



# SFDA GMP Inspection Deficiency Data Trend 2022

**OPERATION SECTOR**

Manufacturer Inspection Support Department

# 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
  
- **09** site manufacturers were suspended or rejected in 2022

# Overview of GMP Inspections Carried Out

- In 2022, a total of **51 GMP inspections** were conducted, resulting in the identification of **717 deficiencies**. Among these inspections, **305** were classified as major or critical deficiencies.

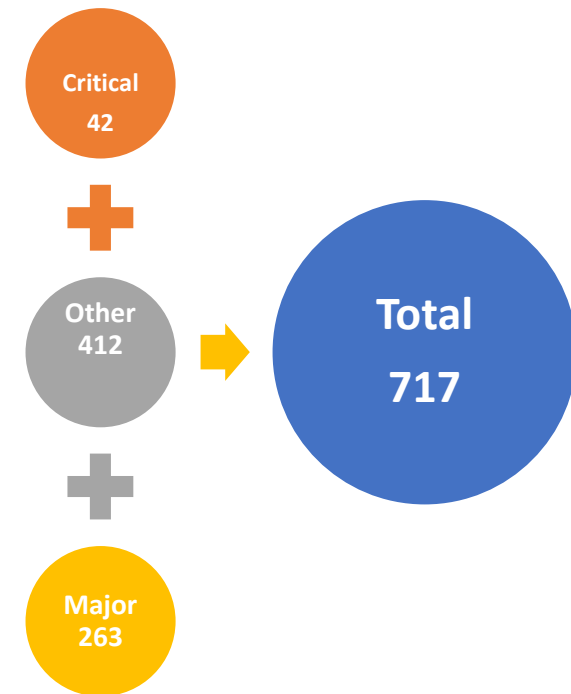
# Total Number of Critical / Major / Other Findings in 2022

## Critical

- 42 Critical deficiencies raised
- 6% of all 717 deficiencies inspections raised Critical deficiencies

## Majors

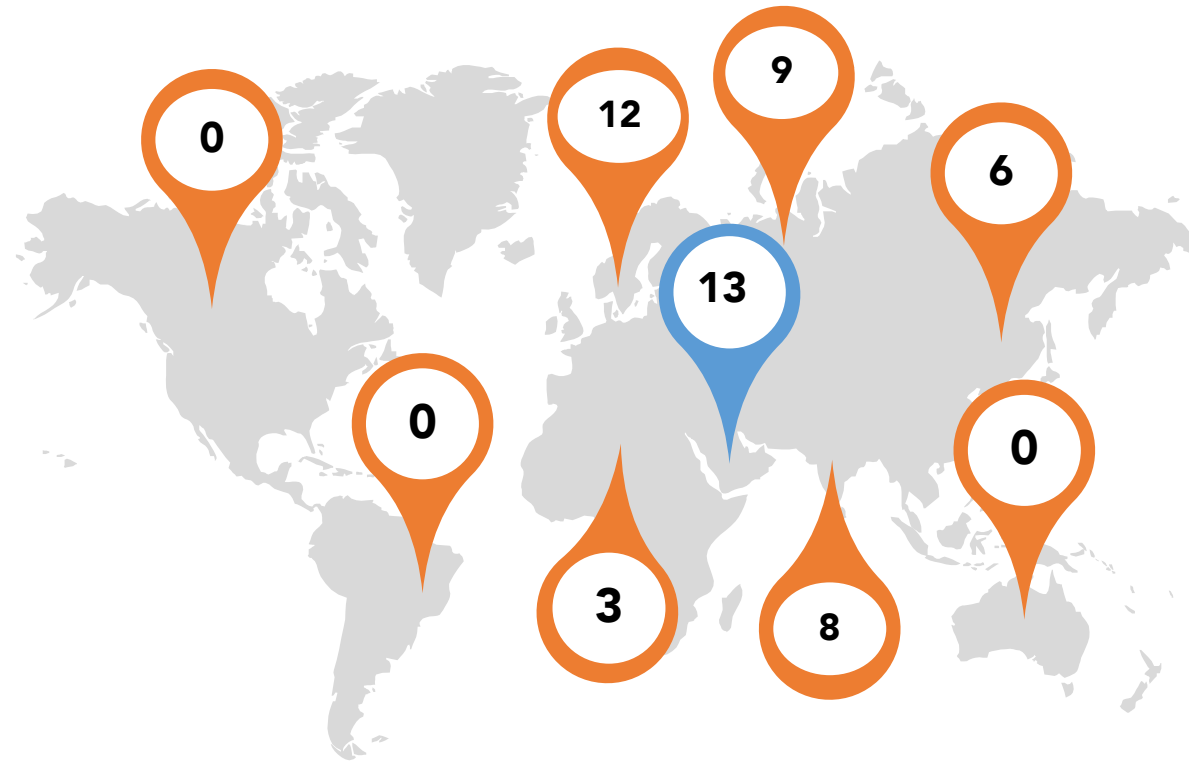
- 263 Major deficiencies raised
- 37% of all 717 deficiencies raised Major deficiencies



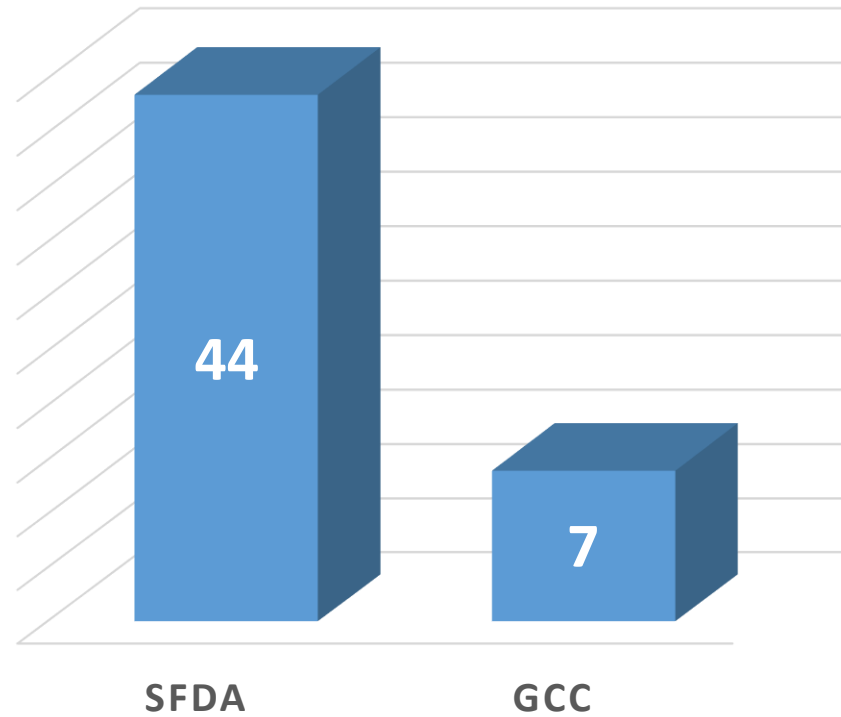
# Overseas Inspections Review according to Continent

**20%** Of the inspection reviews are locally

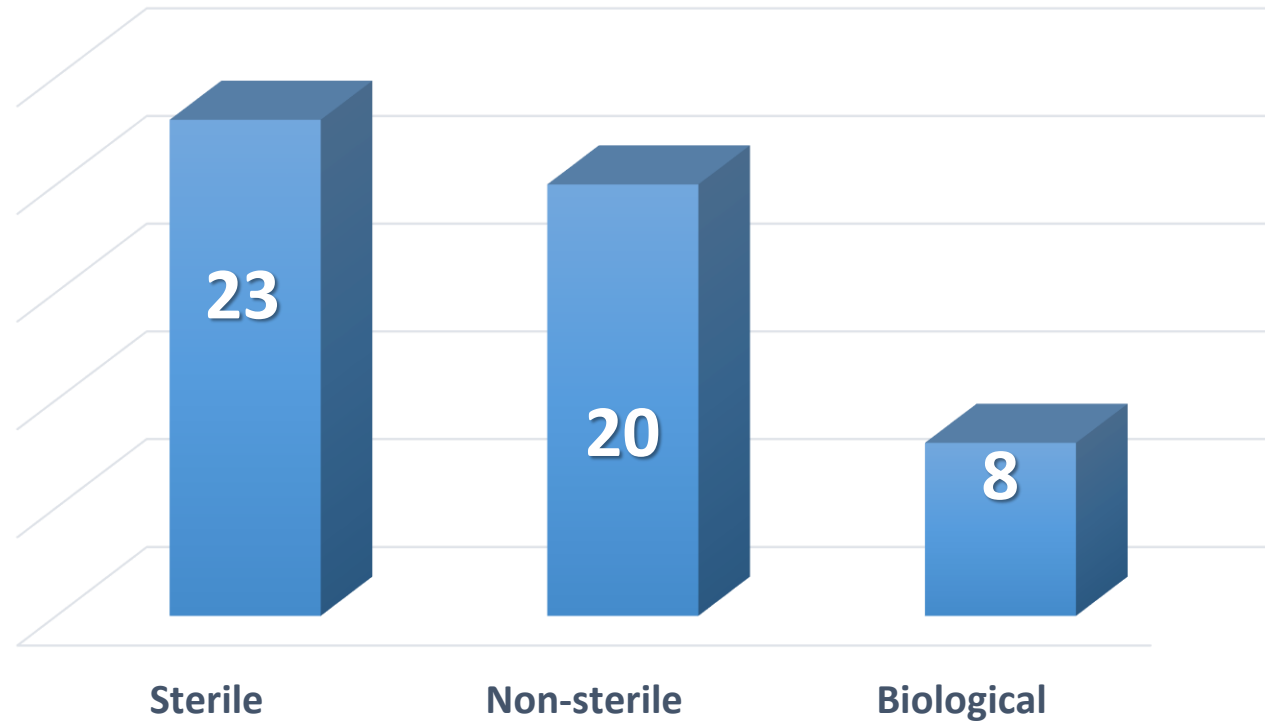
- Local – 13
- Africa – 3
- Australia – 0
- Europe – 12
- Far east – 6
- Indian – 8
- Middle east – 9
- North America – 0
- South America – 0



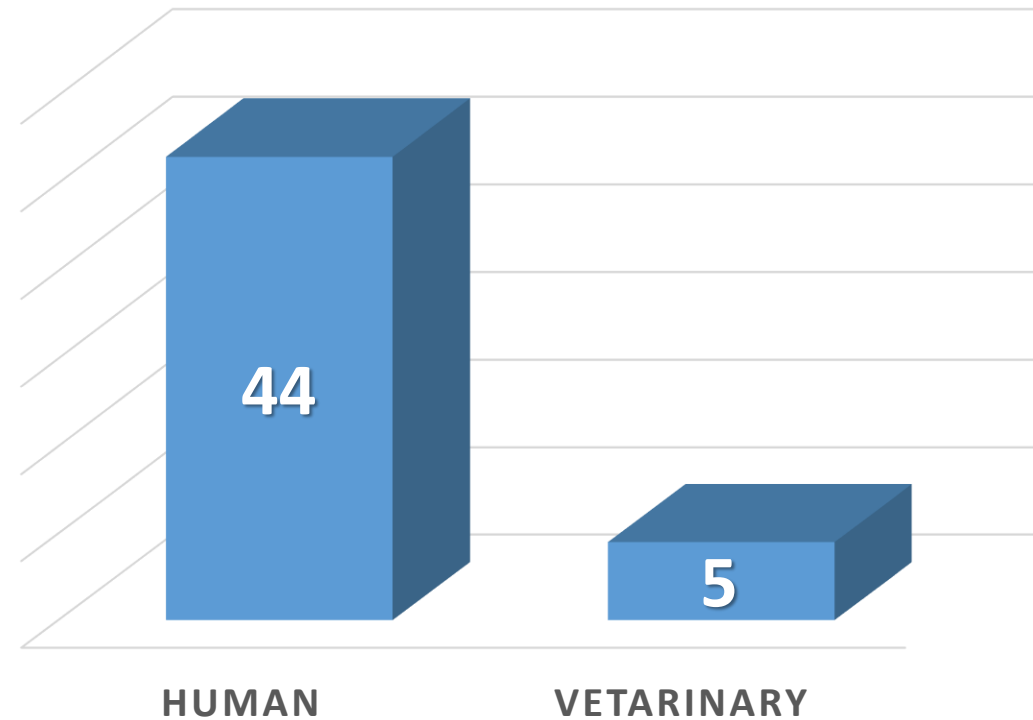
# Overseas Inspections Review according to the Type of Inspection



# Overseas Inspections Review according to Type of Product



# Overseas Inspections Review according to Type of Company

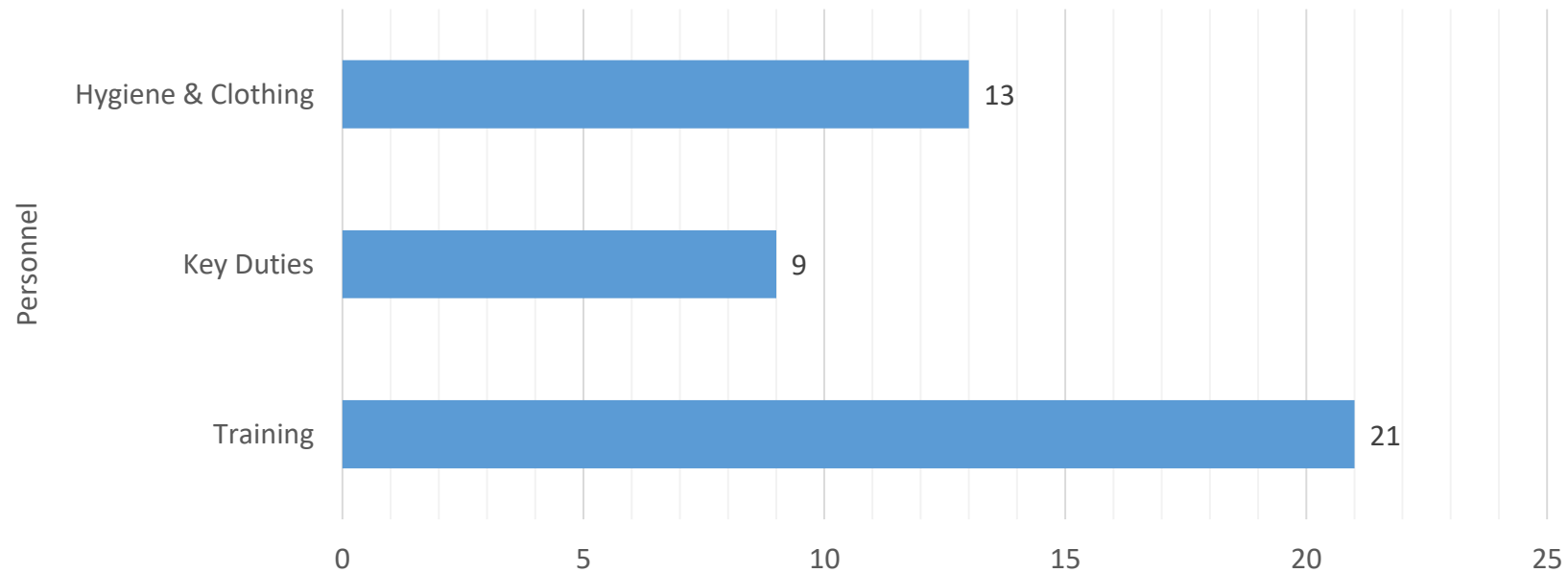




# Most Common Findings for Sites according to systems

## Personnel

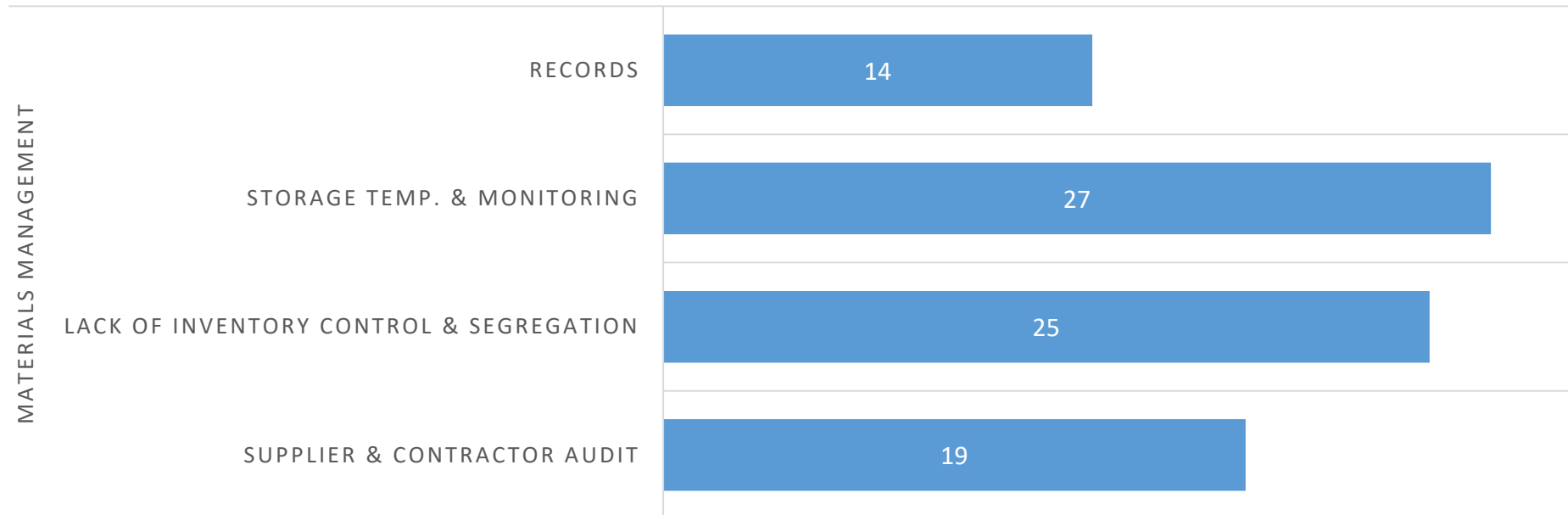
Personnel 43



# Most Common Findings for Sites according to systems

## Material Management

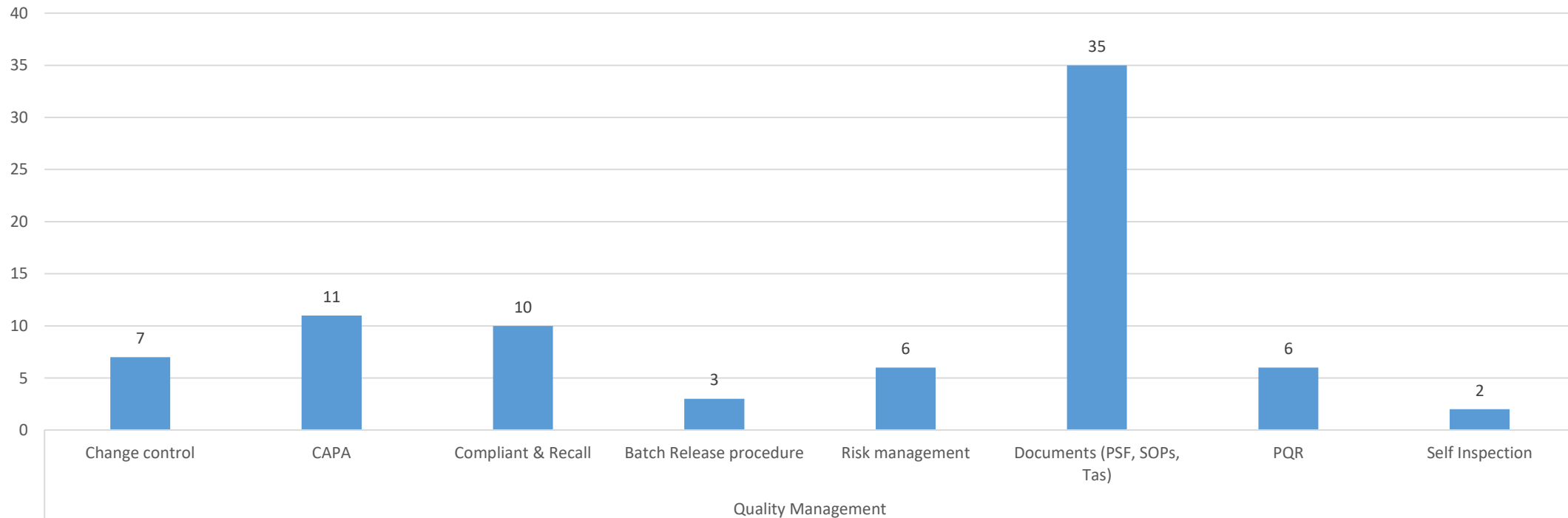
### MATERIALS MANAGEMENT 85



# Most Common Findings for Sites according to systems

## Quality Management

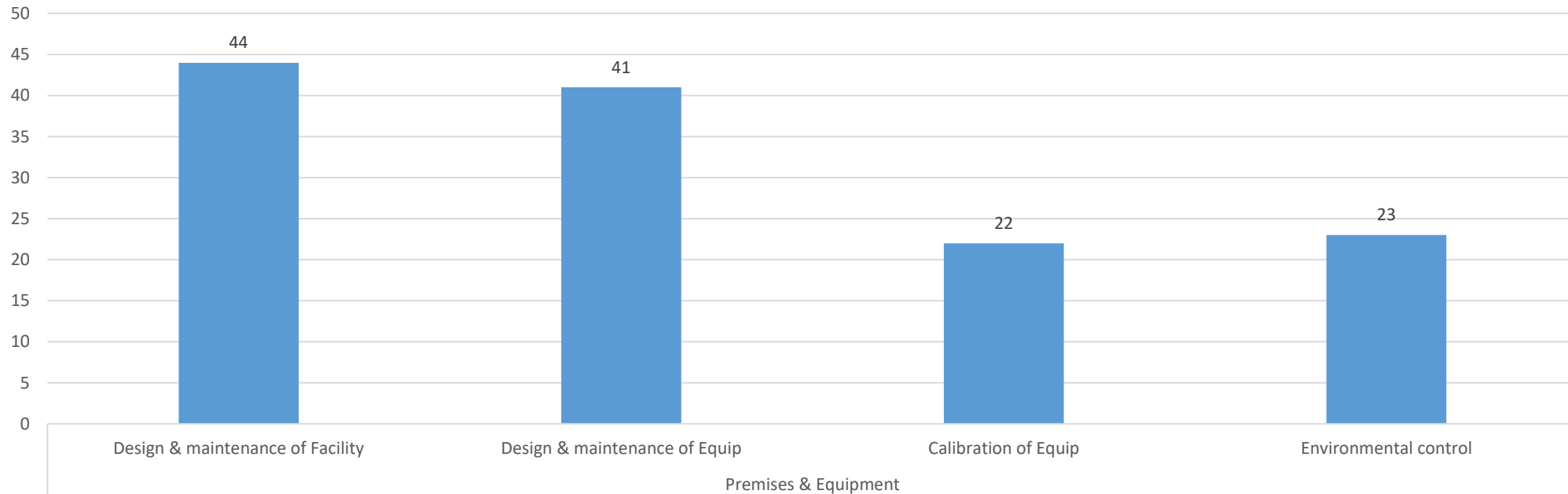
Quality Management 80



# Most Common Findings for Sites according to systems

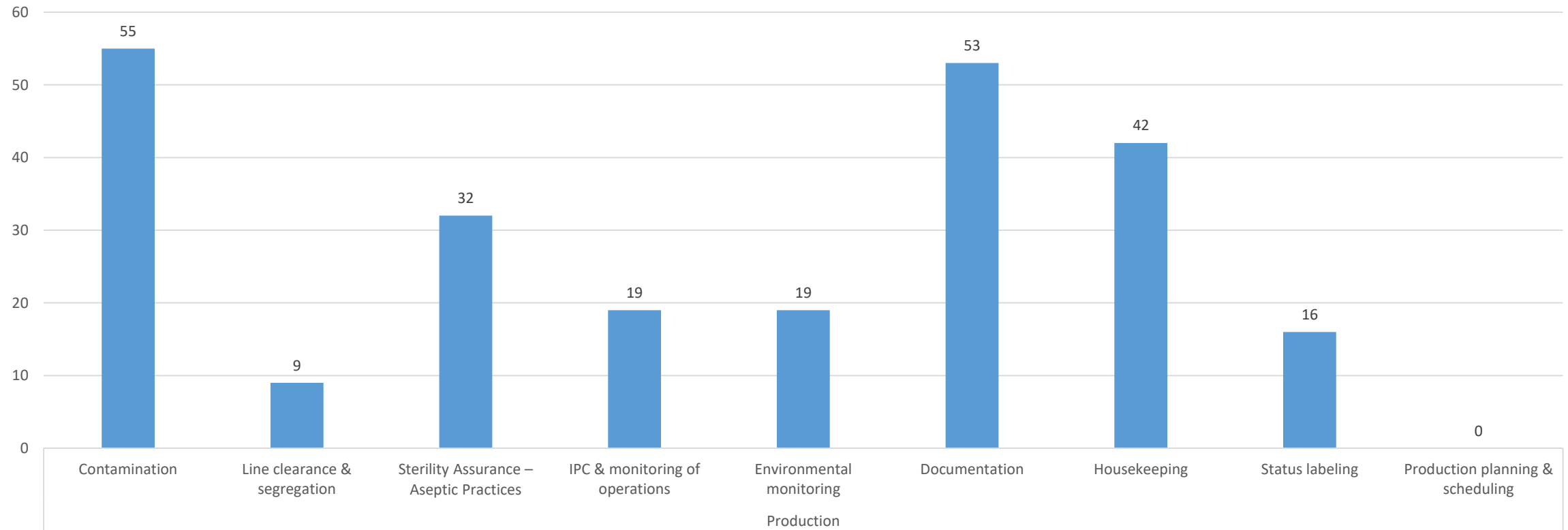
## Premises & Equipment

Premises & Equipment 130



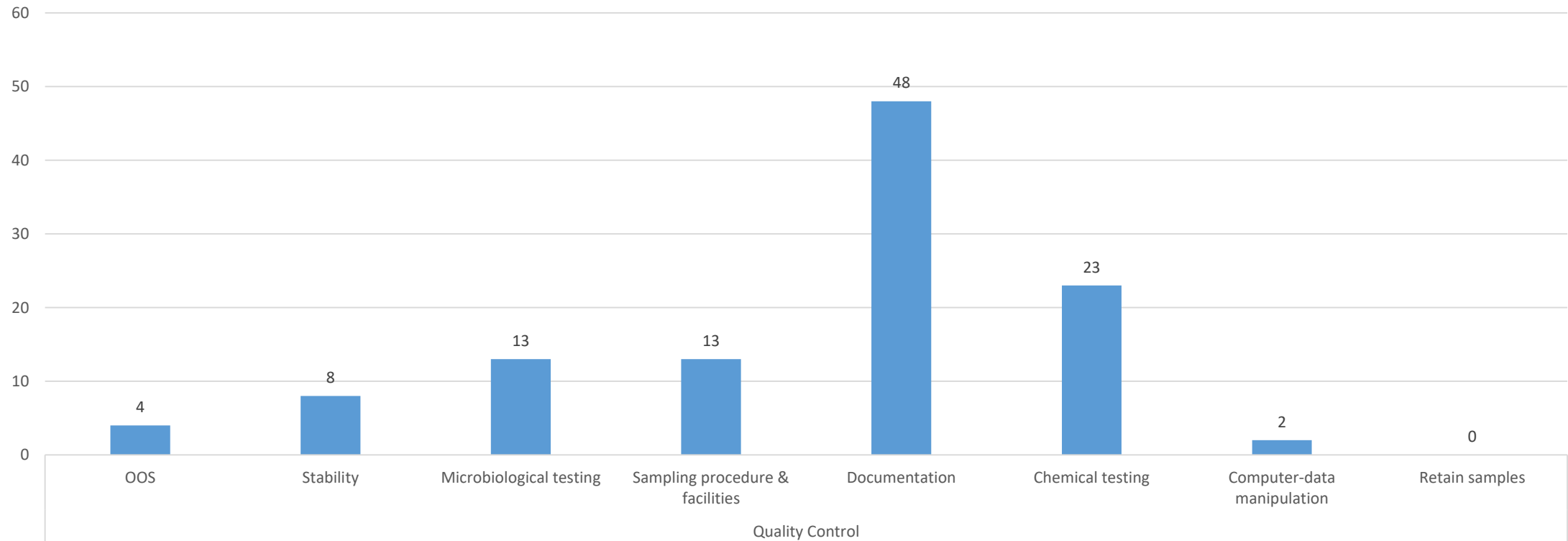
# Most Common Findings for Sites according to systems

Production 245



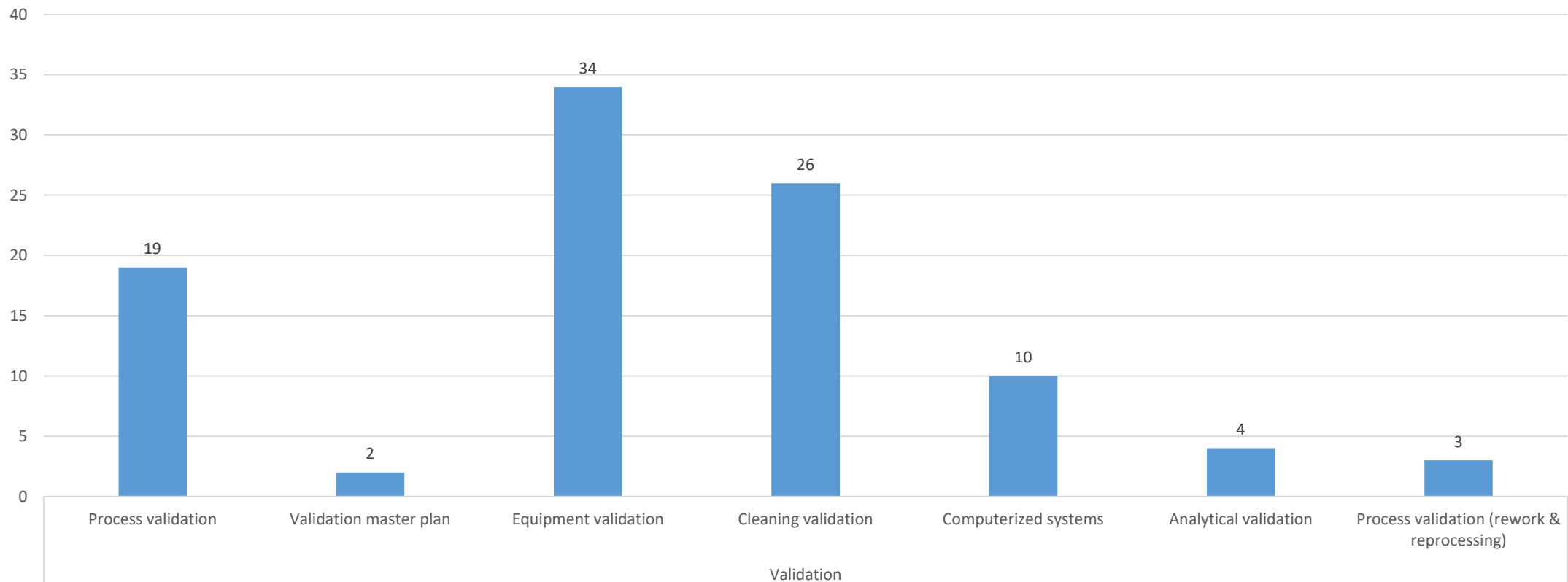
# Most Common Findings for Sites according to systems

Quality Control 111

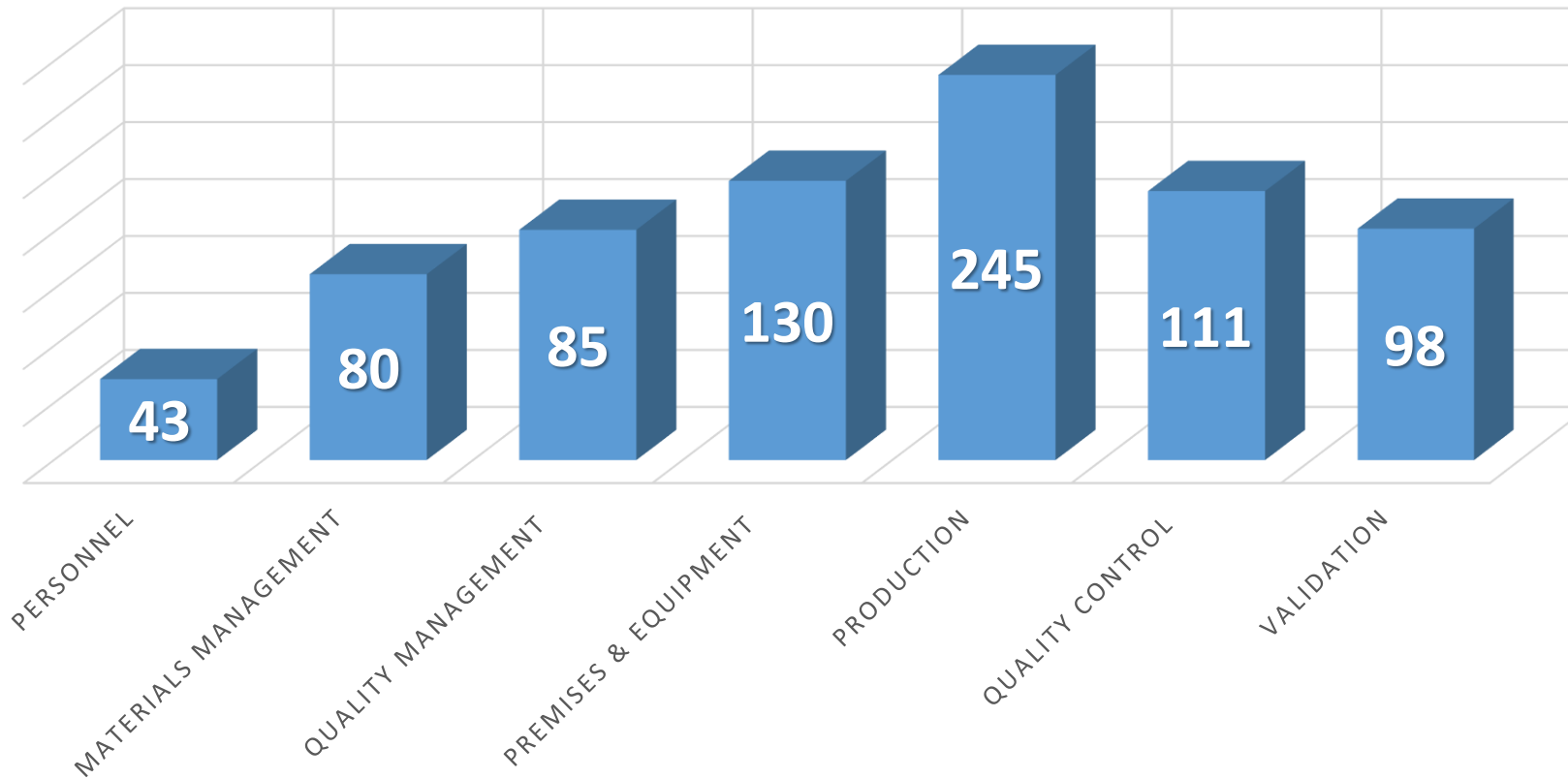


# Most Common Findings for Sites according to systems

Validation 98



# Most Common Findings for Sites according to systems





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Thank you