Pharmacovigilance Inspection Metrics Report for the year 2024

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1. Introduction

Since 2015, PVGA has been conducting desk reviews of companies' pharmacovigilance systems, which involve reviewing compliance documents, such as PSMF documents submitted by organizations, rather than conducting on-site inspections.

Starting March 2020, the EDA started onsite Pharmacovigilance inspections.

The purpose of these inspections was to examine compliance with currently applicable Egypt pharmacovigilance regulations and guidelines.

PV systems are selected for inspection using a risk-based methodology that is aligned with the principles outlined in Good Vigilance Practice (GVP) Guidelines Chapter III, considering the critical pharmacovigilance processes outlined in GVP Guidelines Chapter I.

This report contains data relating to all 29 inspections conducted during 2024. Information on the types of inspection, inspection findings over time, and the data from each inspection arm has been examined.

In addition to analyzing the data from 2023 and 2024, the objective is to compare and assess the differences and their impact on the compliance process.

Findings identified during inspections were graded as critical, major, or minor; the definitions for which are included in Appendix I. The topics under which findings can be categorized are explained in Appendix II.

A list of abbreviations used throughout this report is provided in Appendix III.

2. Inspection model and review of findings

- **System and product-related Pharmacovigilance inspections** are designed to review the procedures, systems, personnel, and facilities in place and determine their compliance with regulatory pharmacovigilance obligations. As part of this review, product-specific examples may be used to demonstrate the operation of the pharmacovigilance system. Product-related pharmacovigilance inspections are primarily focused on product-related pharmacovigilance issues, including product-specific activities and documentation, rather than a general system review. Some aspects of the general system may still be examined as part of a product-related inspection (e.g. the system used for that product).

- **Routine and "for cause" pharmacovigilance inspections** are inspections scheduled in advance as part of inspection programs. There is no specific trigger to initiate these inspections, though a risk-based approach to optimize supervisory activities shall 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 with particular concerns. 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 on a specific product. However, full system inspections may also be performed as a result of a trigger.

- **Pre-authorization inspections** are inspections performed before a marketing authorization is granted. These inspections are conducted with the intention of examining the existing or proposed pharmacovigilance system as it has been described by the applicant in support of the marketing authorization application.

- **Post-authorization inspections** are inspections performed after a marketing authorization is granted and are intended to examine whether the marketing authorization holder complies with its pharmacovigilance obligations. They can be any of the types mentioned above.

- **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, in special situations, 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).

- **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.

- **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.

3. Overview of inspections conducted

There were 26 inspections of local organizations, 3 inspections of multinational organizations,

Figure 1 shows inspections conducted per company type.

All 29 inspections conducted in 2024 were scheduled and conducted in accordance with the routine national inspection schedule. However, 1 out of 29 was a re-inspection.

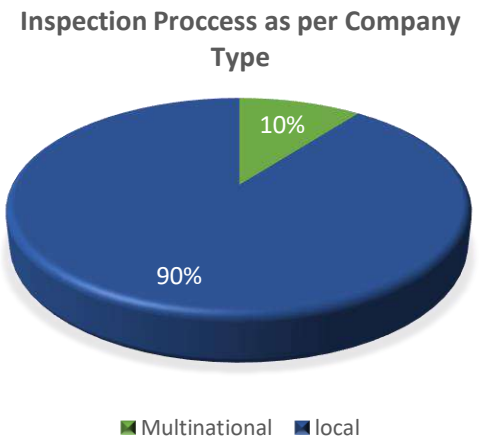


Figure 2 Shows a breakdown of the number of inspections conducted by inspection type

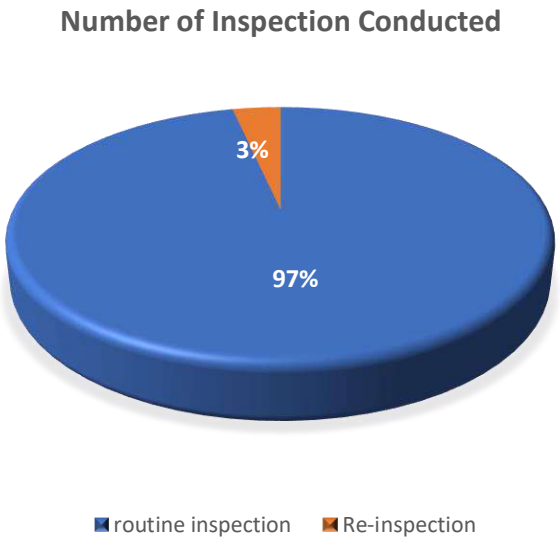


Figure 3 - Findings by topic area

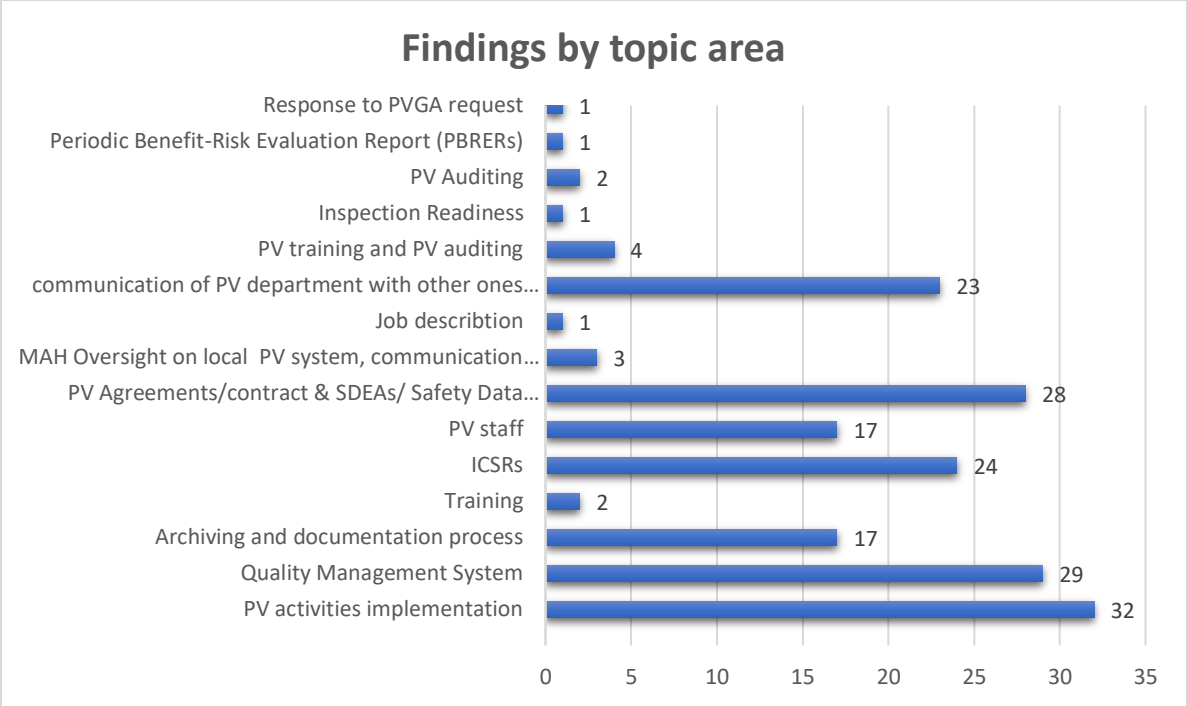
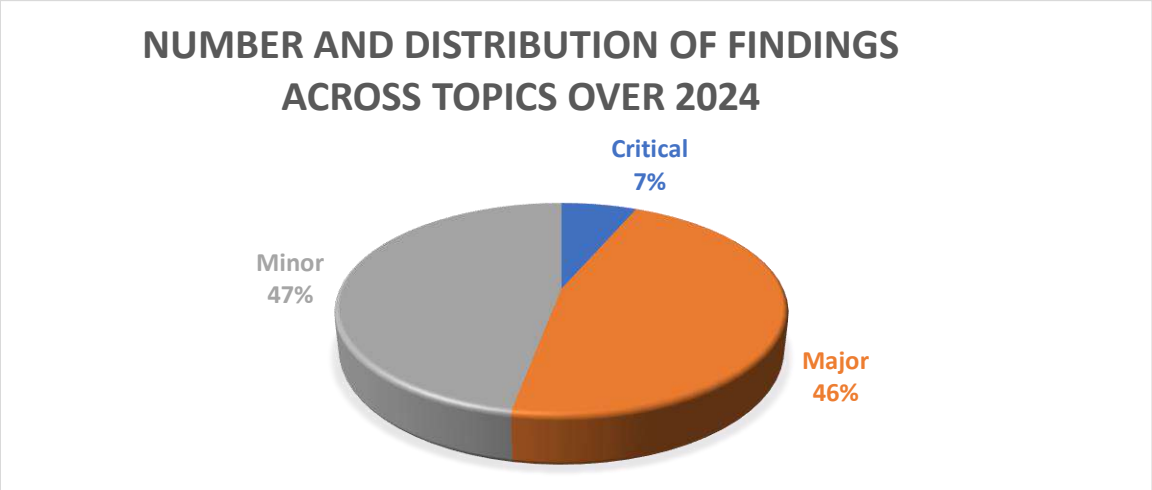


Figure 3 shows a breakdown of inspection findings reported in 2024 by topic area. For the purposes of this report, findings have been grouped by overarching topics across the pharmacovigilance system. The nature of findings covered by each topic is provided in Appendix II.

The highest proportion of observations, regardless of grading, was regarding the integration of the Quality Management System—highlighting the opportunity to enhance system efficiency beyond basic implementation. These findings were present in 100% of the inspected PV systems (29 out of 29).

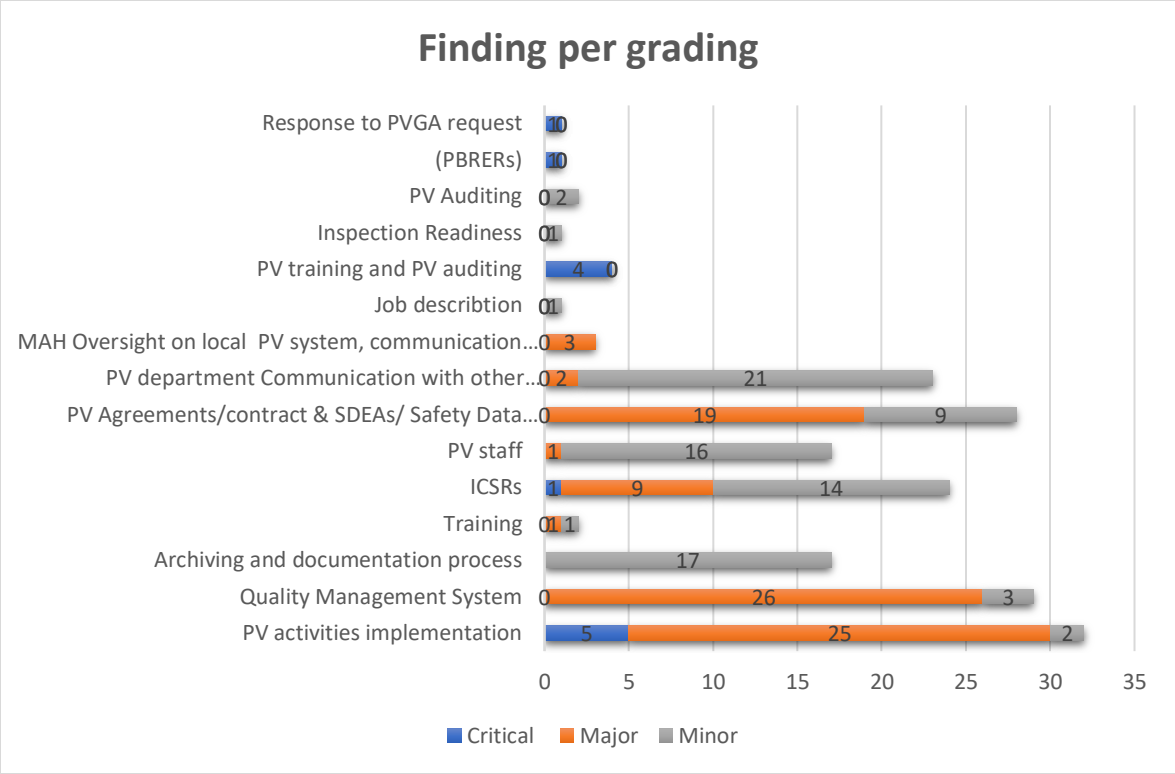
Additionally, findings were noted in 96.5% of systems (28 out of 29) regarding performance expectations in adopting a holistic approach to the implementation across various PV activities. A similar proportion of findings (96.5%) also related to PV Agreements/Contracts and SDEAs/Safety Data Migration

Figure 4 - Number and distribution of findings across topics over 2024



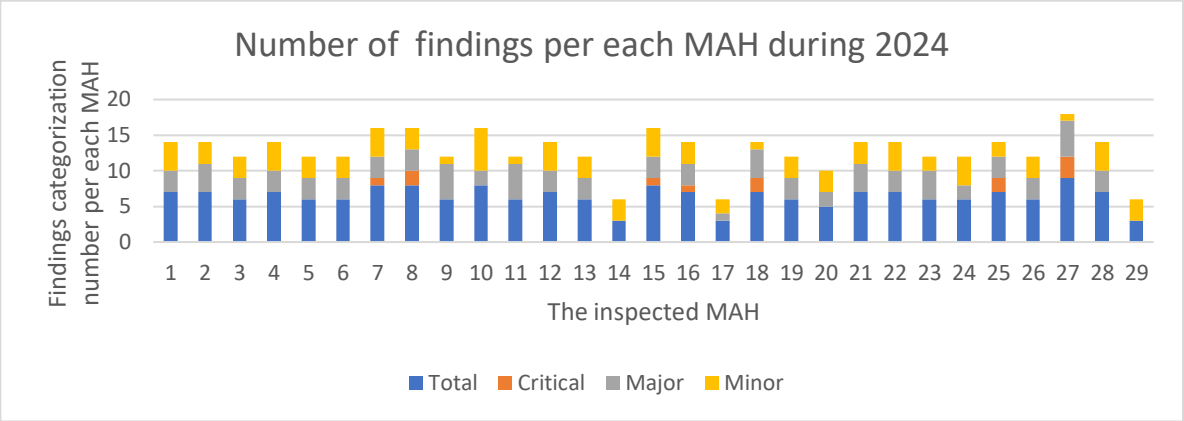
- **"PV activities implementation**" is the topic for which the largest number of critical findings has been detected overall.
- Then comes in 2nd place, **PV training and PV auditing**.
- **"The QMS"** is the topic for which the largest number of major findings has been detected overall, followed in 2nd place by **PV activities implementation**
- **"The Communication of the PV department with other departments locally and globally"** is the topic for which the largest number of Minor findings has been reported overall, then we got in the 2nd **Archiving and documentation process.**

Figure 5 – Breakdown of inspection findings per grading



A visual representation of the distribution of findings grading across inspections can be seen in Figure 5

Figure 6 – Number of findings per MAH during 2024



During this reporting period, the number of critical findings per inspection varied, ranging from zero to three. Considering that, **22 inspections** did not raise any critical findings at all, out of the twenty-nine inspections conducted in 2024.

The number of major findings per inspection varied, ranging from 5 to zero.

The number of minor findings per inspection varied, ranging from 6 to 1.

Figure 7– Number of critical findings per MAH during 2024

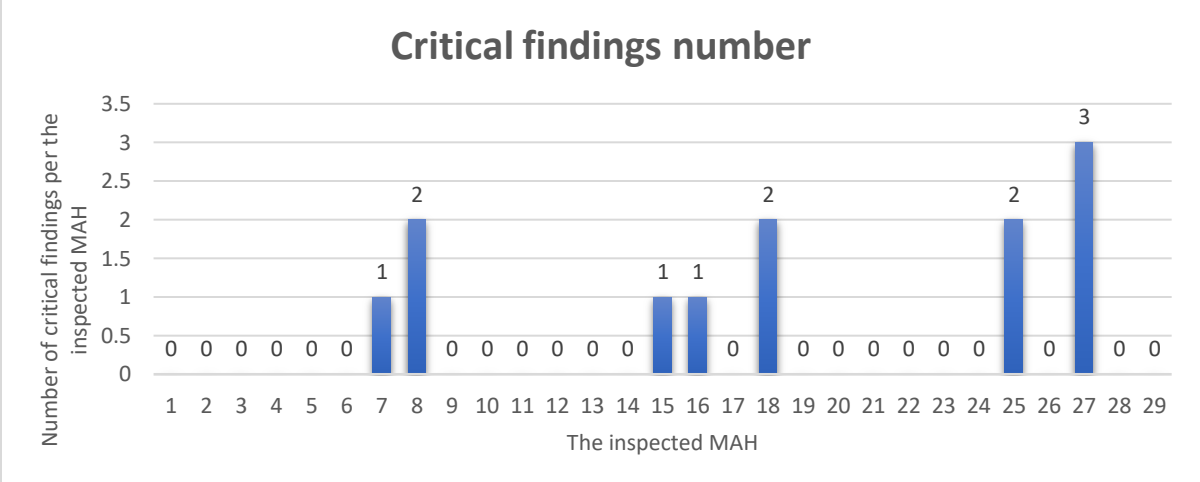


Figure 8 - Breakdown of PV activities implementation in 2024

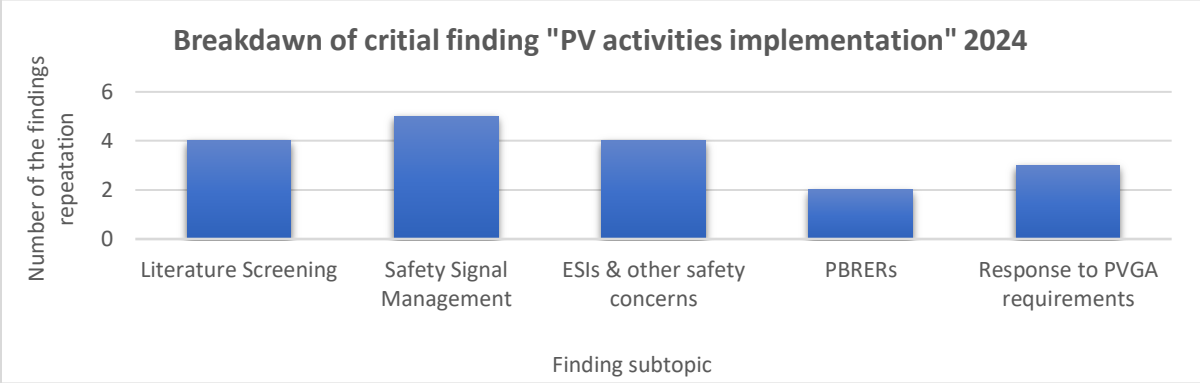


Figure 9 – Number of major findings per MAH during 2024

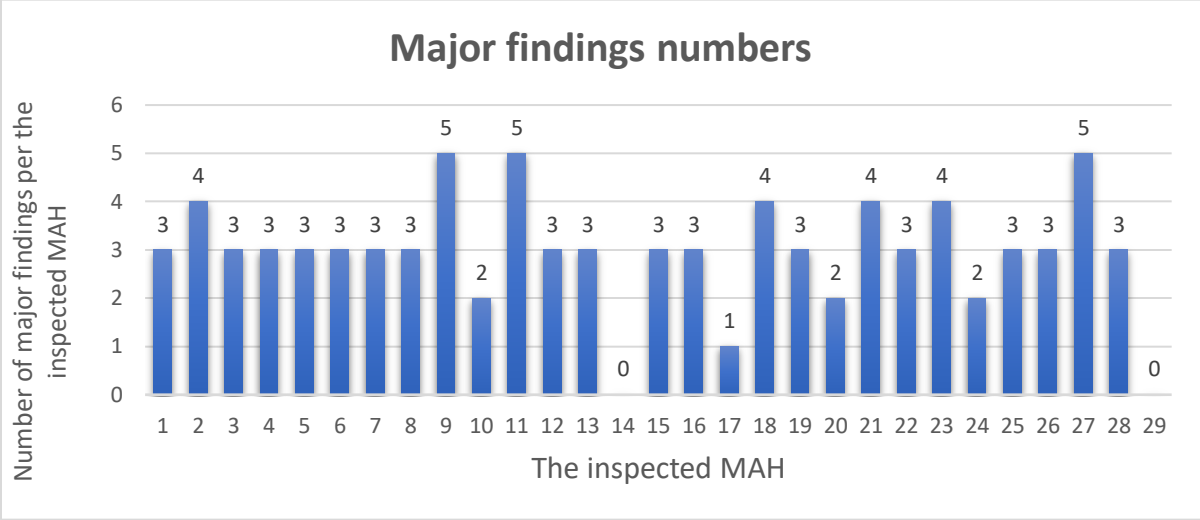


Figure 10 – Breakdown of the major finding areas of the implementation of the quality management system in 2024

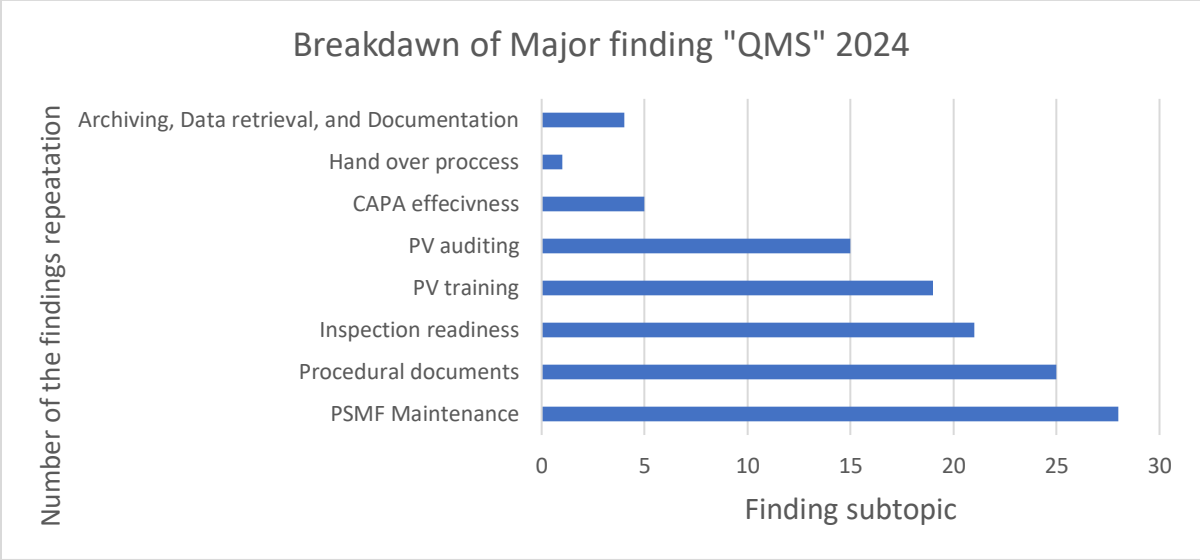


Figure 11 – Number of minor findings per MAH during 2024

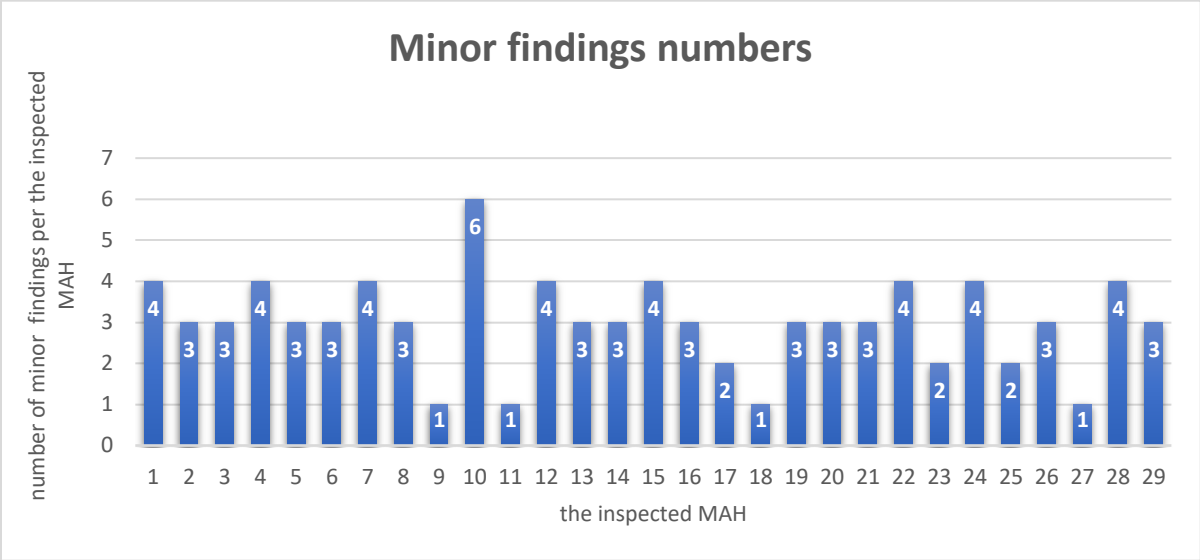
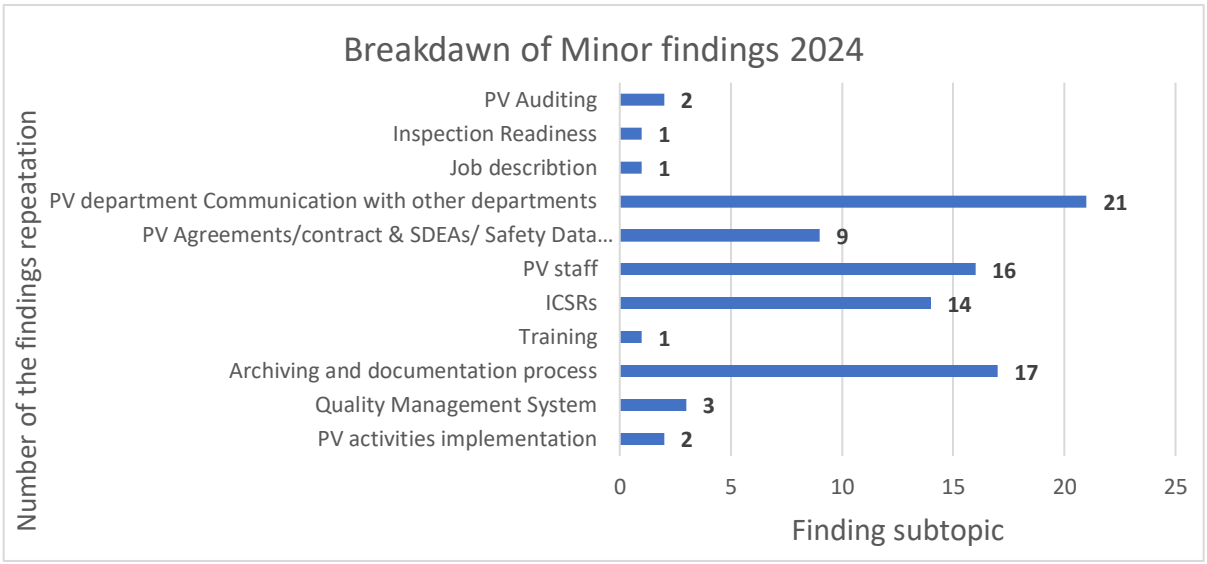
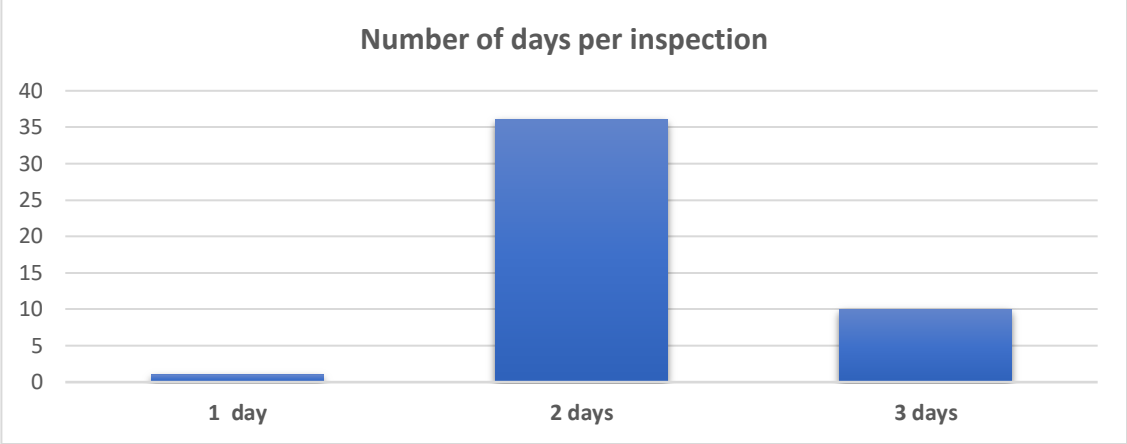


Figure 12 – Breakdown of the minor findings area in 2024



4. Inspections over time

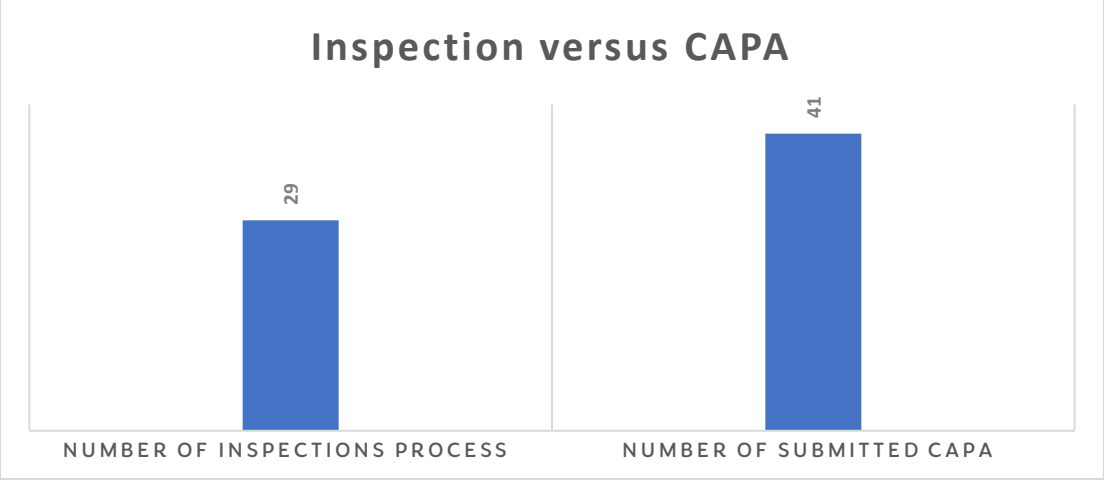
Figure 13 - Number of inspections against the mean number of inspection days per inspection



The duration of the inspection process is determined by the identified risks, in accordance with the risk-based criteria

5. Inspections vs corrective and preventive actions (CAPA)

Figure 14 – Number of inspections Conducted against the number of corresponding submitted CAPA



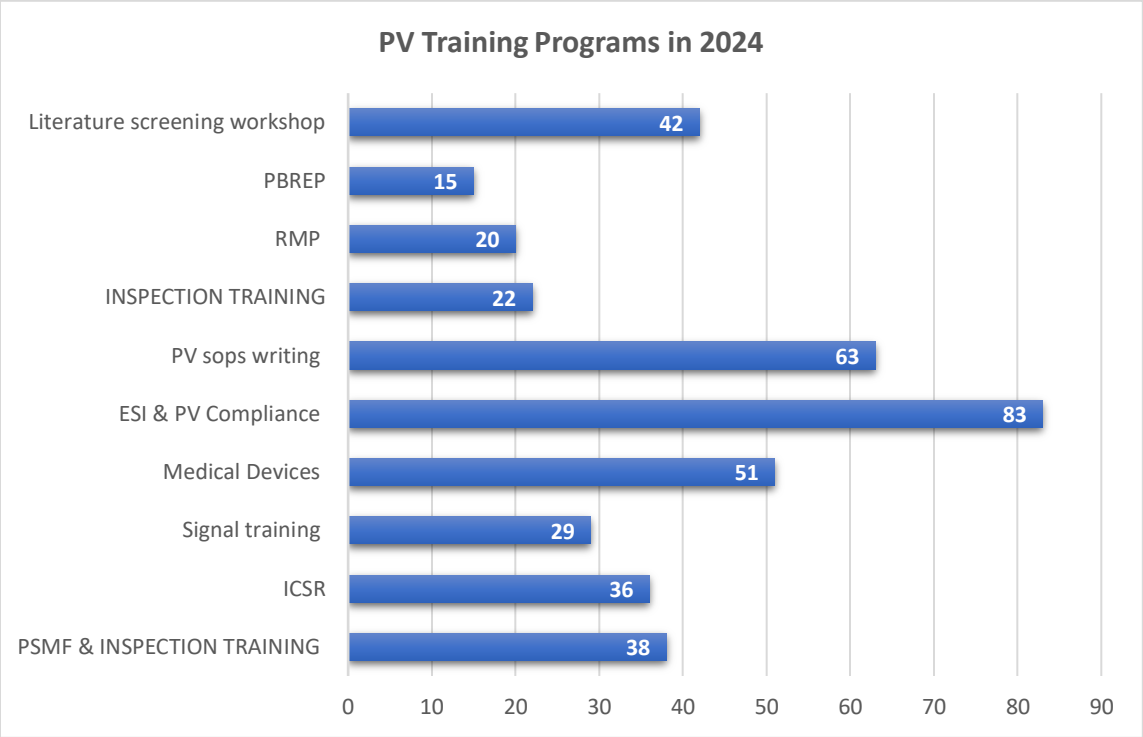
6. PV Training program in 2024

Pharmacovigilance training impact on PV compliance

PVGA provides this training to assist Marketing Authorization Holders (MAHs) in fulfilling their pharmacovigilance (PV) compliance obligations. When it comes to PV inspections, comprehensive training ensures that staff fully understand their roles and the procedures necessary to maintain compliance with both local and international regulations, helping to minimize the risk of non-compliance.

Well-trained staff are better equipped to identify systemic issues, resolve them quickly, and take preventive measures to enhance the overall safety profile of the products. This helps drive continuous improvements in the PV system and lowers the likelihood of regulatory findings.

Figure 15- number of PV training programs with respect to the number of trainees



7. Comparison between the inspection process 2023 and 2024

Figure 16 - Comparison between the number of Inspected Pharmaceutical Companies 2023 Vs 2024

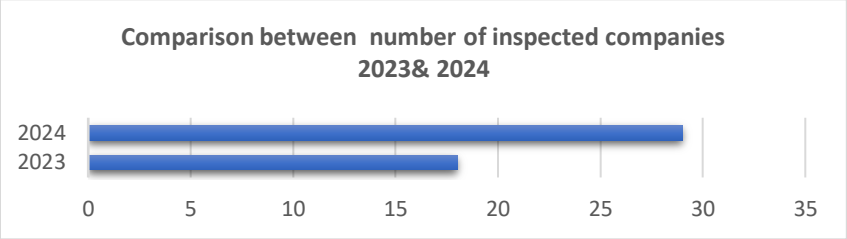


Figure 17 - Observation numbers in comparison to the number of Inspected Pharmaceutical Companies 2023-2024

The number of observations during inspections rose from 103 in 2023 to 185 in 2024, corresponding with the increase in the number of companies inspected. This growth in observations reflects the goal of expanding the inspection scope to include more pharmaceutical companies. By inspecting a larger number of companies, the aim is to ensure comprehensive compliance across the industry, ultimately leading to enhanced safety monitoring and better overall oversight of pharmaceutical practices. This expansion highlights the commitment to improving compliance and safety standards throughout the sector

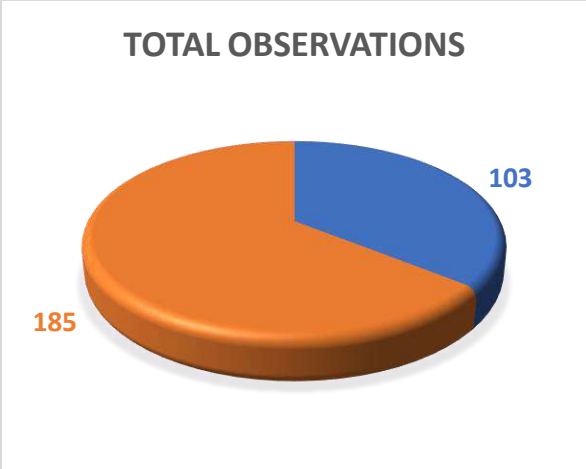
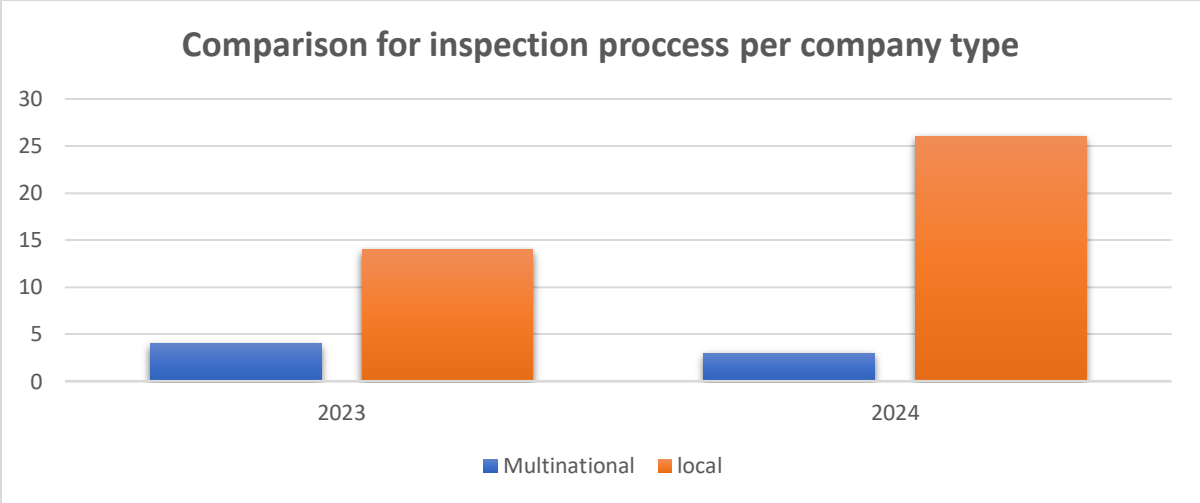


Figure 18- Comparison between types of Inspected Pharmaceutical Companies 2023-2024



Appendix I – Inspection finding definitions

- **Critical** 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. It may include a pattern of deviations classified as major. It also includes engaging in fraud, misrepresentation, or falsification of data.
- **Major** 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. It may include a pattern of deviations classified as minor.
- **Minor** 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. A deficiency may be minor either because it is judged as minor or because there is insufficient information to classify it as major or critical.

Appendix II – Categorization of findings

Topic Area	Subtopic of the reported findings
PV activities implementation	▪ Signal management ▪ ICSRs ▪ Literature screening ▪ PBRER ▪ Emerging Safety Issues & Safety Concerns communications ▪ Response to PVGA requirements
Quality Management System	▪ Agreements/ PV contracts ▪ Inspection readiness ▪ Procedural documents ▪ PSSF/PSMF Maintenance ▪ CAPA effectiveness, implementation and informing the quality departments with deviations ▪ Training ▪ Documentation process ▪ PV auditing ▪ Archiving, Data retrieval, and Documentation

Appendix III – Abbreviations

EDA: Egyptian Drug Authority

PV: Pharmacovigilance

PVGA: Pharmacovigilance General Administration

GVP: Good Pharmacovigilance Practice

PBRER: Periodic benefit risk evaluation report

PSMF: Pharmacovigilance system master file

PSSF: Pharmacovigilance sub-system master file

QMS: Quality management system

CAPA: Corrective and preventive action

RMP: Risk management plan

MAH: Marketing Authorization Holder