

SFDA GMP Inspection Deficiency Data Trend 2024

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Introduction

Good Manufacturing Practices (GMP) serve as the cornerstone of ensuring the safety, quality, and consistency of pharmaceutical products. Compliance with GMP regulations is vital for protecting public health and maintaining consumer trust in the industry. So the factories supervision directorate is delighted to share summary data for GMP Inspections performed in the period 1 January 2024 – 31 December 2024.

The aim of analyzing GMP inspection deficiency data trends is to foster a culture of continuous improvement and ensure that manufacturing facilities consistently adhere to high-quality standards. By understanding the underlying causes of deficiencies and addressing them proactively, the industry can enhance its reputation, and ensure the availability of safe and effective products.

Through a comprehensive analysis of GMP inspection deficiency data trends, we aim to contribute to the collective knowledge base, supporting ongoing efforts to strengthen quality standards and drive continuous improvement in the industries. So Sharing inspection deficiency data assists industries to self-inspect and continuously improve.

Executive Summary:

GMP inspection visit initiated by the following:

- The company submits its product registration through SDR.
- Change in of manufacturing processes location.
- Regular GMP inspection for local manufacturer based on Inspection Priority for Local Manufactures.
- Investigation in case of complain or recall.

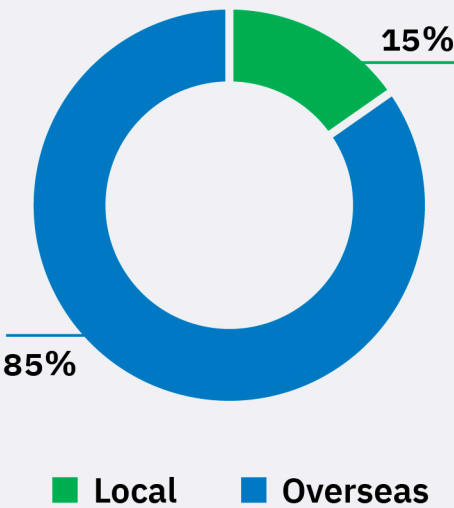
The most common deficiencies are related to quality management, premises, equipment and documents.

29% of deficiencies were observed in Production area while only 6% were found with regard to Personnel.

7 Manufacturers were suspended in 2024.

Overview of GMP Inspections Carried Out

Out of the 1823 GMP deficiencies observed during 159 GMP inspections in 2024, 743 resulted in major deficiencies and 123 were critical deficiencies among the inspections with major and critical deficiencies.



Total Number of Critical / Major / Other Findings in 2024

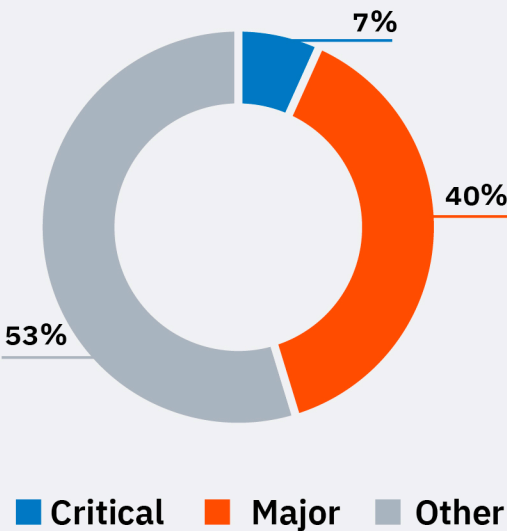
A total of 1,823 deficiencies were detected during inspections in 2024.

Critical

- 123 Critical deficiencies raised
- 7% of all 1,823 deficiencies are classified as critical

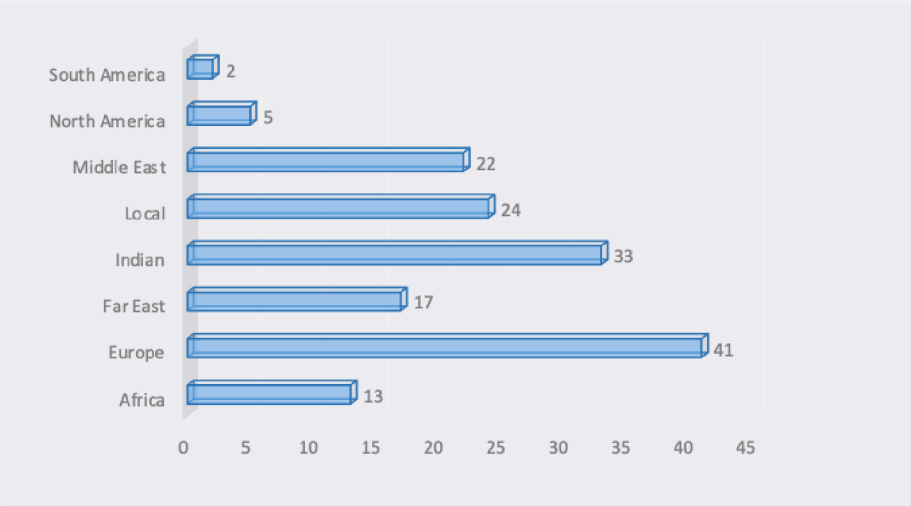
Majors

- 743 Major deficiencies raised
- 40% of all 1,823 deficiencies are classified as Major



Overseas Inspections Review according to Continent

The following overview presents the distribution of inspected manufacturing sites across different regions around the world. The majority of inspection visits were conducted in Europe, accounting for 41 inspections. Moreover, 33 inspections were conducted in India, 13 in Africa, 2 in South America and 5 in North America.

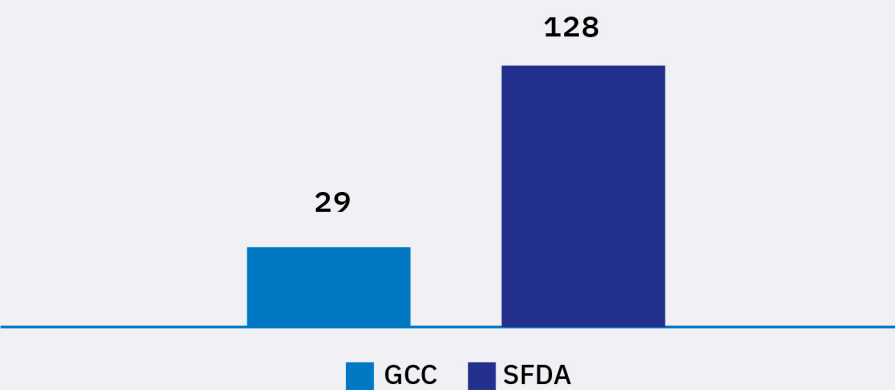


15% of the inspection reviews are locally

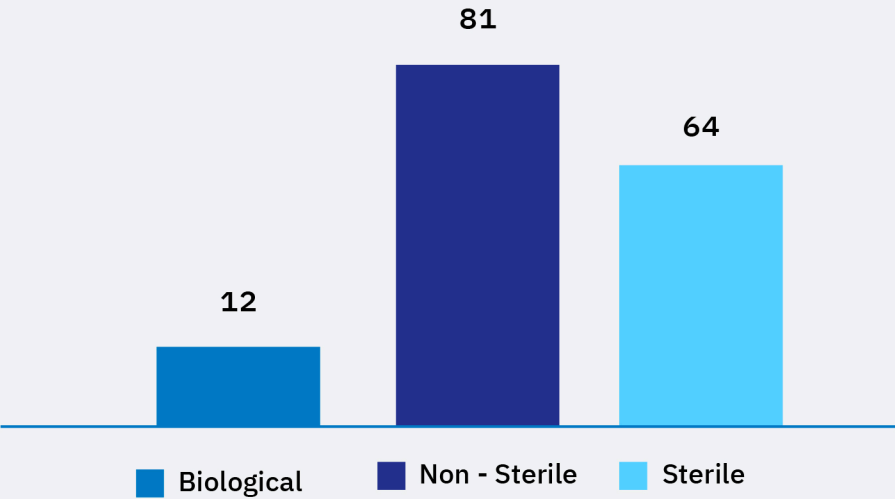
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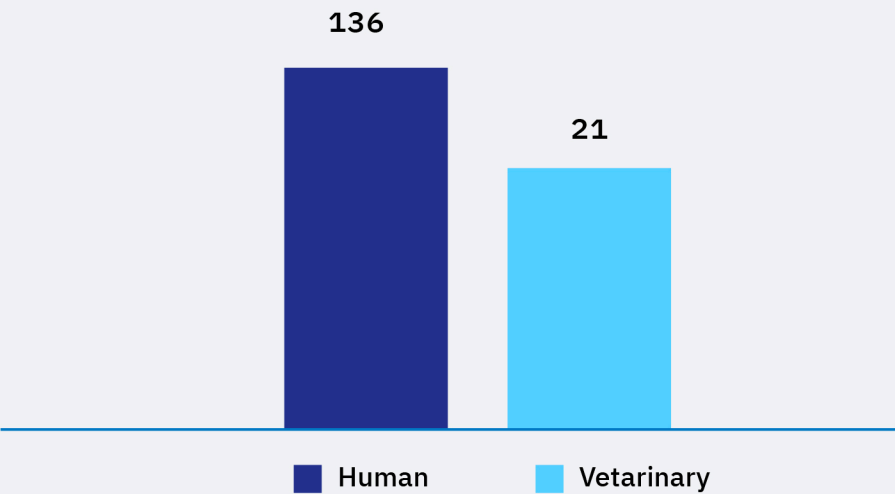
15% of the inspection reviews are locally



Overseas Inspections Review according to Type of Product



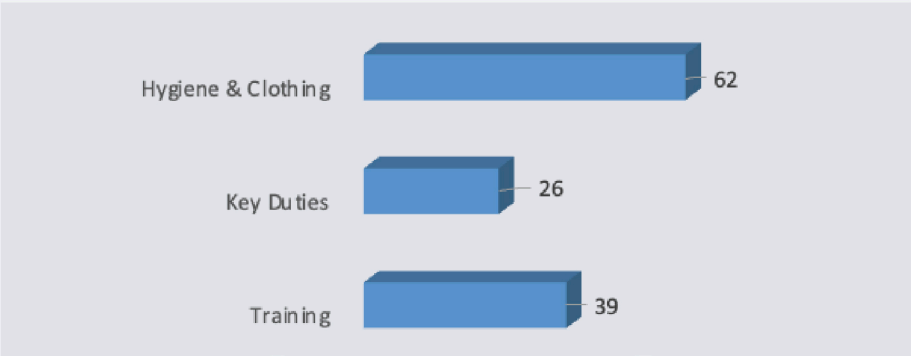
Overseas Inspections Review according to Type of Company



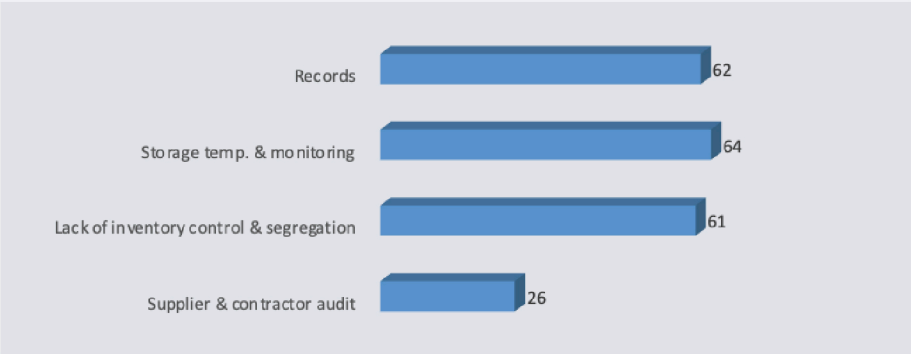
Most Common Findings for Sites according to systems:



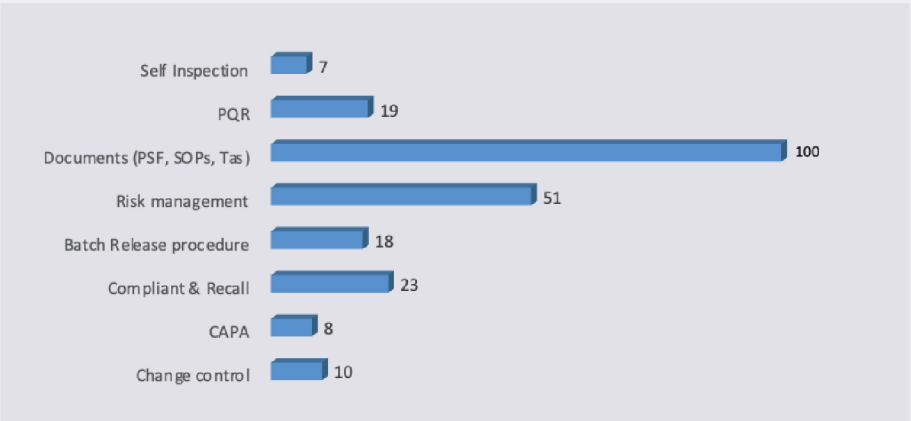
Personnel 111 Deficiencies



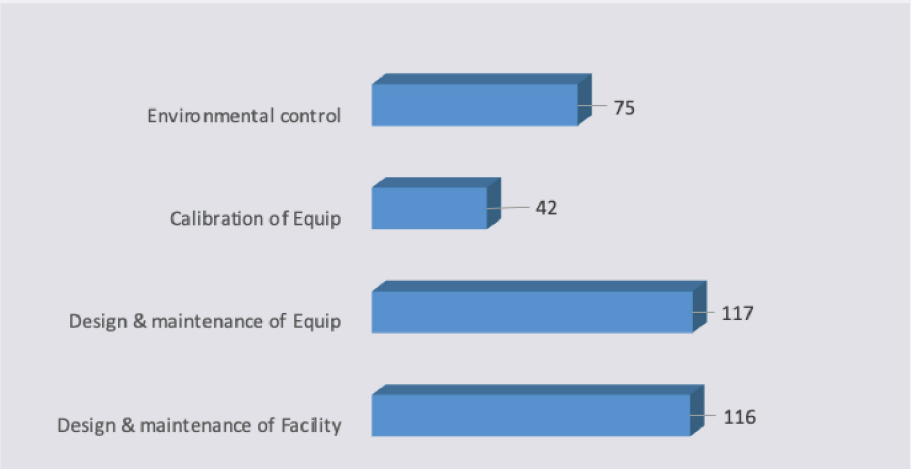
Material Management 203 Deficiencies



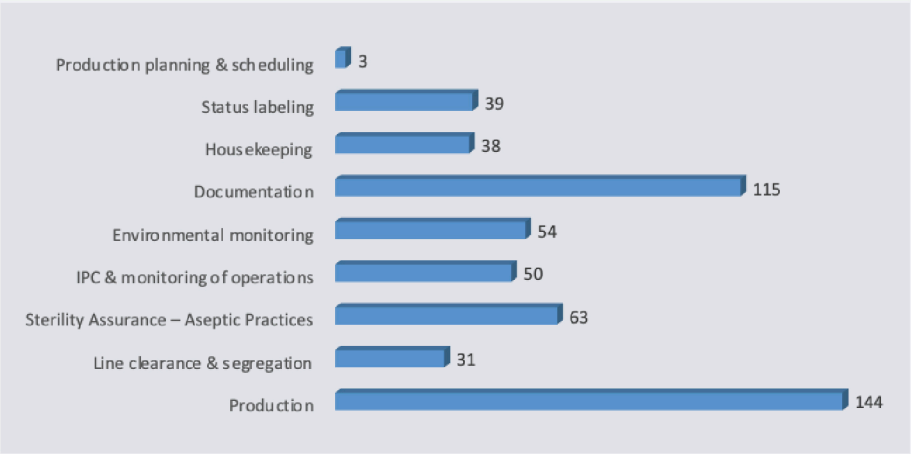
Quality Management 209 Deficiencies



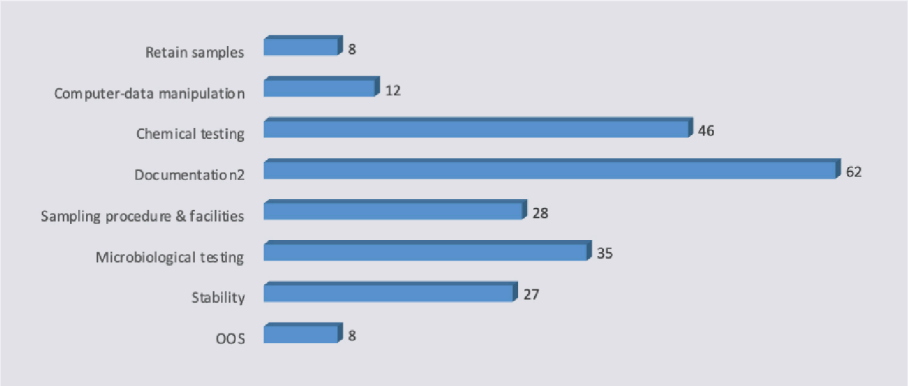
Premises & Equipment 310 Deficiencies



Production 480 Deficiencies



Quality Control 203 Deficiencies



Validation 207 Deficiencies



