

**SFDA GMP Inspection
Deficiency Data Trend
2025**





Contents

| | |
|--|-----------|
| Executive Summary | 3 |
| Overview of GMP Inspections Carried Out..... | 4 |
| Total Number of Critical / Major / Other Findings in 2025..... | 5 |
| Overseas Inspections Review according to Continent | 6 |
| Overseas Inspections Review according to Type of Inspection | 7 |
| Overseas Inspections Review according to Type of Product | 8 |
| Overseas Inspections Review according to Type of Company..... | 8 |
| Most Common Findings for Sites according to systems: | 9 |
| Comparison of Deficiencies Trend:..... | 15 |



Executive Summary:

GMP inspection visits in 2025 were initiated based on defined regulatory and risk-based triggers, including:

- **Submission of product registration applications via SDR system.**
- **Changes to manufacturing processes or manufacturing site locations.**
- **Routine GMP inspections on local manufacturers**, conducted in accordance with **Inspection Priority Framework for Local Manufacturers.**
- **For-cause inspections**, including investigations related to **complaints and product recalls.**

Analysis of inspection outcomes indicated that the **most frequently cited deficiencies** were associated with **Quality Management Systems, premises, equipment, and documentation**, reflecting key areas of GMP compliance risk.

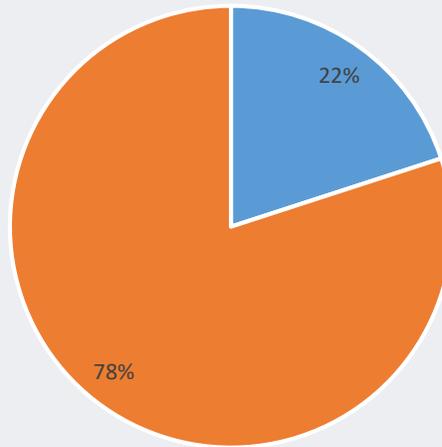
A total of **450 deficiencies** were identified within **production areas**, compared to **86 deficiencies** related to **personnel**, highlighting a higher concentration of findings in operational and facility-related activities.

As a regulatory outcome of inspection findings, **nine manufacturers were suspended during 2025.**



Overview of GMP Inspections Carried Out

During **2025**, a total of **133 inspection visits** were conducted. **Local inspections 22%** of the total visits, while the remaining **78% were overseas inspections**, conducted to ensure compliance with GMP requirements.



■ Local ■ Overseas



Total Number of Critical / Major / Other Findings in 2025

A total of **1,377 GMP deficiencies** were identified during inspections conducted in **2025**.

Critical Deficiencies

- **87 critical deficiencies** were raised.
- This represents approximately **6.3%** of the total deficiencies.

Major Deficiencies

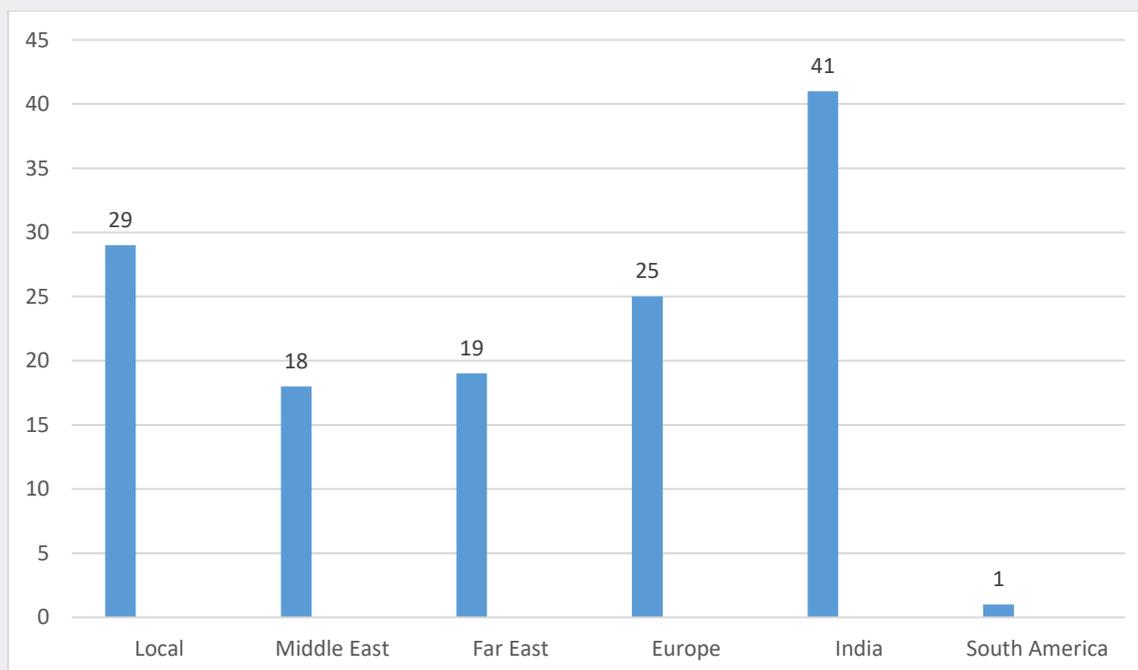
- **743 major deficiencies** were raised.
- This represents approximately **54.0%** of the total deficiencies.



Overseas Inspections Review according to Continent

During **2025**, a total of **133 GMP inspections** were conducted across manufacturing sites of different nationalities. **Indian manufacturers accounted for the highest share, with 41 inspections (31%)**, followed by **local manufacturers**, which accounted for **29 inspections (22%)**.

European manufacturers accounted for **25 inspections (19%)**, while manufacturers from the **Far East 19 inspections (14%)**, and the **Middle East** accounted for **18 inspections (13%)**. Inspections conducted at **South American** manufacturing sites were limited to **one inspection (1%)**, while **no inspections** were conducted in **Africa** or **Australia** during the reporting period.

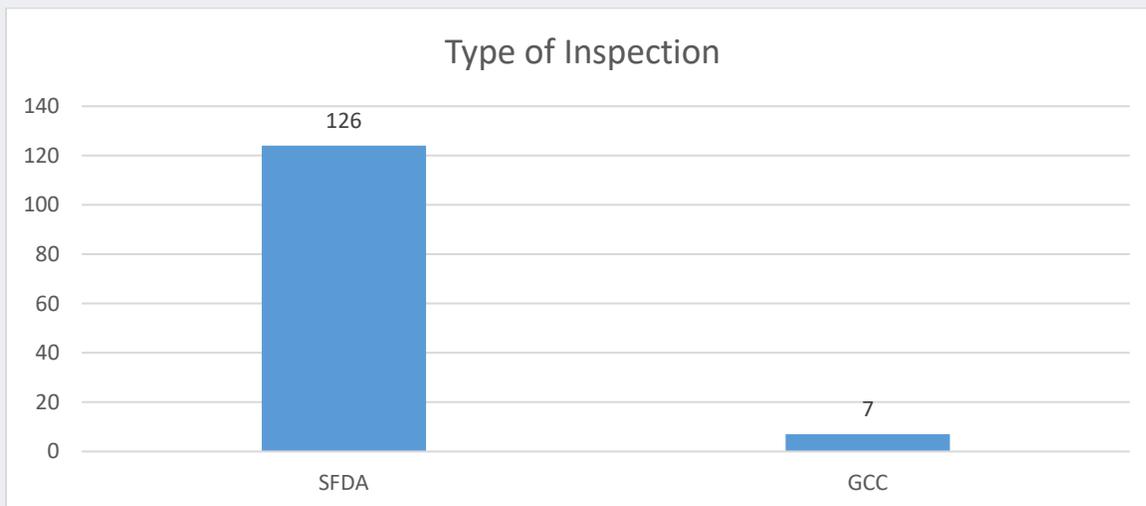


Overseas Inspections Review according to the Type of Inspection

During **2025**, a total of **133 GMP inspection visits** were conducted under different inspection frameworks and scopes.

Type of Inspection

- **SFDA inspections** constituted the majority, with **126 inspections**, representing approximately **94%** of the total inspection visits.
- **GCC joint inspections** accounted for **7 inspections**, representing approximately **6%** of the total.

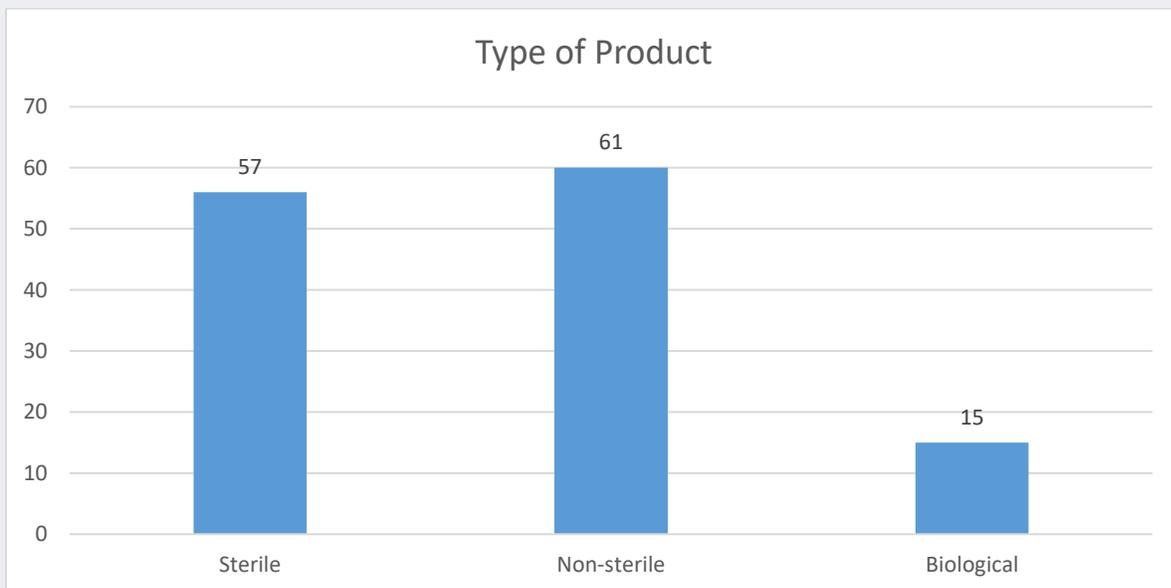




Overseas Inspections Review according to Type of Product

Type of Product

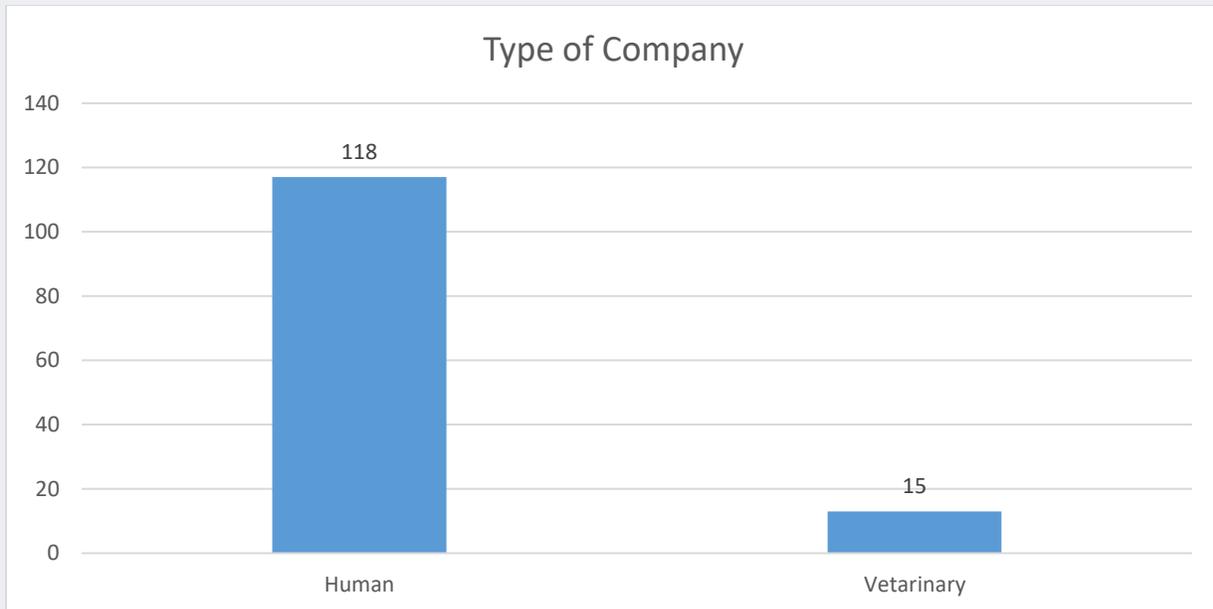
- **Non-sterile products** were the most frequently inspected category, covered in **61 inspection visits (46%)**.
- **Sterile products** were inspected in **57 visits (43%)**.
- **Biological products** were included in **15 inspection visits (11%)**.
(Note: some inspection visits covered more than one product category.)



Overseas Inspections Review according to Type of Company

Type of Company

- **Human pharmaceutical manufacturers** accounted for **approximately 90%** of the inspection visits.
- **Veterinary pharmaceutical manufacturers** represented **approximately 10%** of the total



Most Common Findings for Sites according to systems:

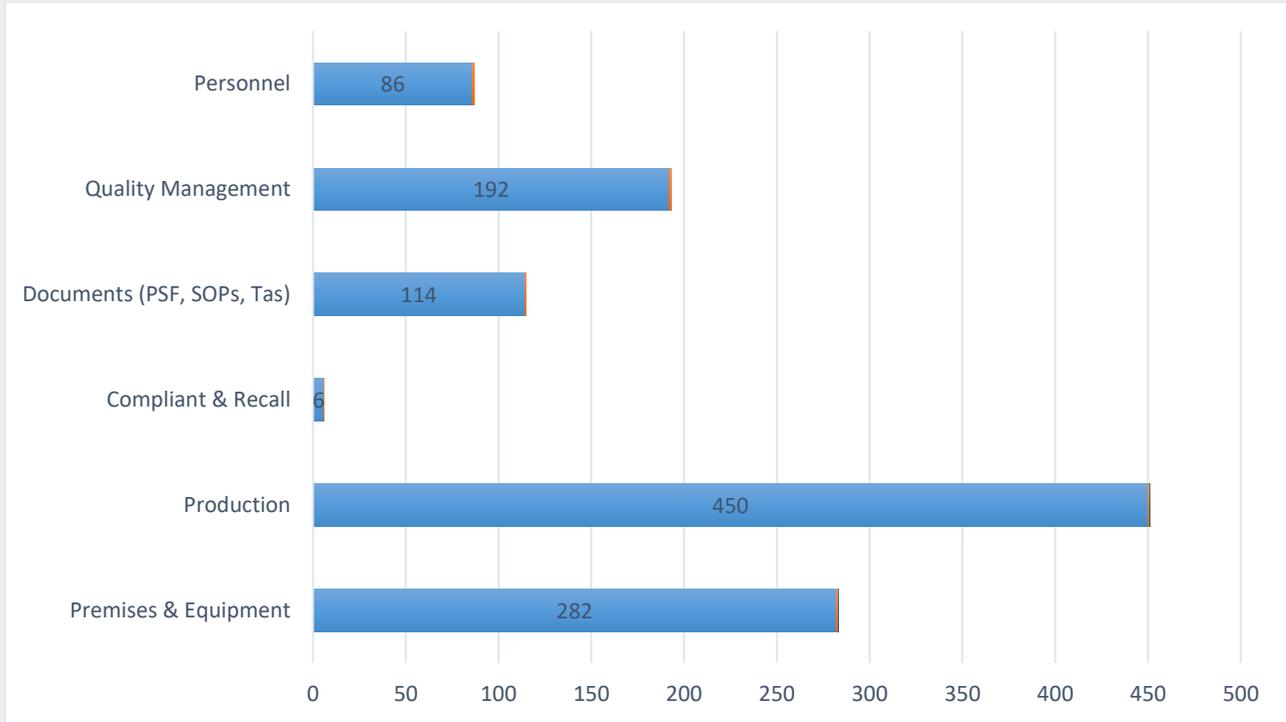
A review of GMP inspection outcomes in 2025 indicates that the majority of observations were associated with **manufacturing operations**, reflecting challenges in the overall control of production activities. Additional observations were commonly related to **facilities and equipment**, highlighting the importance of maintaining appropriate infrastructure and operational conditions.

Findings related to **quality control activities** were also noted, particularly in areas associated with laboratory practices and supporting documentation. Observations concerning **materials management** pointed to issues in storage conditions, material handling, and record-keeping.

Deficiencies linked to **validation activities** reflected gaps in the establishment and maintenance of validated processes and systems, while **quality management system-related observations** emphasized the need for strengthened governance, documentation practices, and risk management approaches.

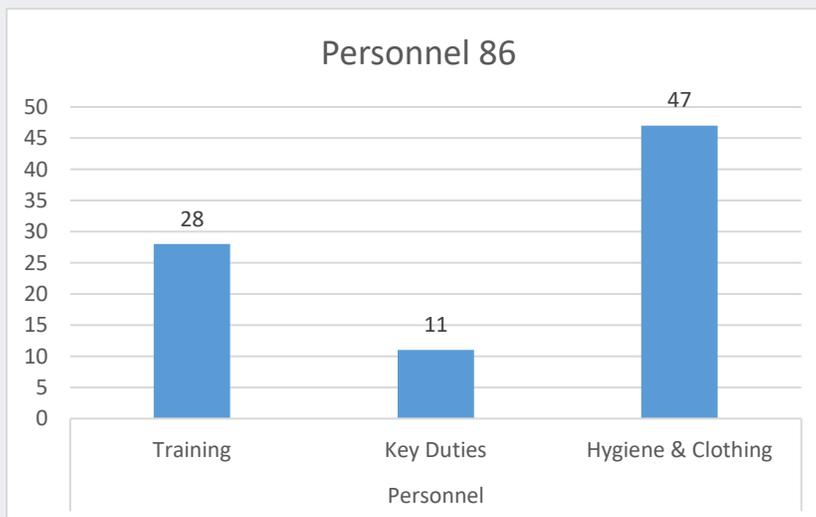
Personnel-related observations were less frequent in comparison to other areas and were mainly associated with training and hygiene practices.

From a **criticality perspective**, a limited proportion of observations were classified as **critical**, while a larger share was identified as **major**, indicating areas requiring prioritized corrective and preventive actions to ensure sustained GMP compliance.



Personnel

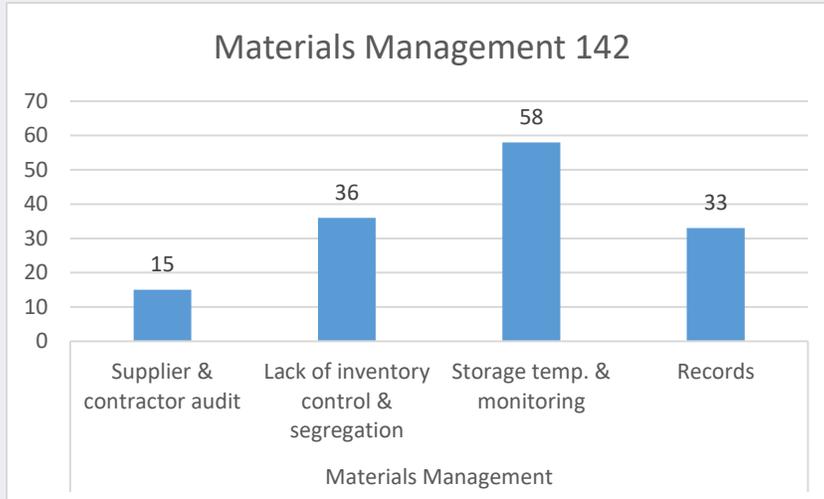
86 Deficiencies





Material Management

142 Deficiencies



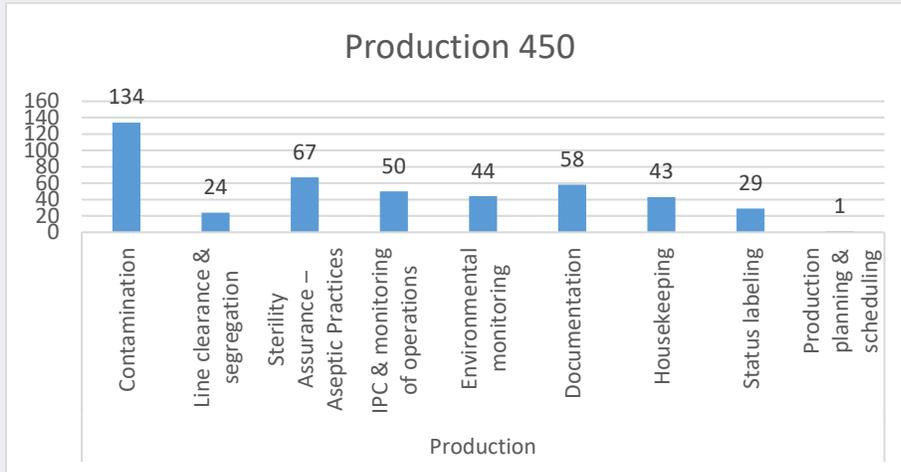
Quality Management

192 Deficiencies

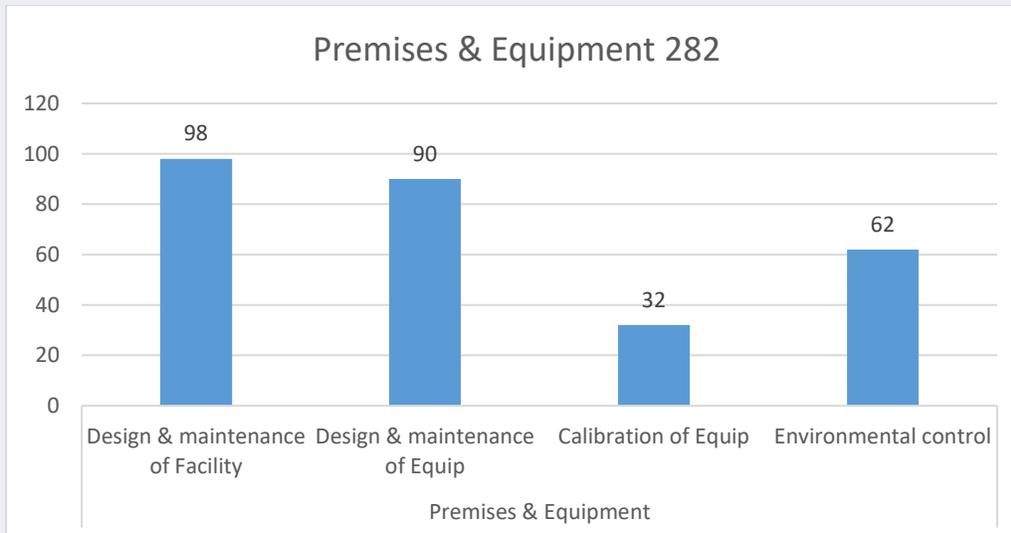




Production: 450 Deficiencies



Premises & Equipment 282 Deficiencies





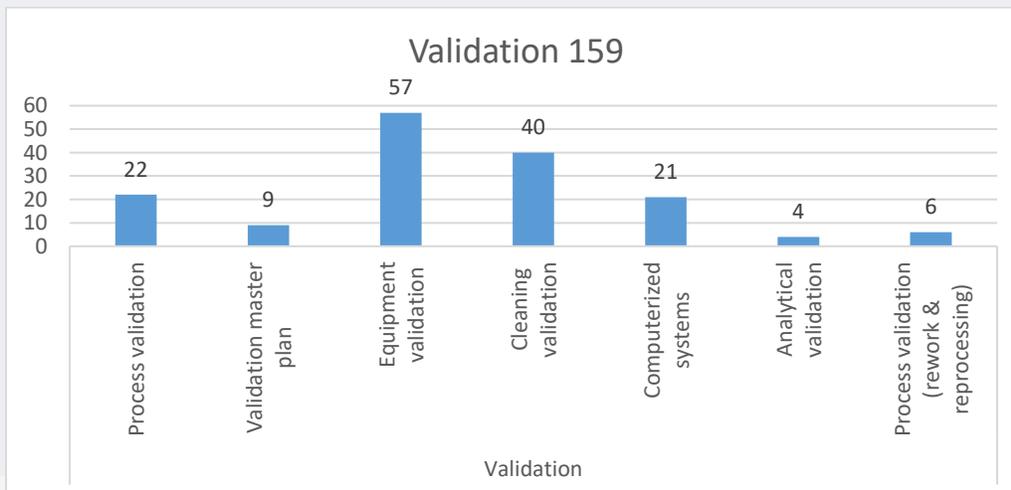
Quality Control

178 Deficiencies



Validation

159 Deficiencies



**Comparison of Deficiency
Data Trend
Review of previous years
(2024, 2023, 2022)**

Number of inspections:

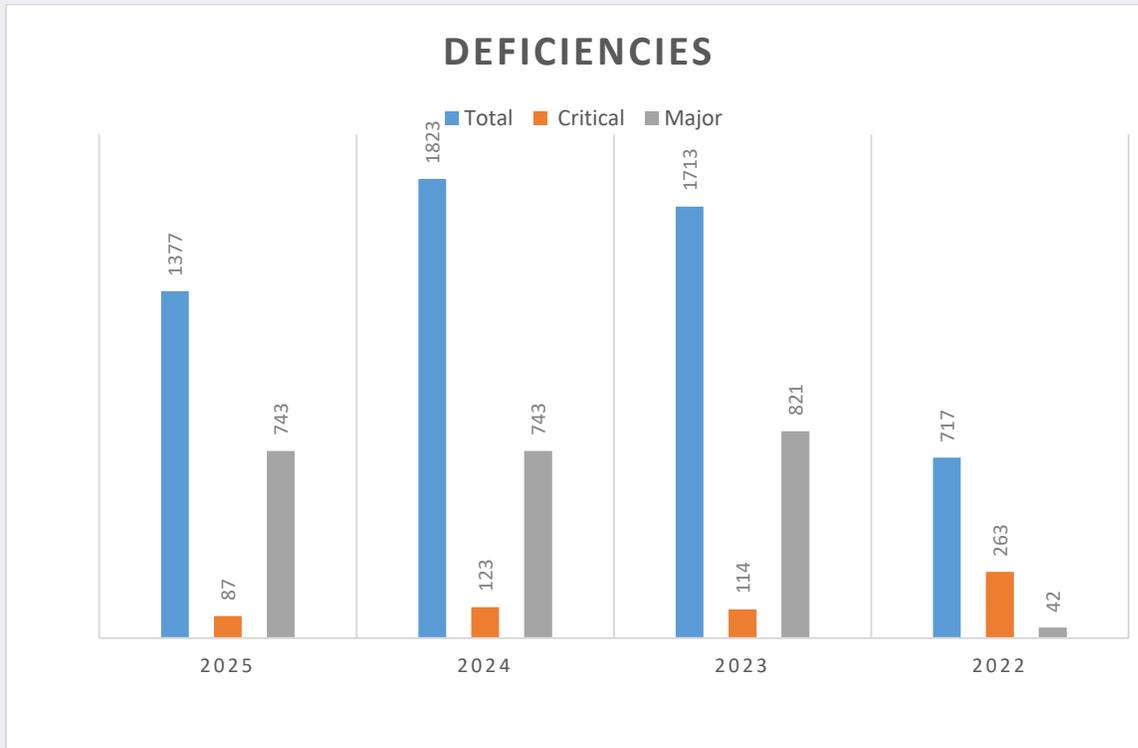
A review of the total number of GMP inspection by years indicate that the highest number of inspections conducted was in 2024 with 159 visit and the lowest was in 2022 with 51 visits





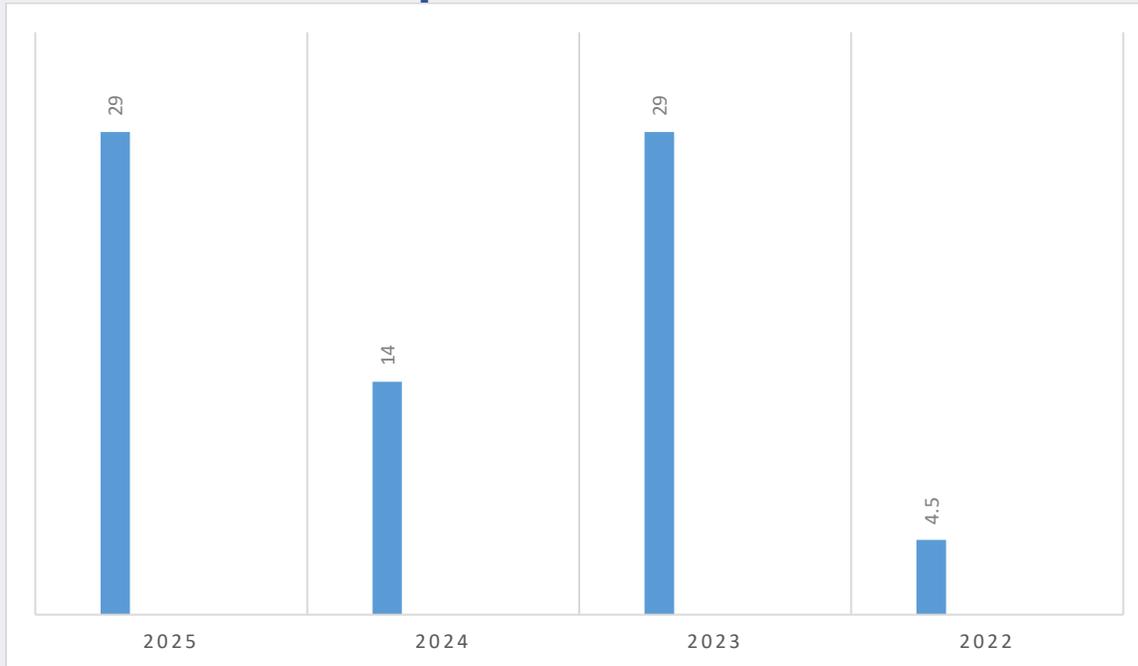
Number of Deficiencies:

The percentage of critical deficiencies remained consistently low across the years , averaging around 6%. In contrast the share of major observations increased over time, reaching 54% in 2025 which may reflect enhanced focus on identifying significant compliance gaps.

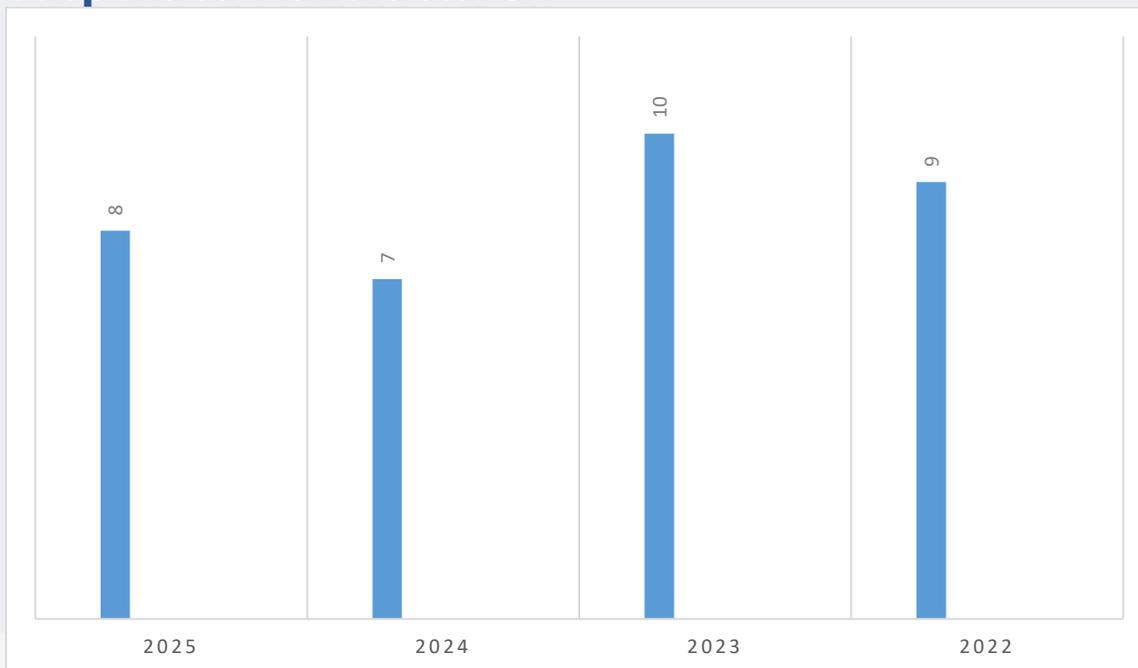




Number of local inspections:

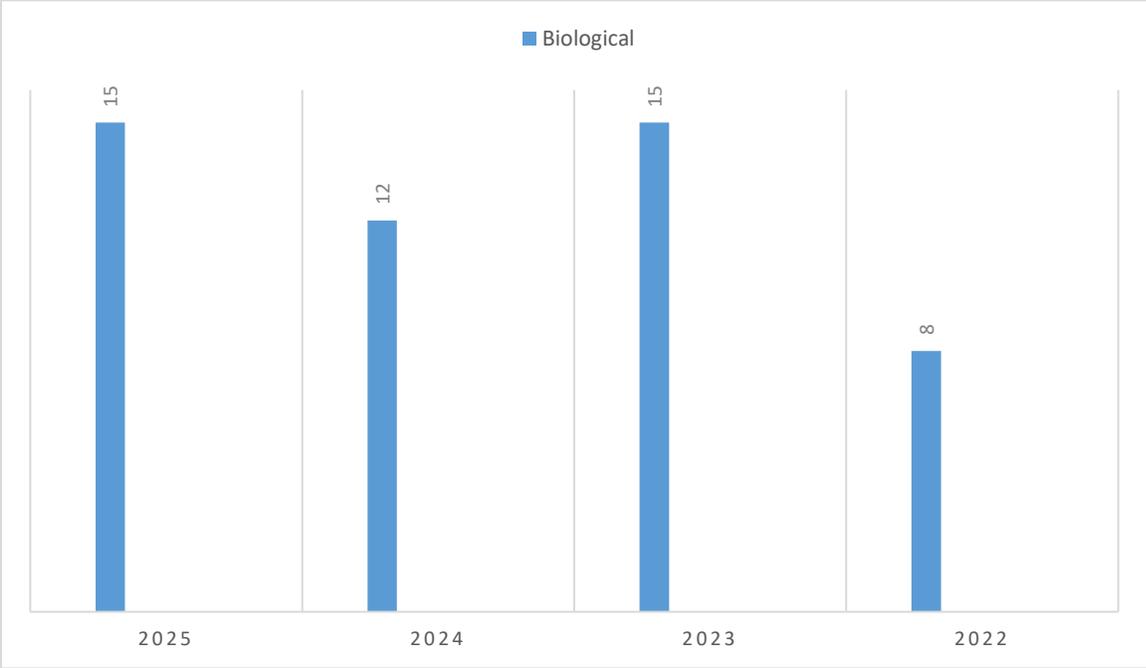


Suspended Manufacturer:



Inspection of biological products companies:

A review of number of inspections conducted on the biological companies indicate that the lowest number is in 2022 with 8 inspection while in 2025 and 2023 a 15 inspection were conducted



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Saudi Food & Drug Authority

