Kingdom of Saudi Arabia
Saudi Food & Drug Authority

SFDA GMP Inspection Deficiency Data Trend

2023

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.
- The factories supervision directorate is delighted to share summary data for GMP Inspections performed in the period January 2023 – December 2023.
- 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.

Introduction

- 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.
- Sharing inspection deficiency data assists industries to self-inspect and continuously improve.

Executive Summary

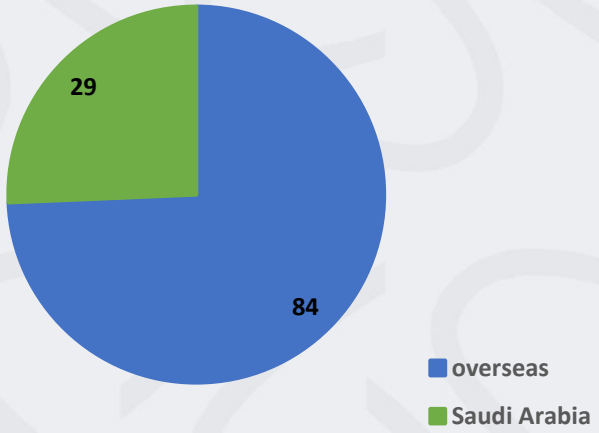
- GMP inspections are initiated by the following:
  - The company submits its product registration through SDR.
  - Change in the manufacturing processes location.
  - Regular GMP inspection for local manufacturers based on Risk Based Approach.
  - GMP inspection for new local manufacturer
  - Investigation in case of complain or recall.

Executive Summary

- The total number of inspection deficiency was **1713**
- The most common deficiencies are related to:
  - Quality Management.
  - Premises.
  - Equipment.
  - Documents.
- **27.37%** of deficiencies were observed in Production area while only **5.66%** were found with regard to Personnel
- **10** Manufacturers were suspended in 2023

Overview of GMP Inspections Carried Out

Out of the **1,713** GMP deficiencies observed during **113** GMP inspections in 2023, **778** resulted in major deficiencies,**114** were critical deficiencies, and **821** were other deficiencies among the inspections

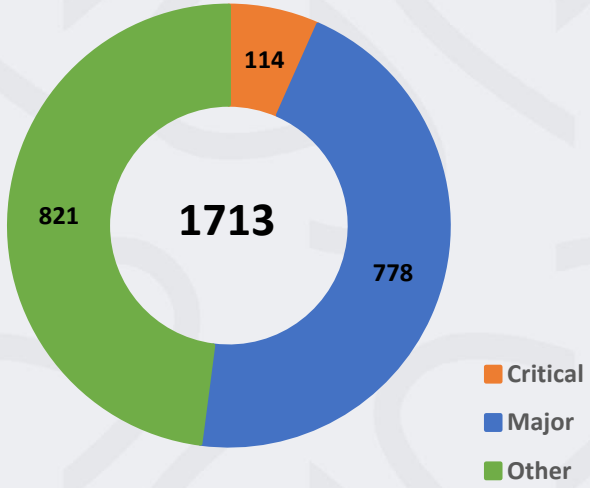


Total Number of Critical / Major / Other Deficiencies in 2023

- Critical
  - **114** Critical deficiencies raised
  - **6.7%** of all **1713** deficiencies are classified as critical

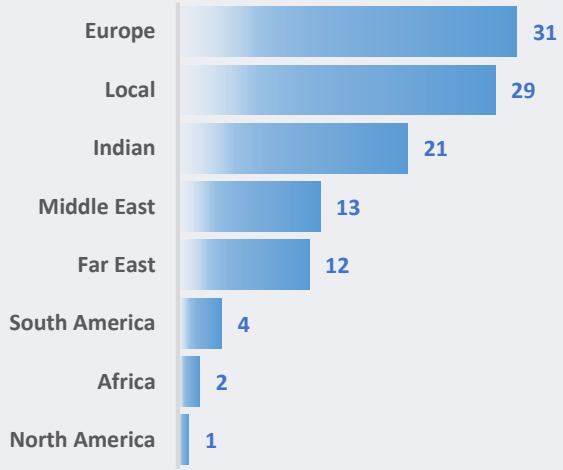
- Majors
  - **778** Major deficiencies raised
  - **45.4%** of all **1713** deficiencies are classified as Major

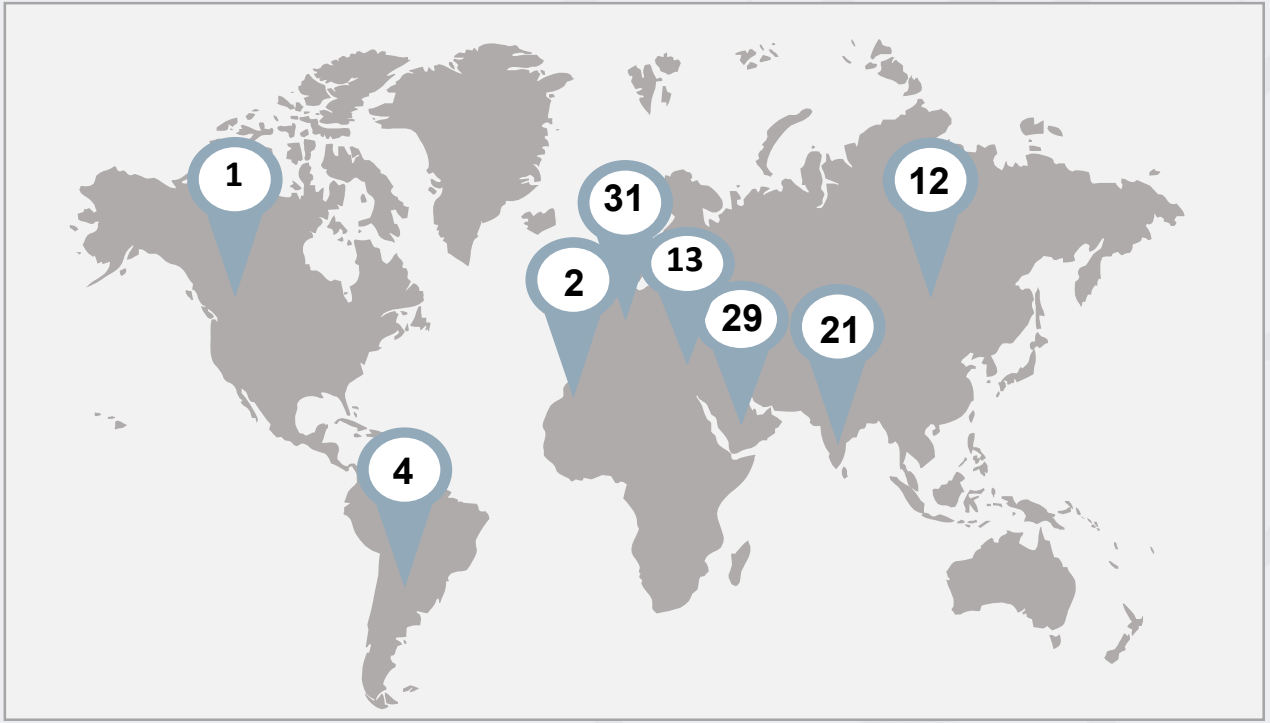
- Others
  - **821** Critical deficiencies raised
  - **47.9%** of all **1713** deficiencies are classified as critical



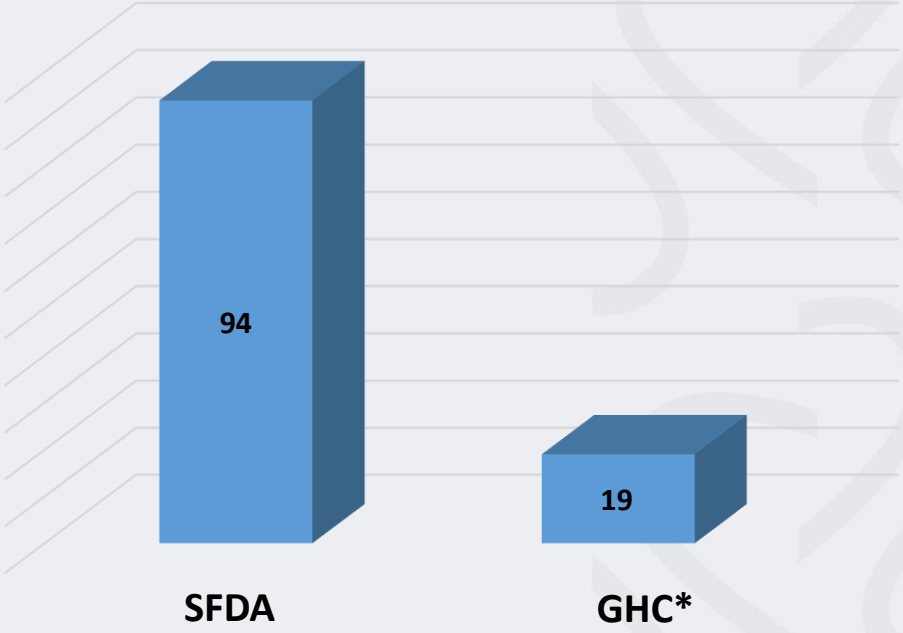
Overseas Inspections Review According to Continent

26% Of the inspection reviews are locally



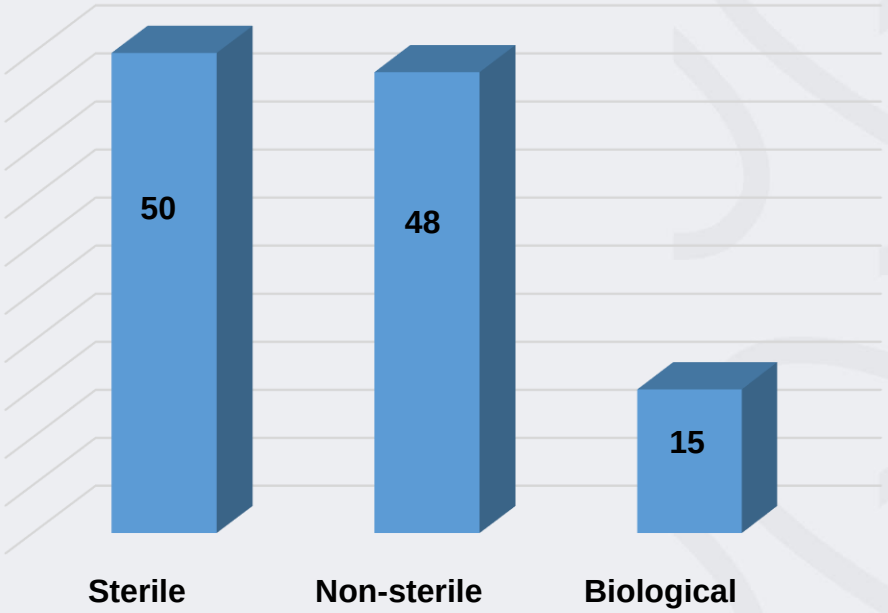


Overseas Inspections Review According to the *Type of Inspection*

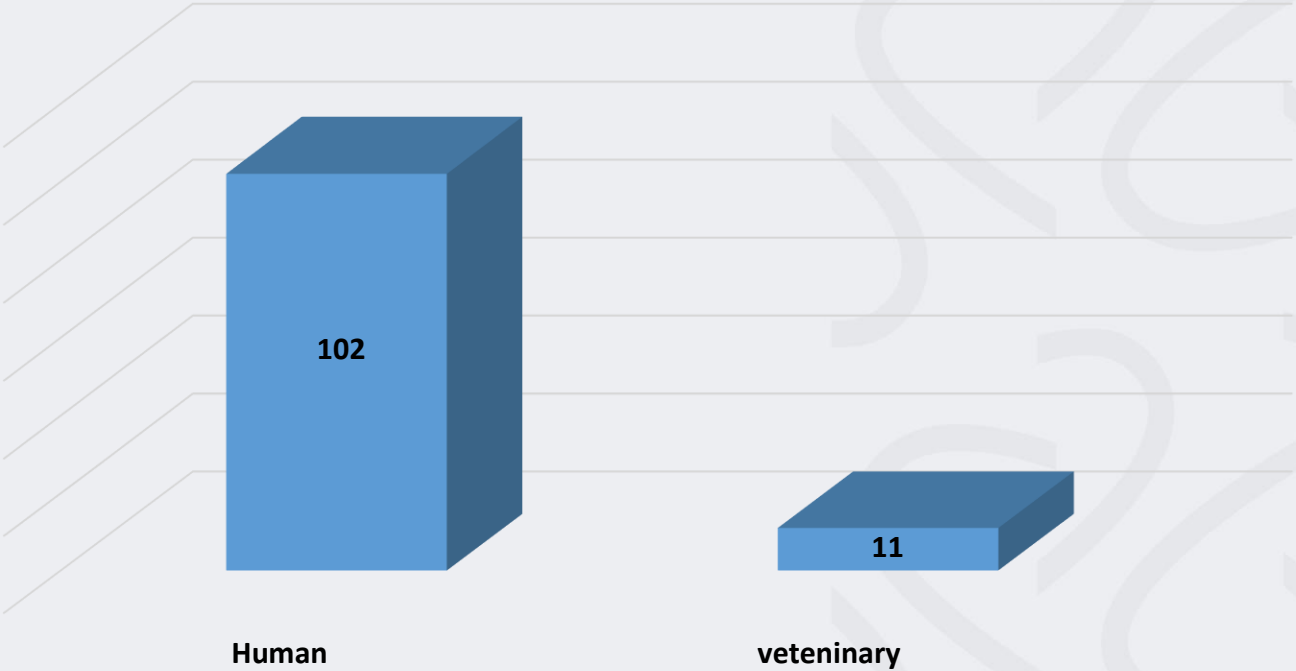


- GHC: Gulf Health Council

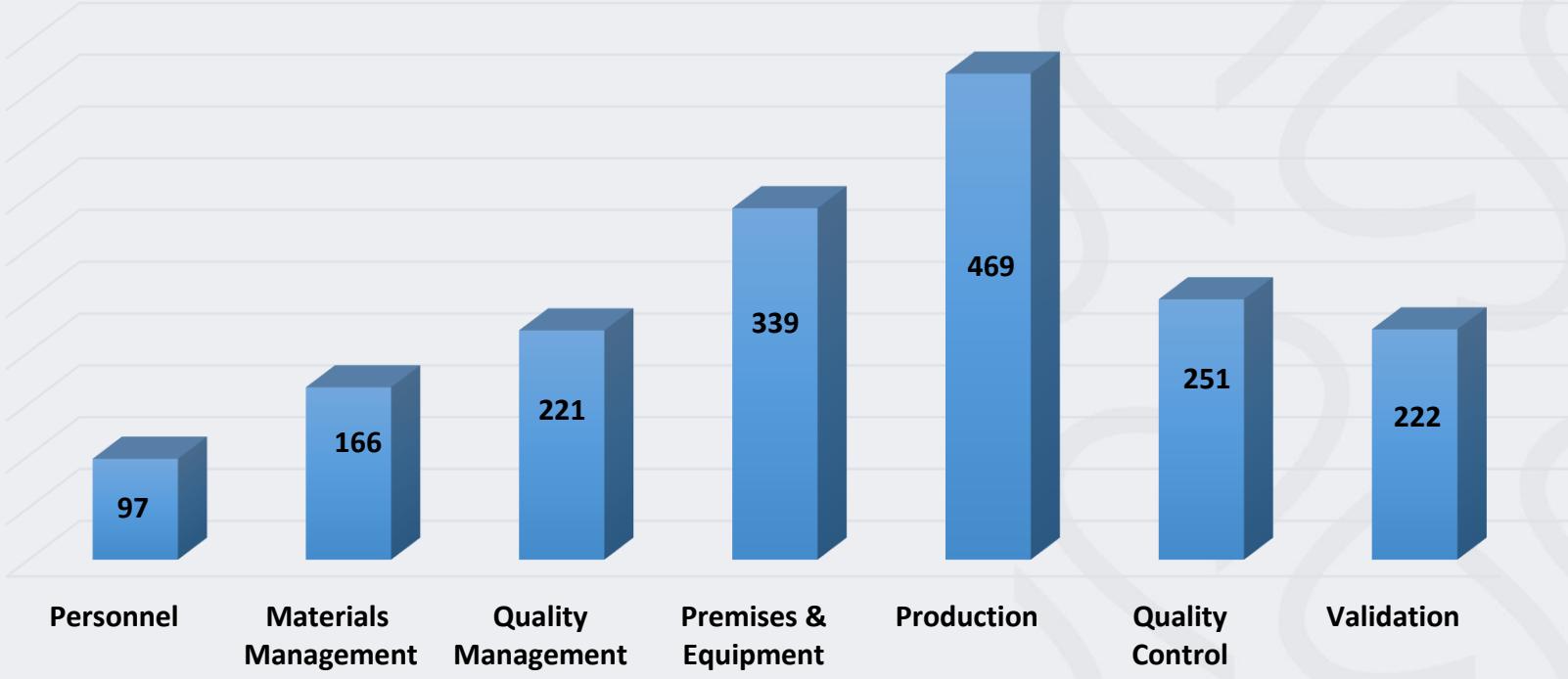
Overseas Inspections Review According to *Type of Product*



Overseas Inspections Review According to *Type of Company*



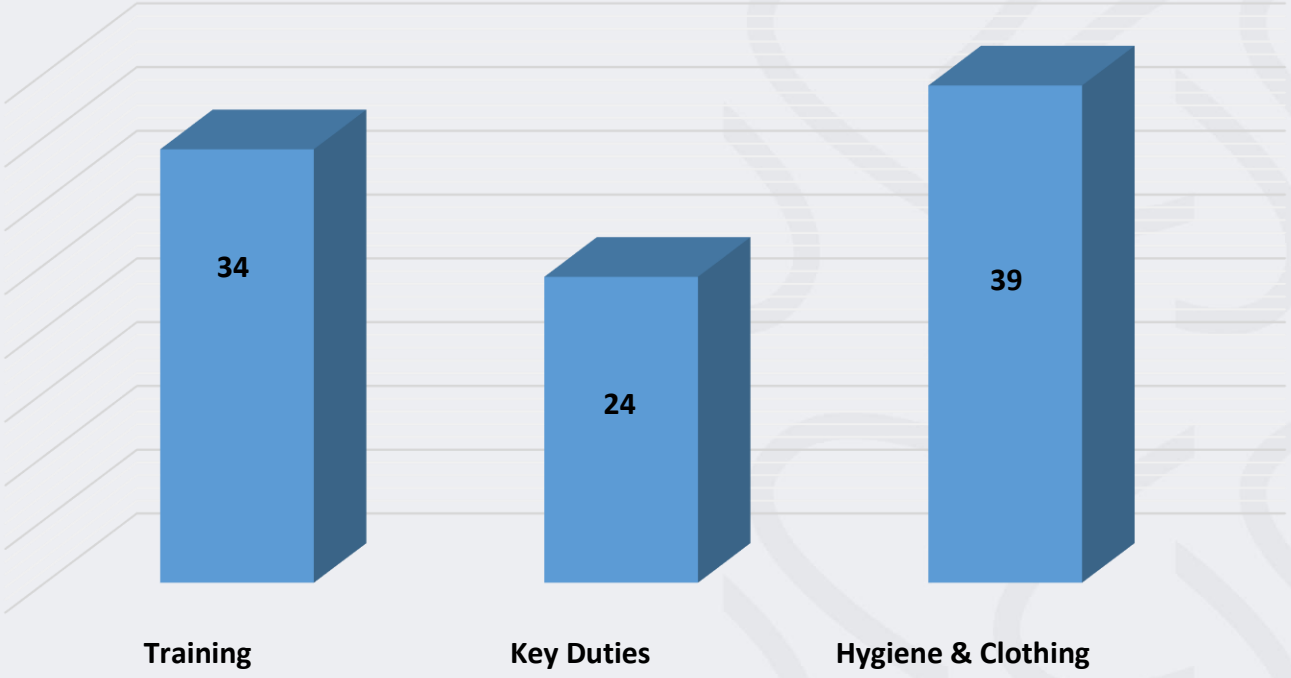
Most Common Deficiencies According *to GMP System*



Most Common Deficiencies related to Personnel

Personnel

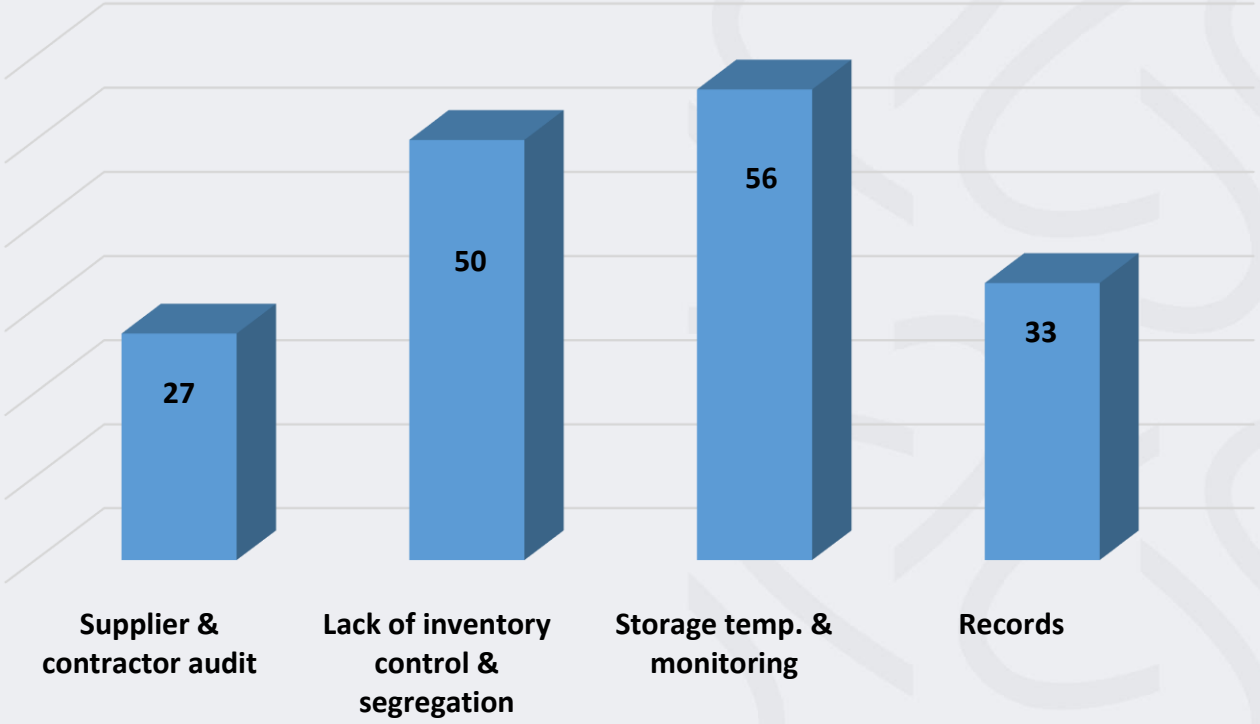
97 Deficiencies



Most Common Deficiencies related to Material Management

Material Management

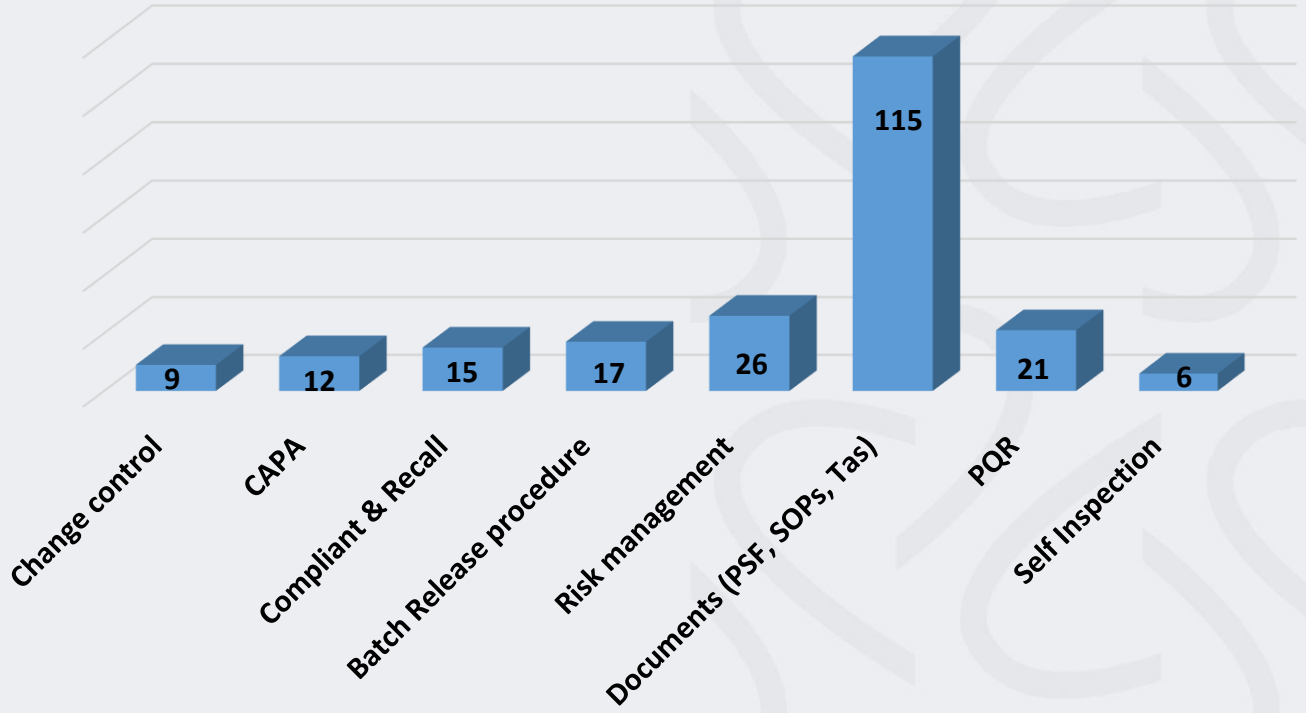
166 Deficiencies



Most Common Deficiencies related to Quality Management

Quality Management

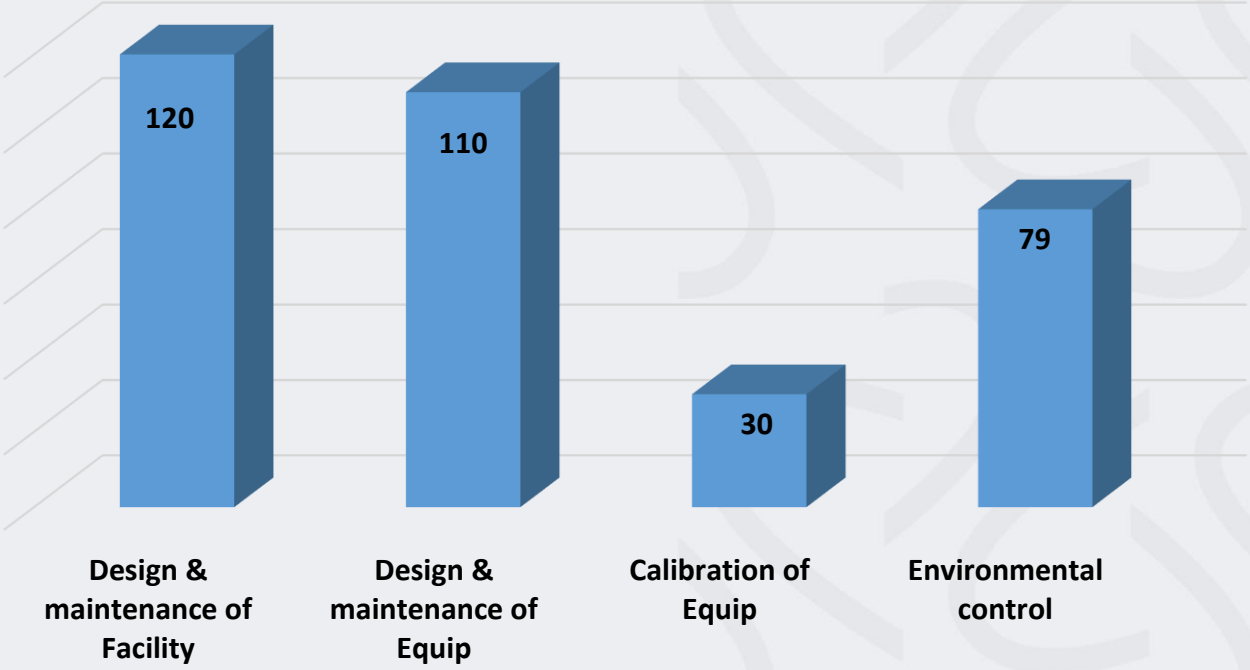
221 Deficiencies



Most Common Deficiencies related to Premises & Equipment

Premises & Equipment

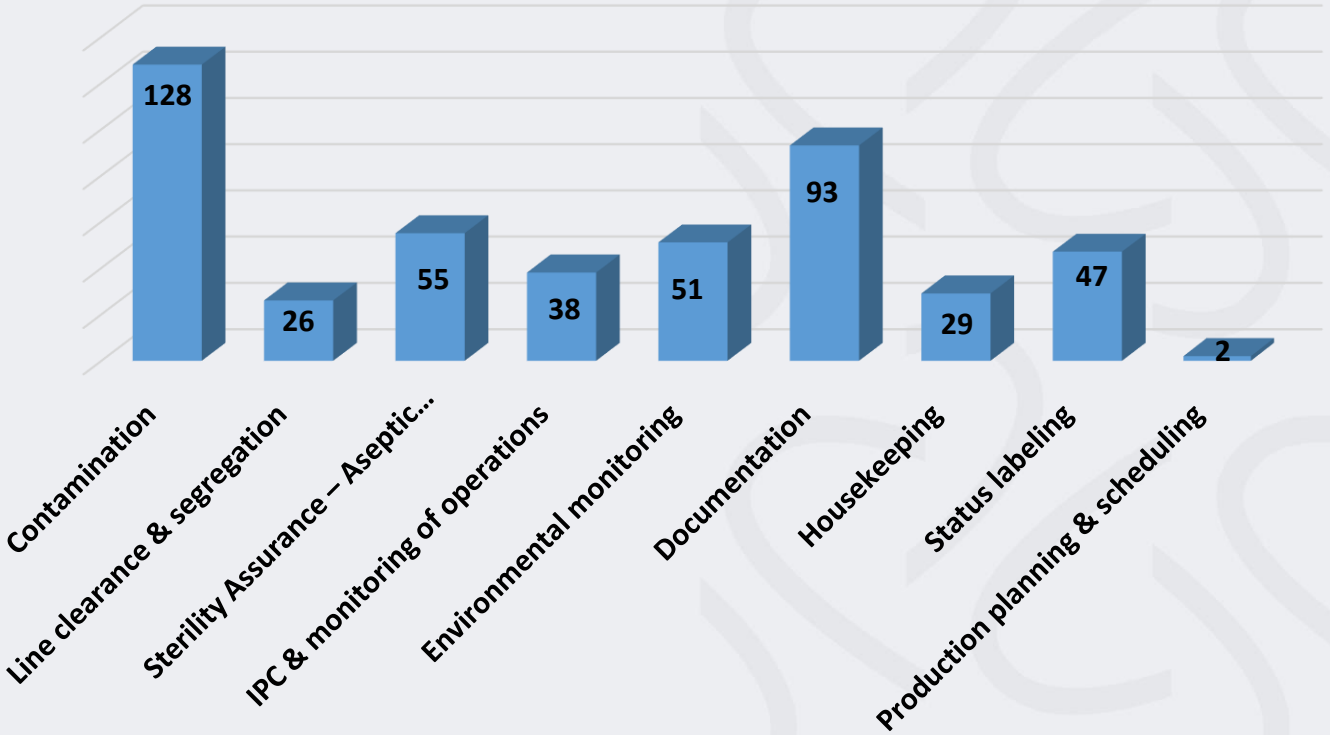
339 Deficiencies



Most Common Deficiencies related to Production

Production

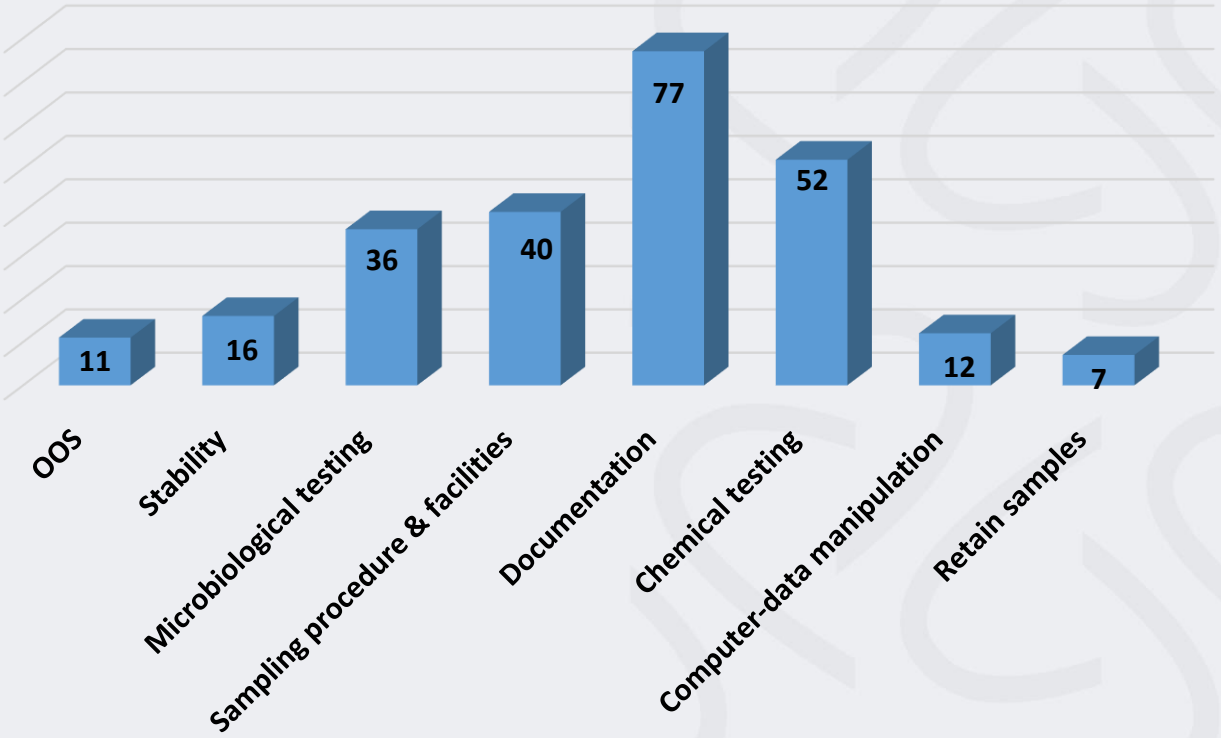
469 Deficiencies



Most Common Deficiencies Related to Quality Control

Quality Control

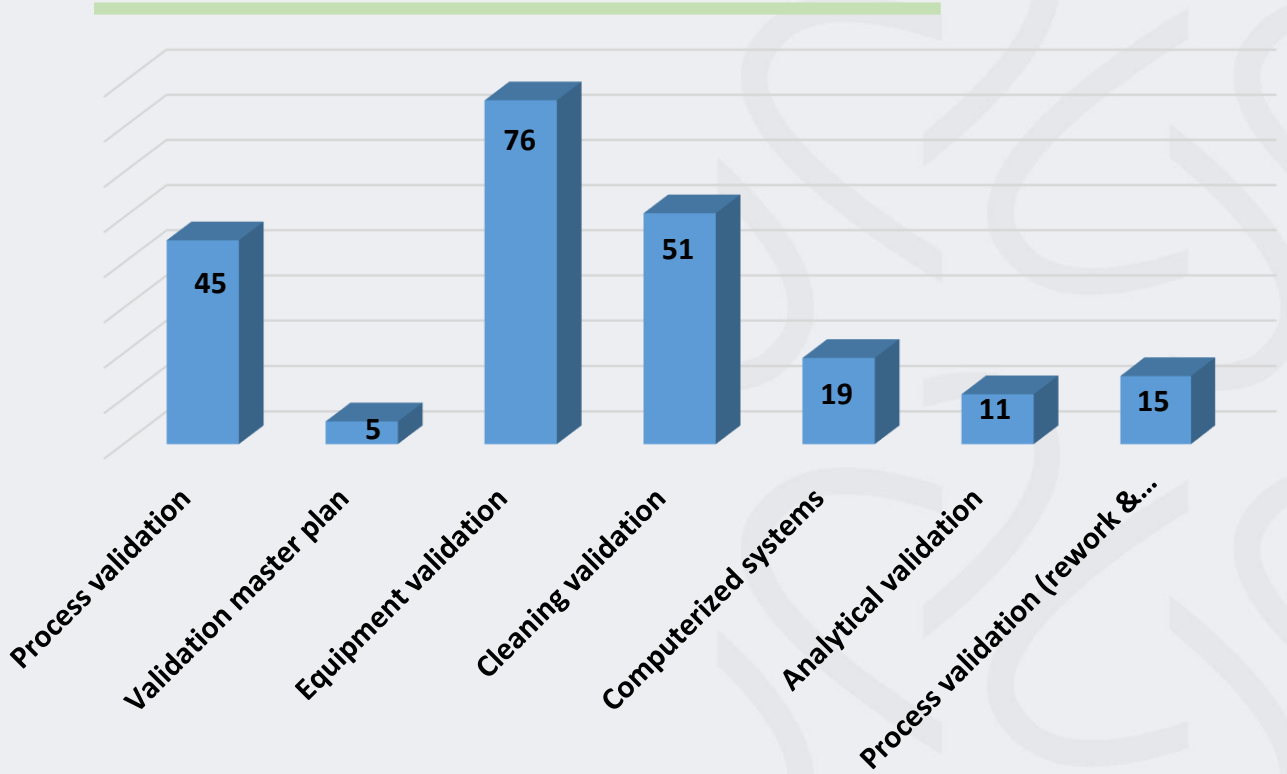
251 Deficiencies



Most Common Deficiencies Related to Validation

Validation

222 Deficiencies



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Thank You