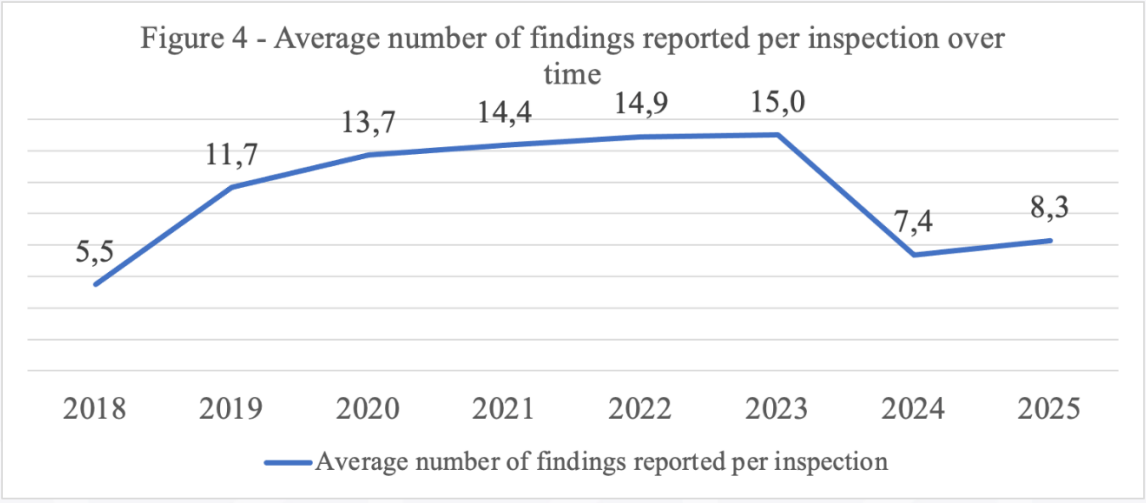
3 Summary of findings during the reported period

During the 2025 reporting period, a total of 19 critical findings, 137 major findings, and 61 minor findings were identified. It is important to note that a single reported finding may encompass multiple instances of non-compliance against the requirements of the Saudi Good Pharmacovigilance Practices (GVP) or may reflect the cumulative impact on the pharmacovigilance system.

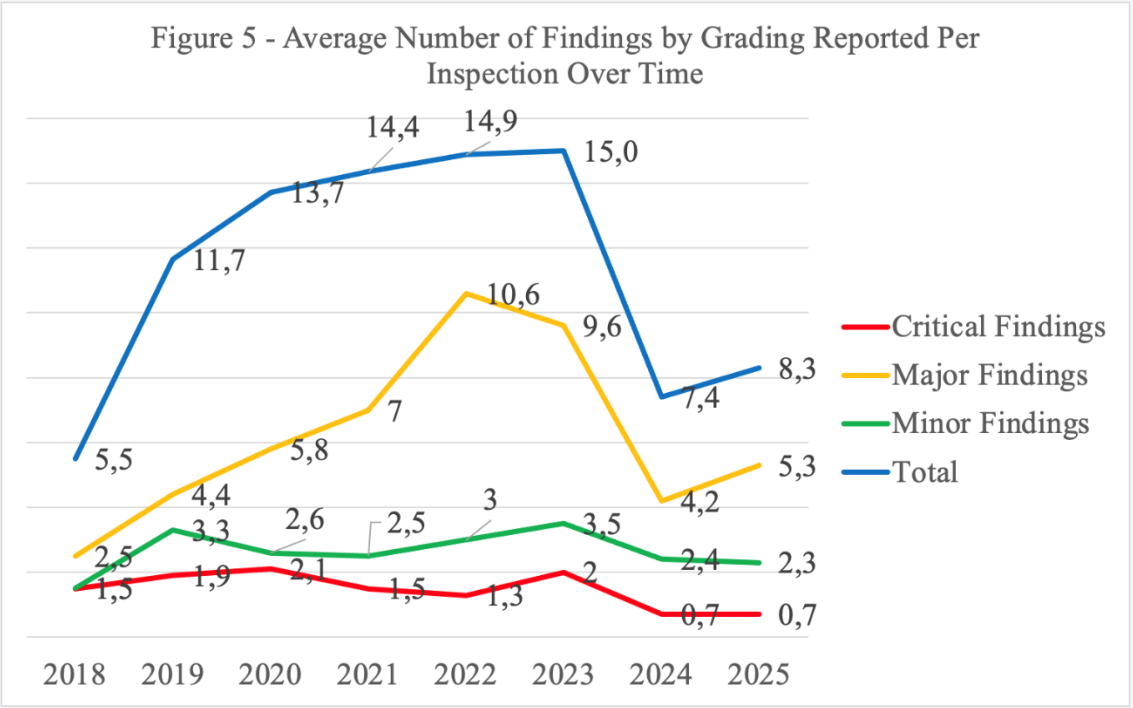


Among the inspections conducted, there were instances where a targeted scope was applied. These inspections, referred to as trigger inspections, focused on a specific technical area and were initiated by the NPC departments, with the purpose of reviewing the overall system within the selected area of focus.

With respect to inspection outcomes over time, the average number of findings per inspection (irrespective of grading) increased in 2025. The average increased from 7.4 to 8.3, representing a 12.2% increase, as shown in Figure 4.



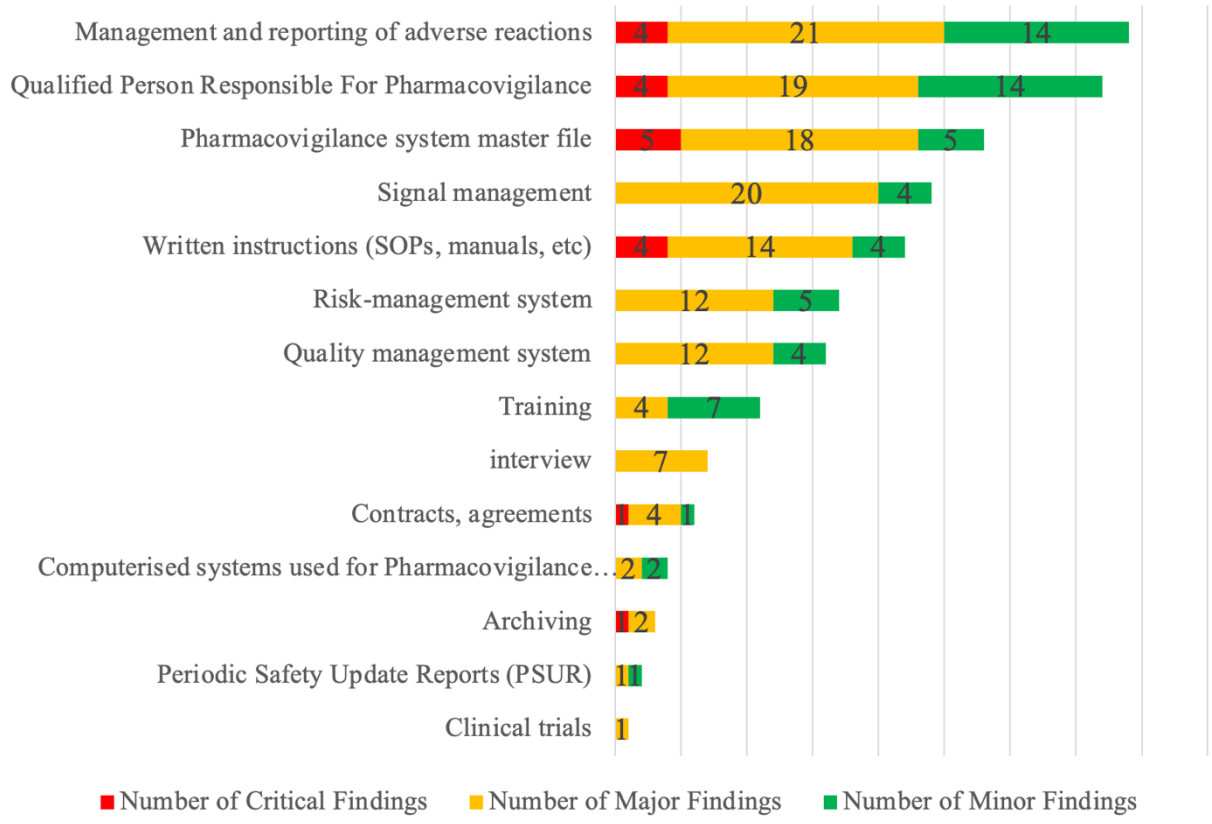
A review of the annual average findings by grading is presented in Figure 5.



Over the years, the average number of critical findings per inspection has remained stable at 0.7, while the average number of major findings per inspection increased. Overall, the average number of findings per inspection has slightly increased, with major findings increasing from 4.2 to 5.3 and minor findings slightly decreasing from 2.4 to 2.3. Variations in findings over time may be influenced by multiple factors, including the introduction of an update to the Saudi GVP during 2025—which required MAHs to adapt and implement changes—and the application of risk-based inspection planning and targeted inspection scopes in certain cases.

When findings were analyzed by topic area, Figure 6 shows that the highest proportion of findings (regardless of grading) related to the management of adverse drug reactions, accounting for 18% (39 out of 217 findings). This was followed by the Qualified Person Responsible for Pharmacovigilance (QPPV) at 17.1% (37 out of 217), and the Pharmacovigilance System Master File (PSMF) at 12.9% (28 out of 217). Notably, these three topics also represented a significant proportion of findings in 2022 and 2023, indicating their continued importance as areas for improvement. Signal Management ranked next with 24 findings (11.1%), followed by Written Instructions (SOPs, manuals) at 10.1%. The remaining findings were distributed across Risk-Management Systems, Training, PSURs, and Contracts/Agreements, each representing smaller proportions.

Figure 6 - Findings by topic area for 2025



4 Critical findings

4.1 Critical findings reported during 2025

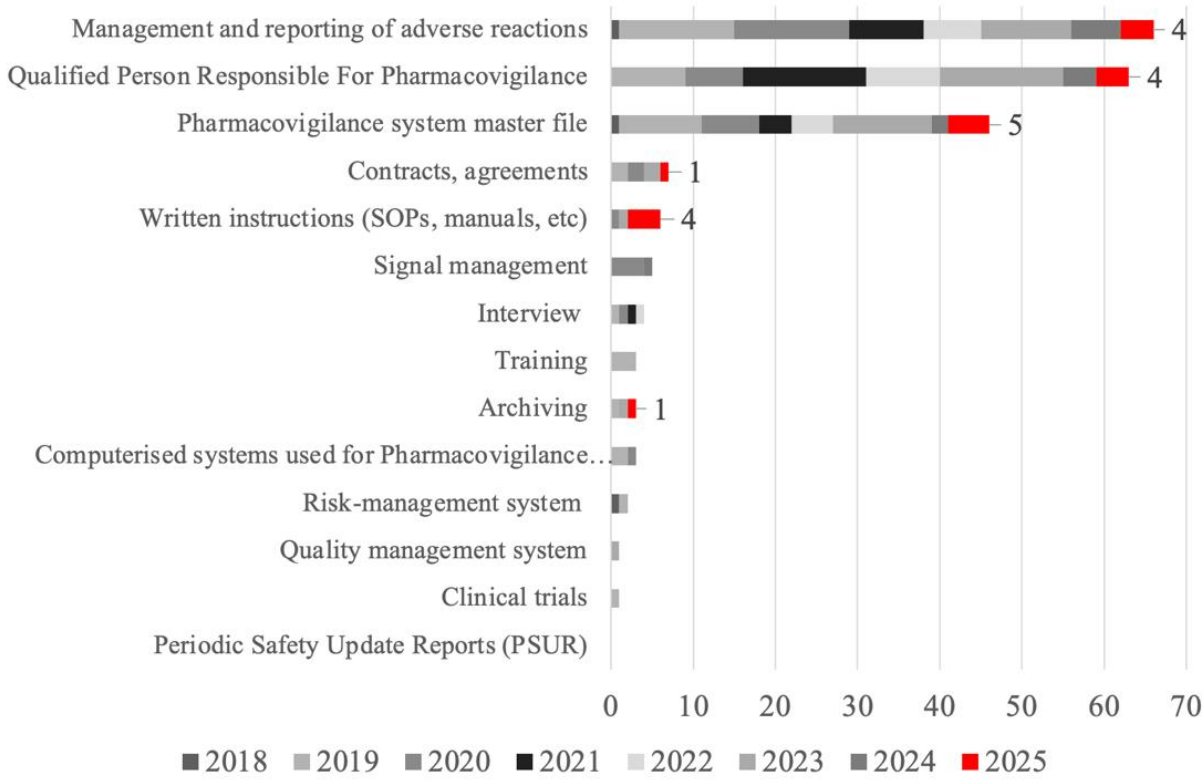
In 2025, a total of 19 critical findings were identified across 7 inspections. This corresponds to an average of approximately 2.7 critical findings per inspection where critical findings were identified (i.e., 19 critical findings across 7 inspections). The critical findings were observed within the following topic areas: Qualified Person Responsible for Pharmacovigilance (QPPV), Pharmacovigilance System Master File (PSMF), Management and reporting of adverse reactions, Contracts and agreements, Written instructions (SOPs, manuals, etc.), and Archiving.

4.2 Distribution of critical findings over time

From November 2018 to 31 December 2025, a total of 137 critical findings were reported. During the current reporting period (2025), 19 critical findings were identified across 7 out of 26 inspections, representing a constant value compared to the previous five reporting periods.

Figure 7 provides an overview of the number and distribution of critical findings across inspection topic areas since November 2018. The findings are grouped under broad categories that represent different components of the pharmacovigilance system. A more detailed breakdown of the specific nature of the findings within each category is provided in Appendix III.

Figure 7 - Number and distribution of critical findings across topics since 2018 until 2025



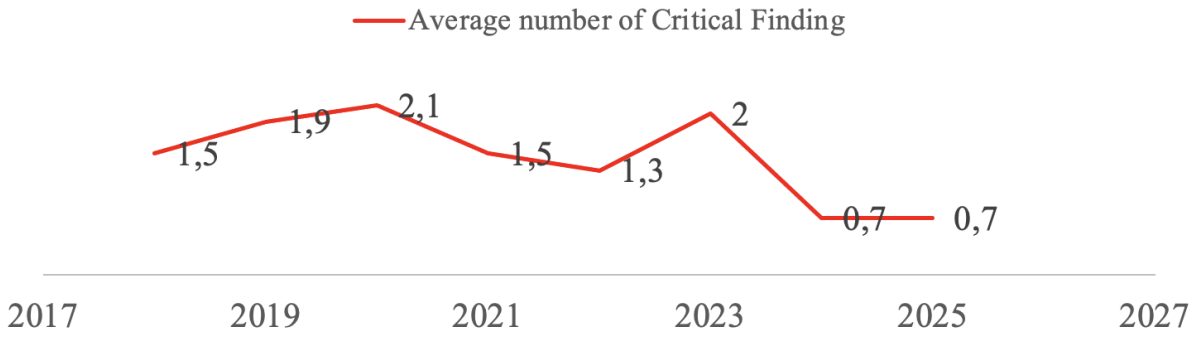
Over time, Management and reporting of adverse reactions remains the topic with the highest number of critical findings. In 2025, four critical findings in this area were related to data collection methods. QPPV also continued to yield critical findings, with four critical findings reported in 2025. Similarly, the PSMF has historically been an area associated with frequent critical findings, and five critical findings were reported in this area in 2025. The recurrence of critical findings across these topics over multiple years indicates a continued need for focused attention and improvement.

A notable trend was also observed in relation to Written Instructions (e.g., SOPs, manuals, and procedural documents), where the number of observations increased fourfold compared to previous years, despite only one critical finding being reported in 2019 and 2023. Conversely,

findings related to Contracts and Agreements showed a 50% decrease compared to previous years; however, critical findings continued to be identified, with two critical observations reported in 2019, 2020, and 2023.

Overall, in 2025, an average of approximately 0.7 critical findings per inspection was reported across all inspections, which is consistent with the previous reporting period, as shown in Figure8.

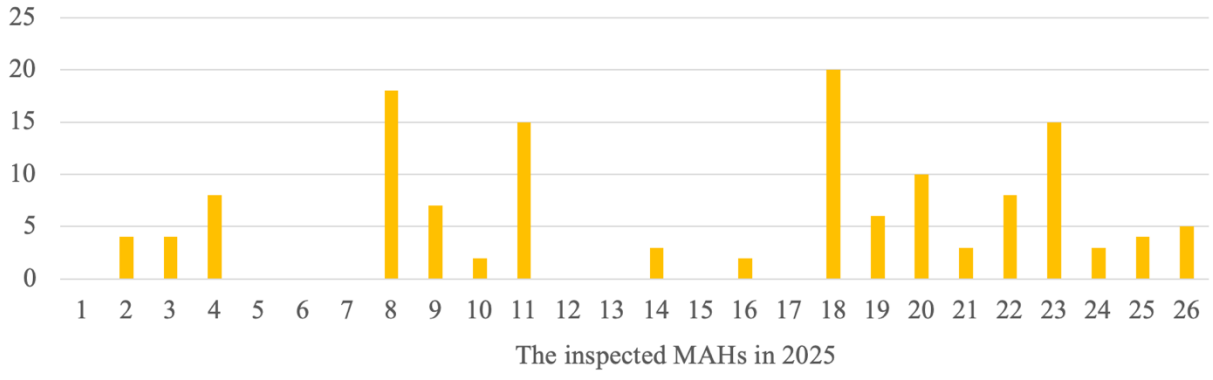
Figure 8 - Average Number of Critical Finding Per Reported Inspection Over Time



5 Major findings

During the 2025 reporting period, the number of major findings per inspection varied from 0 to 20. Notably, eight inspections did not generate any major findings. Across the 26 inspections conducted in 2025, the average number of major findings per inspection was 5.3. The distribution of major findings across inspections is presented in Figure 9.

Figure 9 - Number of major findings reported by the number of inspections in 2025



A total of 137 major findings were identified in 2025. These findings were categorized under broad topic areas covering multiple components of the pharmacovigilance system. For further details on the specific nature of findings within each topic, please refer to Appendix II.

Figure 10 - Percentage of major findings reported for each topic area during 2025

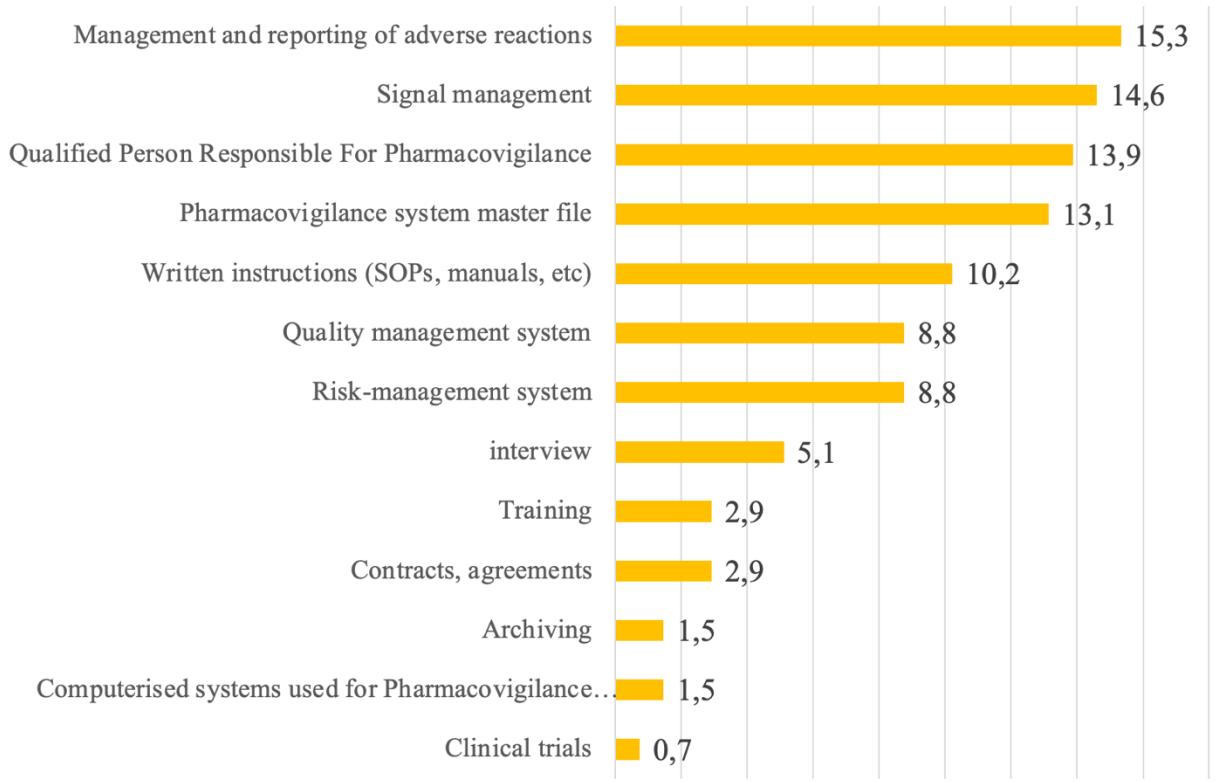
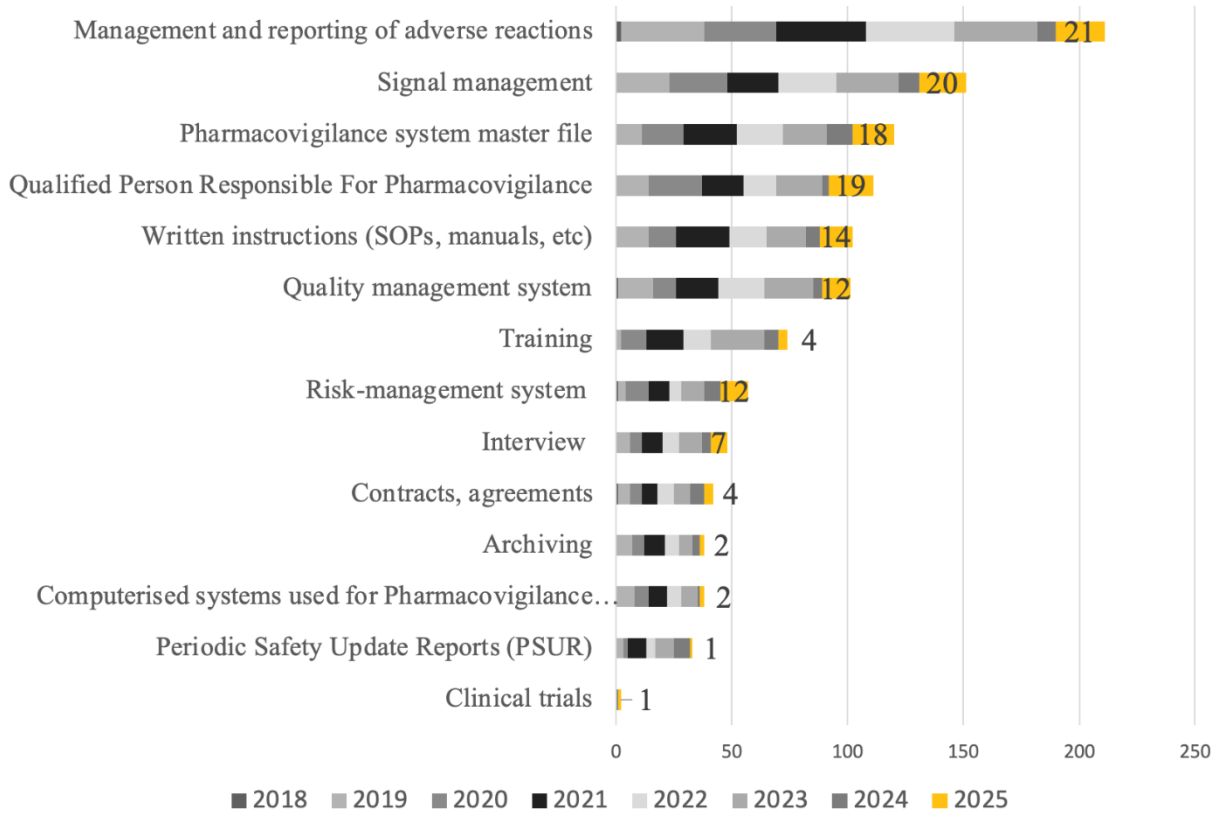


Figure 10 illustrates the distribution of major findings by topic and highlights the following key areas: Management and Reporting of Adverse Reactions accounted for the highest proportion with 21 findings (15.3%), followed by Signal Management with 20 findings (14.6%). Findings related to the Qualified Person Responsible for Pharmacovigilance (QPPV) represented 19 findings (13.9%), reflecting deficiencies that may relate to QPPV oversight, role expectations, and delegation arrangements during QPPV absence. The Pharmacovigilance System Master File (PSMF) accounted for 18 findings (13.1%), indicating potential gaps in the documentation, organization, or maintenance of the PSMF. Written Instructions (SOPs, manuals) accounted for 14 findings (10.2%), highlighting deficiencies in the development, implementation, or adherence to key procedural documents. Addressing major findings in these domains is essential to strengthen pharmacovigilance practices, support patient safety, and maintain compliance with regulatory requirements.

Figure 11 - Number and distribution of major findings across topics over time since 2018 until 2025

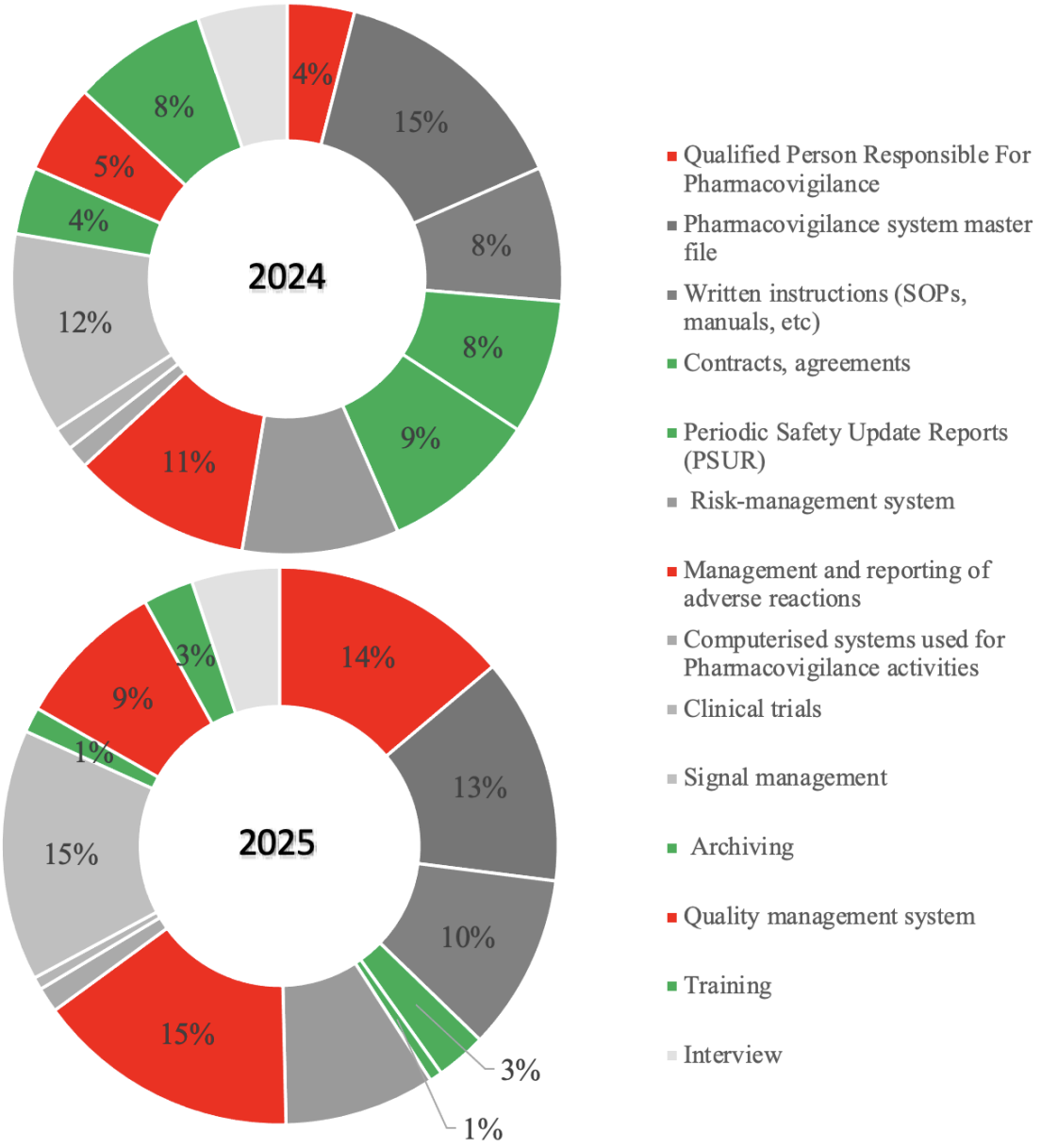


From November 2018 to 31 December 2025, a total of 1,128 major findings were reported, representing approximately 64.6% of all findings over the period. In the current reporting period, 137 major findings were identified across 18 out of 26 inspections. Figure 11 illustrates the distribution of major findings by topic since November 2018.

A comparison of major findings between the 2024 and 2025 reporting periods indicates variability in the proportional distribution across inspection domains, while the overall profile remains broadly consistent. Several topics increased in their proportional share of major findings: QPPV increased from 4% in 2024 to 14% in 2025; Management and Reporting of Adverse Reactions increased from 11% to 15%; and Quality Management System (QMS)-related findings increased from 5% to 9%, as shown in Figure 12. These areas reflect persistent challenges related to pharmacovigilance oversight, governance, and quality framework implementation, and are directly linked to an MAH's ability to detect, assess, and manage safety risks in a timely and compliant manner.

In contrast, other topics decreased in their proportional distribution: Contracts and Agreements decreased from 8% in 2024 to 3% in 2025; PSURs decreased from 9% to 1%; Archiving decreased from 4% to 1%; and Training decreased from 8% to 3%. This may indicate improved alignment with regulatory requirements in these areas, potentially supported by targeted corrective actions and increased regulatory awareness following previous inspections, as well as improved procedural standardization and documentation practices within inspected entities.

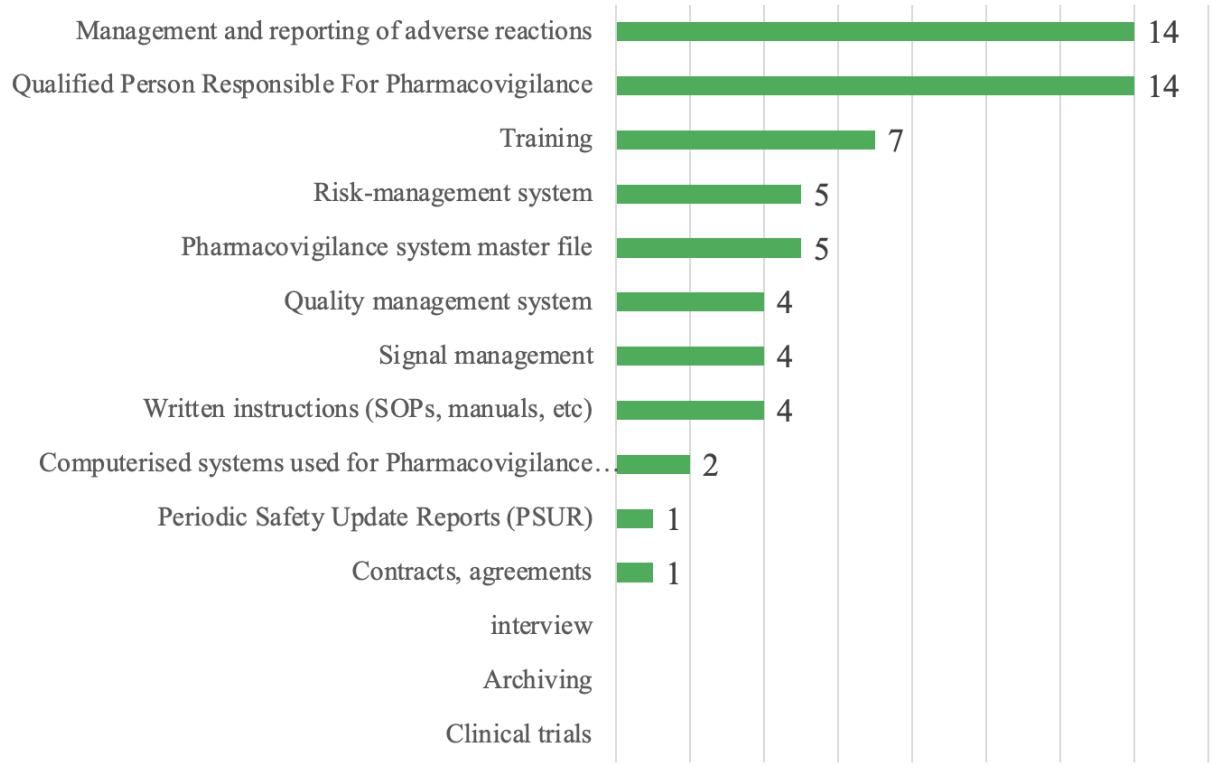
Figure 12 – Percentage change in the major findings between inspection findings from 2024 to 2025 by topic area



6 Minor findings

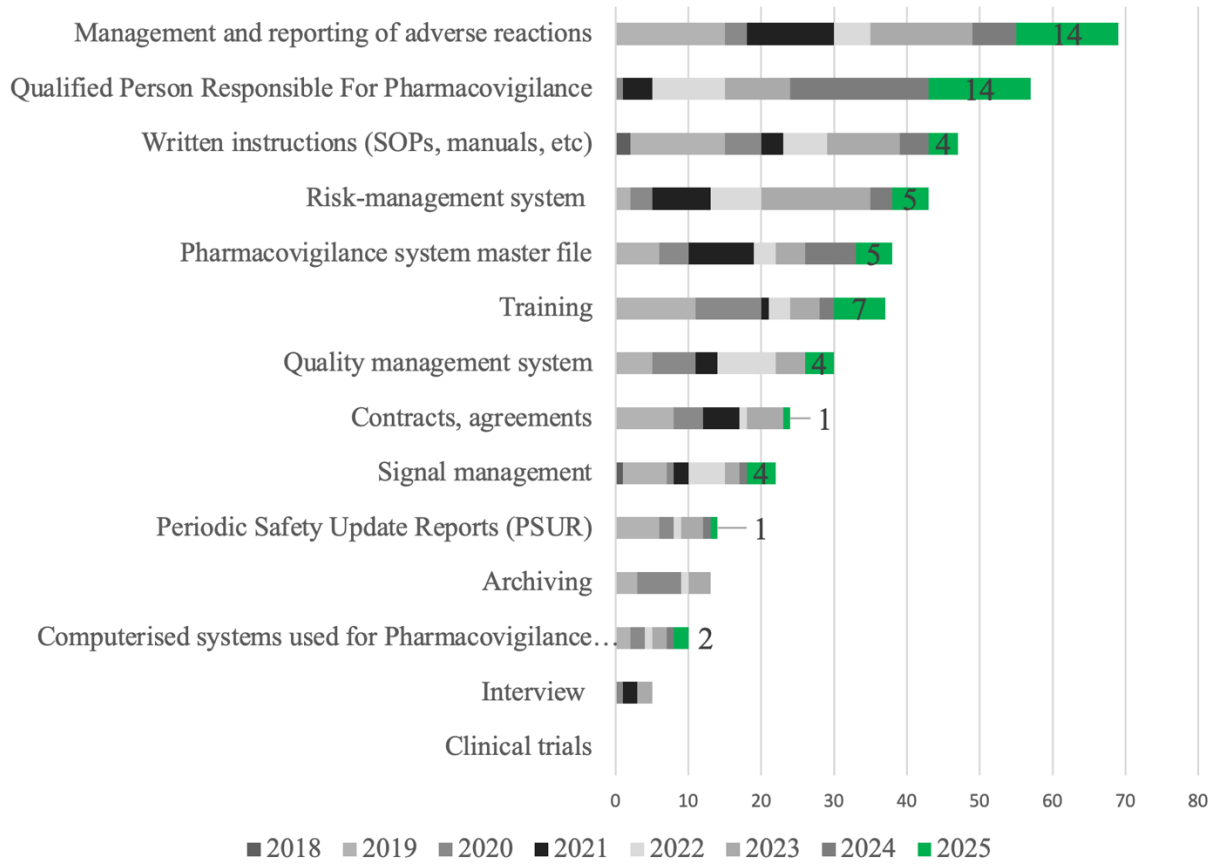
In 2025, a total of 61 minor findings were identified. Figure 13 provides an overview of the proportion of minor findings by topic area for the 2025 reporting period, illustrating the distribution of minor observations across the different pharmacovigilance domains assessed during inspections.

Figure 13 - Proportion of minor findings reported for each topic area in 2025



The highest proportion of minor findings was observed in Management and Reporting of Adverse Reactions and the Qualified Person Responsible for Pharmacovigilance (QPPV), with both areas contributing at comparable levels. This was followed by findings related to Training. Collectively, these areas accounted for a substantial share of minor findings, indicating opportunities to further strengthen compliance, improve documentation quality, and reinforce the consistent implementation of pharmacovigilance requirements.

Figure 14 - Number and distribution of minor findings across topics since 2018 until 2025



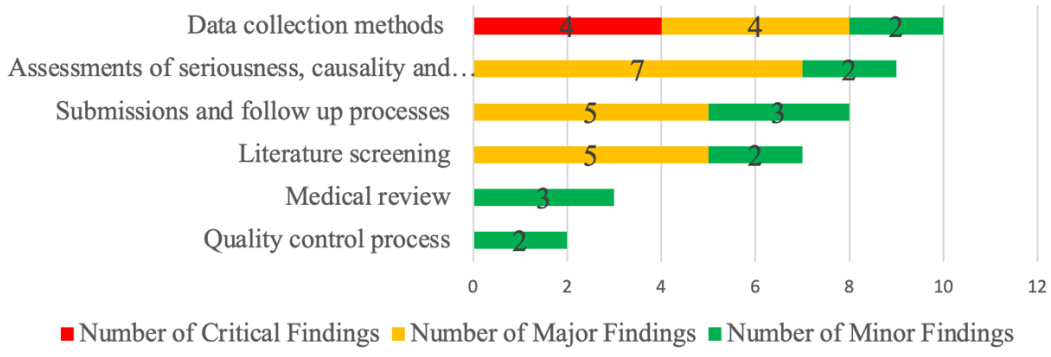
Over time, Management and Reporting of Adverse Reactions has remained a leading contributor to minor findings and continued to show elevated activity in 2025. QPPV findings also remained prominent during the same period, indicating recurring gaps requiring ongoing attention. Minor findings related to Training and Risk-Management Systems were also observed in 2025. In contrast, while Contracts and Agreements contributed to minor findings historically, the proportion observed in 2025 was lower compared to previous years.

7 Focus topics

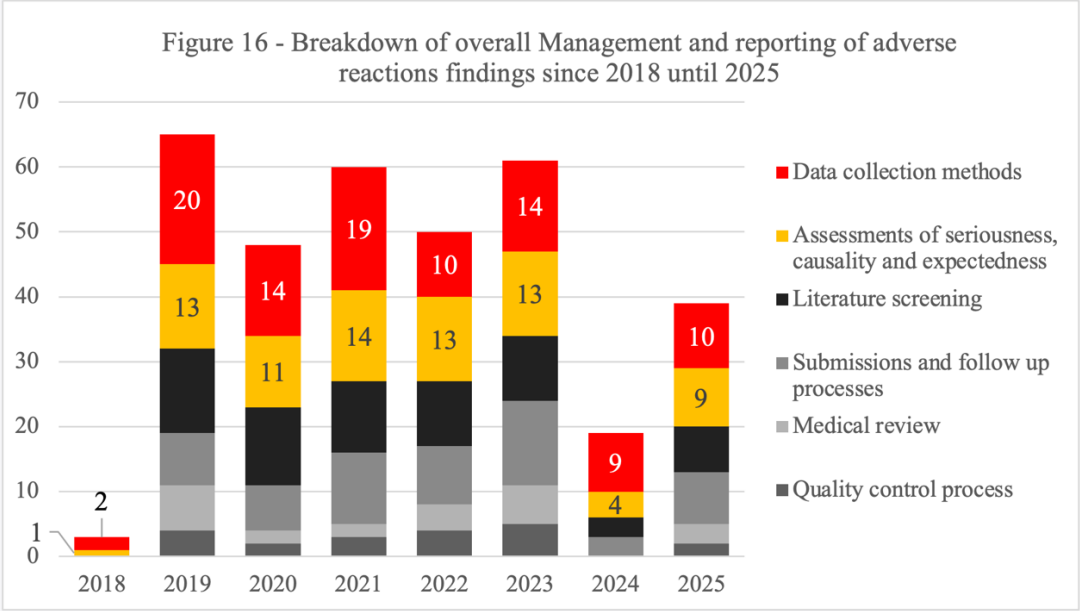
During the reporting period, and irrespective of finding grading, the topic with the highest number of total findings was Management and Reporting of Adverse Reactions. This was followed by the Qualified Person Responsible for Pharmacovigilance (QPPV) and the Pharmacovigilance System Master File (PSMF). Together, these areas accounted for the largest proportion of findings identified during inspections, highlighting their critical importance for compliance, system effectiveness, and targeted improvement initiatives.

7.1 Management and reporting of adverse reactions

Figure 15 - Breakdown of Management and reporting of adverse reactions findings in 2025



Across recent reporting periods, Management and Reporting of Adverse Reactions has consistently been the leading topic for inspection findings Figures 15. In the current reporting period, this topic represented 39 out of 217 findings (approximately 18%). Figure 16 presents a detailed breakdown of these findings by sub-topic, supporting identification of the areas where findings were most concentrated and where trends warrant focused attention.



By reviewing the color segments across the years, Data collection methods consistently represents the largest or second-largest portion of findings within the Management and Reporting of Adverse Reactions topic. Even in the comparatively lower year of 2024, this sub-topic accounted for nearly half of the findings (9 out of ~19), suggesting a persistent and recurring weakness in the way adverse reaction data are collected. In addition, Assessments of seriousness, causality, and expectedness emerges as a secondary contributor, while the lower segments remain relatively stable over time, indicating a continuing baseline level of non-compliance that has not substantially reduced over the past seven years.

The consistently high number of findings in this area underscores the need for robust processes and controls to ensure effective collection, assessment, and reporting of adverse reactions. Implementing corrective actions in this domain is essential to strengthen pharmacovigilance practice and support patient safety.

The largest concentration of findings within this topic related to data collection methods. Specifically, 10 findings were associated with limited channels for receiving adverse drug event reports. The most common non-compliance issues included:

- Absence of a phone number or Arabic website for the public to report adverse events.
- Lack of a system to document and process locally received cases.
- Inability of the local QPPV to access the MAH safety database to manage local ICSRs.
- Inability of the local QPPV to access Saudi market medical representatives for adverse event report collection.

- Lack of a database or Excel sheet for documenting local cases.
- Presence of the Saudi Arabia webpage in the global drop-down list.
- Lack of connection between the available website and key pharmacovigilance links.
- Outdated information on the MAH website for the public to report adverse events.

The second-largest group of findings related to deficiencies in assessing seriousness, causality, and expectedness of reported adverse events. Nine findings were identified, with the most common issues being exclusion of the local QPPV from these processes or lack of awareness of how these assessments were performed.

In addition, eight findings related to submissions and follow-up processes within the management and reporting of adverse reactions. The most frequent issues included:

- Failure to update the local SOP in line with SFDA–NPC regulations for reporting local ICSRs and quality reports.
- Absence of an SOP or defined requirements for submissions and follow-ups.
- Insufficient awareness by the local QPPV of ICSR submission timeframes and follow-up criteria.

Furthermore, seven findings were related to literature screening, where common non-compliances included:

- Failure to conduct literature screening of local journals in Saudi Arabia.
- Lack of a defined screening timeframe and insufficient documentation of previous attempts.
- Lack of involvement from both the global team and the local QPPV in literature screening activities.
- Absence of an SOP describing the local literature screening process (frequency, documentation, and local QPPV involvement).
- Absence of an SOP describing oversight of the vendor responsible for literature screening (periodicity, reconciliation, and MAH auditing).
- Inconsistency between SOPs and actual practice.
- Failure to perform literature screening as required in the SOP and safety agreement.
- Absence of periodic reconciliation with the global team regarding literature screening outcomes.
- Performance of literature screening by the QPPV without appropriate review or proofing.

In addition, 5 findings highlighted gaps in medical review and quality control processes, where either SOPs were not available or actual practices were not aligned with documented procedures.

A recurring theme across multiple subtopics was the limited governance and oversight role of the Local QPPV, particularly where pharmacovigilance activities were delegated to global teams or vendors without adequate documentation, supervision, or reconciliation mechanisms.

Furthermore, discrepancies between documented SOPs and actual practices, as well as incomplete alignment with updated Saudi GVP requirements, indicate the need for strengthened lifecycle management of the pharmacovigilance system.

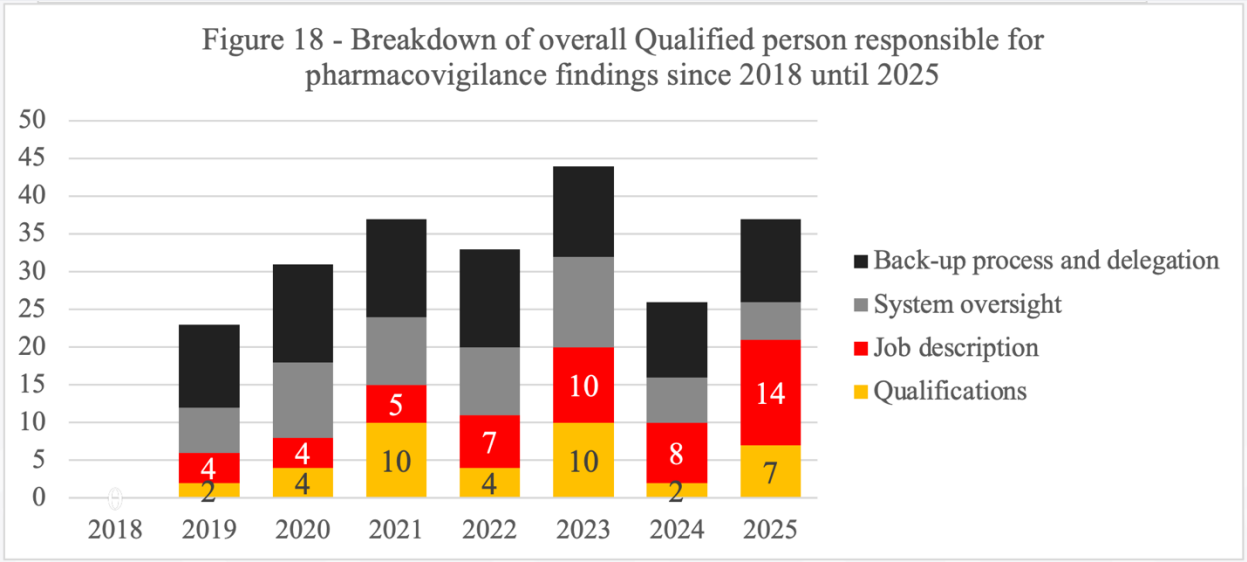
7.2 Qualified person responsible for pharmacovigilance

In 2025, findings related to the Qualified Person Responsible for Pharmacovigilance (QPPV) accounted for the highest number of findings among all topics, with 37 out of 217 findings (17.1%) attributed to this area. For a detailed breakdown of QPPV findings by sub-topic, please refer to the relevant figure 17.

Figure 17 - Breakdown of Qualified person responsible for pharmacovigilance findings in 2025

Within the QPPV topic, job description represented the sub-topic with the highest number of findings (14 findings). This was followed by findings related to back-up process and delegation (11 findings), Qualifications (11 findings), and system oversight (5 findings). These sub-topics included critical, major, and minor findings.

Figure 18 indicates that Job Description is the most variable sub-topic over time, reaching 14 findings in 2025, while Qualifications fluctuated across years. In contrast, Back-up process and delegation and System oversight remained consistently present across the reporting periods, indicating persistent structural gaps that have not been effectively reduced over time and continue to require sustained corrective action.



The most common non-compliances observed under back-up process and delegation included:

- Absence of a clear, written back-up and delegation SOP or process.
- Inadequate documentation and implementation of the back-up and delegation process.

Under system oversight, a common non-compliance was the lack of awareness or involvement of the local QPPV in implemented PV activities or delegated responsibilities, both locally and globally.

For the job description of the local QPPV, the most prevalent non-compliance issues were:

- Absence of a job description specifically addressing local pharmacovigilance activities.
- Failure of the local QPPV to sign the provided job description.
- Lack of clarity regarding the responsibilities of the local QPPV in the job description.
- Inadequate implementation of the available job description.
- Omission of certain responsibilities of the local QPPV in the job description.

Lastly, common non-compliances related to qualifications of the local QPPV included:

- The local QPPV not dedicating full-time capacity to pharmacovigilance activities.
- Inspection being conducted by a Deputy-QPPV with no local QPPV present at the MAH.
- Failure of the MAH to assign a local QPPV.
- Lack of awareness by the local QPPV of the requirements outlined in the Saudi GVP guideline.

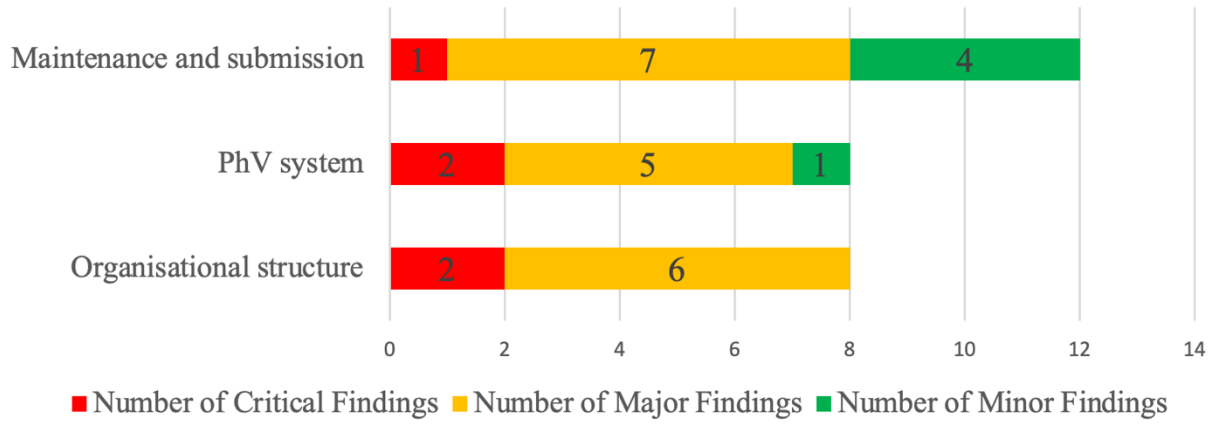
In addition, several findings highlighted weaknesses in regulatory oversight and inspection readiness, including limited awareness by the local QPPV of marketed products in Saudi Arabia, incomplete management of QPPV and Deputy QPPV changes, and inadequate maintenance of regulatory records with SFDA.

A recurring pattern across multiple sub-topics was the gap between documented procedures and actual practices, indicating deficiencies in governance execution rather than procedural availability.

7.3 The pharmacovigilance system master file

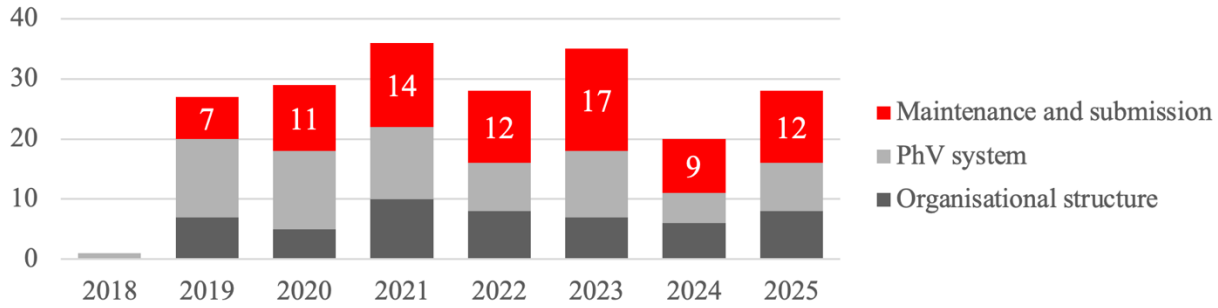
In 2025, the Pharmacovigilance System Master File (PSMF) represented the third-largest category of findings. Out of a total of 217 findings, 28 were related to the PSMF (12.9). For a detailed breakdown of these findings, please refer to the relevant Figure 19.

Figure 19 - Breakdown of The Pharmacovigilance system master file findings in 2025



As illustrated in Figure 20, the pattern across years appears relatively consistent, suggesting a persistent baseline of findings. Maintenance and submission remains the primary contributor, frequently accounting for a substantial proportion of findings. The continued presence of findings related to organizational structure and the pharmacovigilance system indicates that, while the specific issues may vary, structural aspects of PSMF governance and implementation require sustained attention to achieve a long-term reduction.

Figure 20 - Breakdown of overall The Pharmacovigilance system master file findings since 2018 until 2025



Within the PSMF topic, Maintenance and submission recorded the highest number of findings (9 findings), followed by Organizational structure (6 findings) and Pharmacovigilance system (5 findings). These sub-topics included critical, major, and minor findings.

Common non-compliances in “Maintenance and submission” included:

- Incompatibility of the provided PSMF/PSSF with the template required under the Saudi GVP guidelines.
- Absence of SOPs describing preparation, maintenance, and update frequency of the local PSMF/PSSF.
- Limited accessibility of the local QPPV to the MAH PSMF unless requested by the SFDA.
- Missing PSMF/PSSF document at the inspected MAH.
- Lack of clarity regarding the authorizing party and required signatories.
- Use of generalized language in the PSSF that does not reflect harmonization between the regional team and the local QPPV.
- Availability of an outdated PSMF with gaps in critical information.

Common non-compliances in “Organizational structure” included:

- Inadequate representation of actual practice and the relationship between the local QPPV and the global team.

- Organizational structure provided in draft form and not authorized by the MAH.

Common non-compliances in “Pharmacovigilance system” included:

- Limited awareness or knowledge of the pharmacovigilance system in the MAH’s global office and/or restricted access for the local QPPV.
- Absence of an electronic system for handling pharmacovigilance activities.

In addition, several findings highlighted deficiencies in governance and documentation accuracy, including misaligned reporting lines affecting the functional independence of the Local QPPV, inconsistencies between system access and its reflection in the PSMF/PSSF, and the use of generalized or multi-MAH documentation not compliant with the single PSMF requirement under Saudi GVP.

These gaps indicate weaknesses in pharmacovigilance system governance, documentation lifecycle management, and regulatory transparency.

8 Engaging the stakeholders in Saudi GVP update

In 2025, the inspection team organized three workshops for all Qualified Persons Responsible for Pharmacovigilance (QPPVs) and their deputies. The workshops aimed to raise awareness of the updated Saudi Good Pharmacovigilance Practices (GVP) (released in August 2025) and to address challenges encountered by professionals in fulfilling their roles. The sessions provided an overview of the updated requirements, including the revised timeframes for pharmacovigilance activities and relevant legislative changes introduced in the guideline update.

In addition, the workshops served as a platform to identify knowledge gaps and to discuss practical challenges faced by attendees in day-to-day operations. Representatives from the National Pharmacovigilance Center (NPC) participated to provide clarification on departmental updates and to respond to questions and concerns raised during the sessions.

To evaluate workshop effectiveness, the NPC implemented pre- and post-assessments to measure participants’ understanding before and after the sessions. The NPC also conducted a satisfaction survey to gather feedback on the workshops and to capture participants’ expectations and suggestions for future events of a similar nature.

9 Summary

During 2025, the National Pharmacovigilance Center (NPC) within the Saudi Food and Drug Authority (SFDA) conducted 26 pharmacovigilance inspections of Marketing Authorization Holders (MAHs), comprising 12 routine and 14 for-cause inspections. A total of 217 findings were identified, including 19 critical, 137 major, and 61 minor findings. The inspection outcomes show that the most significant compliance pressures continue to sit within a small number of core pharmacovigilance domains, which together represent the majority of observations across all grading. Across all findings (irrespective of grading), the leading topic was Management and Reporting of Adverse Reactions (39/217; 18%), followed by Qualified Person Responsible for Pharmacovigilance (QPPV) (37/217; 17.1%) and the Pharmacovigilance System Master File (PSMF) (28/217; 12.9%). These were followed by Signal Management (24 findings; 11.1%) and Written Instructions (SOPs/manuals) (10.1%).

Collectively, these topics represent the primary areas where MAHs most frequently fell short of expectations and where improvements would be expected to deliver the greatest impact on overall pharmacovigilance compliance. The pattern is also evident when focusing specifically on major findings. In 2025, the largest proportions of major findings were recorded in Management and Reporting of Adverse Reactions (21; 15.3%), Signal Management (20; 14.6%), QPPV (19; 13.9%), PSMF (18; 13.1%), and Written Instructions (14; 10.2%).

For critical findings, 19 critical findings were identified across 7 inspections, spanning key system elements including QPPV, PSMF, Management and Reporting of Adverse Reactions, as well as Contracts and Agreements, Written Instructions, and Archiving—indicating that critical risks were not limited to a single operational area. Minor findings were most prominent in Management and Reporting of Adverse Reactions and QPPV (at comparable levels), followed by Training, which points to continued opportunities to strengthen implementation consistency and supporting documentation.

Finally, the report notes that the Saudi GVP guideline update introduced in August 2025, including changes to reporting timeframes and RMP activities, affected MAH compliance during the reporting year.

Appendix I: Inspection type definitions

*excerpt from page 100-105 of the Guideline on Good Pharmacovigilance Practices (GVP)

(Version 2.0, September 2015).

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.

Emergency Trigger inspection

An urgent inspection is performed by the Pharmacovigilance Inspection Team (PIT) to assess potential safety concerns associated with a pharmaceutical product. This inspection is generally initiated in response to emerging public health threats, taking precedence over the scheduled inspection plan and carried out with utmost priority to ensure timely assessment and mitigation of risks.

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 prioritize 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 2.0, September 2015).

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 findings

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 IV – Abbreviations

ADR Adverse Drug Reaction

AE	Adverse Event
aRMM	Additional Risk Minimization Measure
CAPA	Corrective and Preventative Action
GVP	Good Pharmacovigilance Practice
ICSR	Individual Case Safety Report
MAH	Marketing Authorization 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