

SFDA GMP Inspection Deficiency Data Trend 2020

OPERATION SECTOR

Manufacturer Inspection Support Department

Executive Summary

➤ Due to the outcome of global pandemic in 2020 the SFDA introduced some initiatives due to the difficulties in traveling resulting in registration of 181 pharmaceutical companies in 2020 and the other were by conducting of inspection as follow on :

1- Pharmaceutical manufacturing companies .

2- Blood Banks .

Executive Summary

1- Pharmaceutical Companies:

- Deficiencies relating to Quality Management 'Documents (PSF, SOPs, TAS)' and Premises & Equipment 'Design & maintenance of Facility' are by far the most prevalent observed during inspections.
- 38 % of deficiencies were observed in Premises and equipment area while only 2% were observed in OOS Personnel
- ❖ 1 Manufacturers were suspended in 2020
- ❖ 1 manufacturer receive a warning letter in 2020

Overview of GMP Inspections Carried Out

59 GMP inspections carried out in 2020 , 689 resulted in Major / Critical/ Other Deficiencies of the inspections

- 45 were in the Saudi Arabia
- 14 were overseas

Overview of Blood banks Inspections Carried Out



2- Blood Banks :

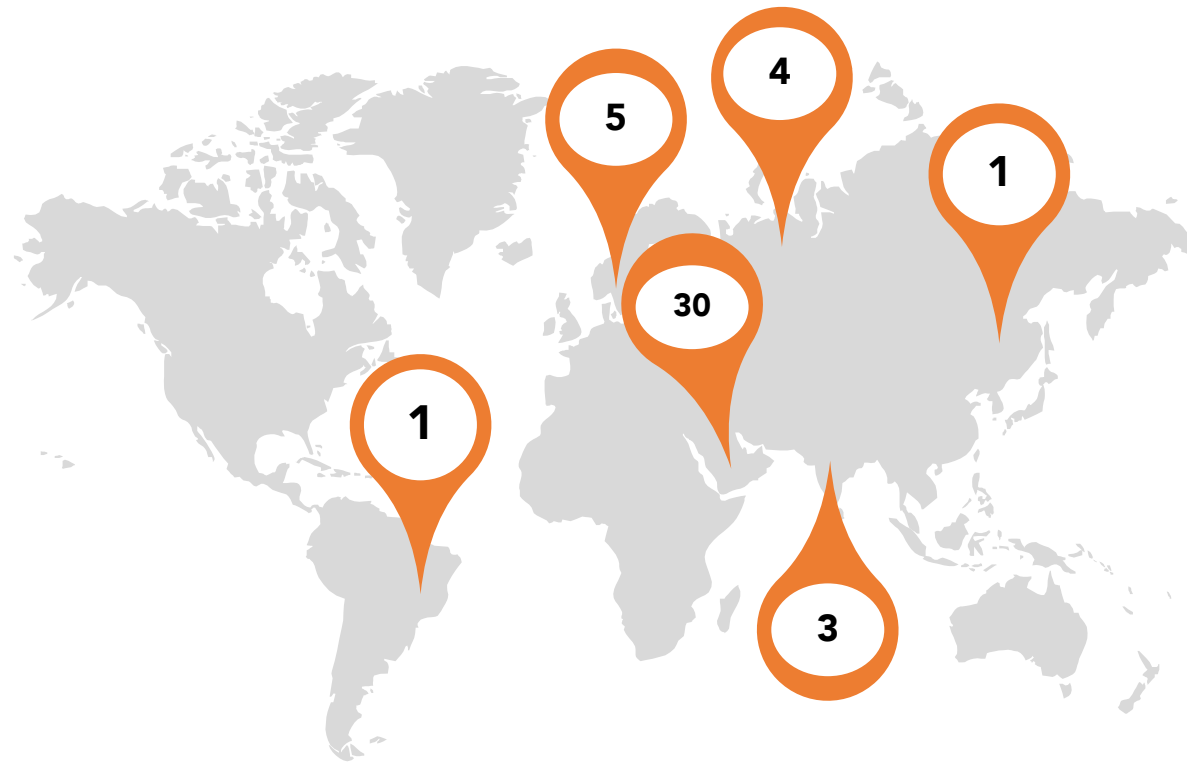
8 inspections carried out in 2020 for blood banks , 131 resulted in Major or Critical Deficiencies of the inspections with Major/Critical deficiencies:

- 2 in western region
- 2 in central region
- 1 in eastern region
- 3 in southern region

1- GMP Inspections Review according to Continent (Pharmaceutical)

76% Of the inspection reviews are locally

Local – 45
Europe – 5
Far east – 1
Indian – 3
Middle east – 4
South America – 1



Total Number of Critical / Major / Other Findings in 2020

Critical

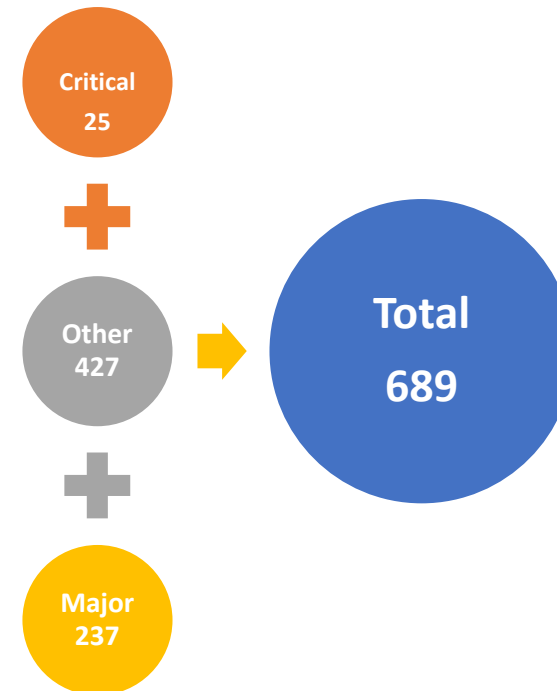
- 25 Critical deficiencies raised
- 4% of all 689 inspections raised Critical deficiencies

Majors

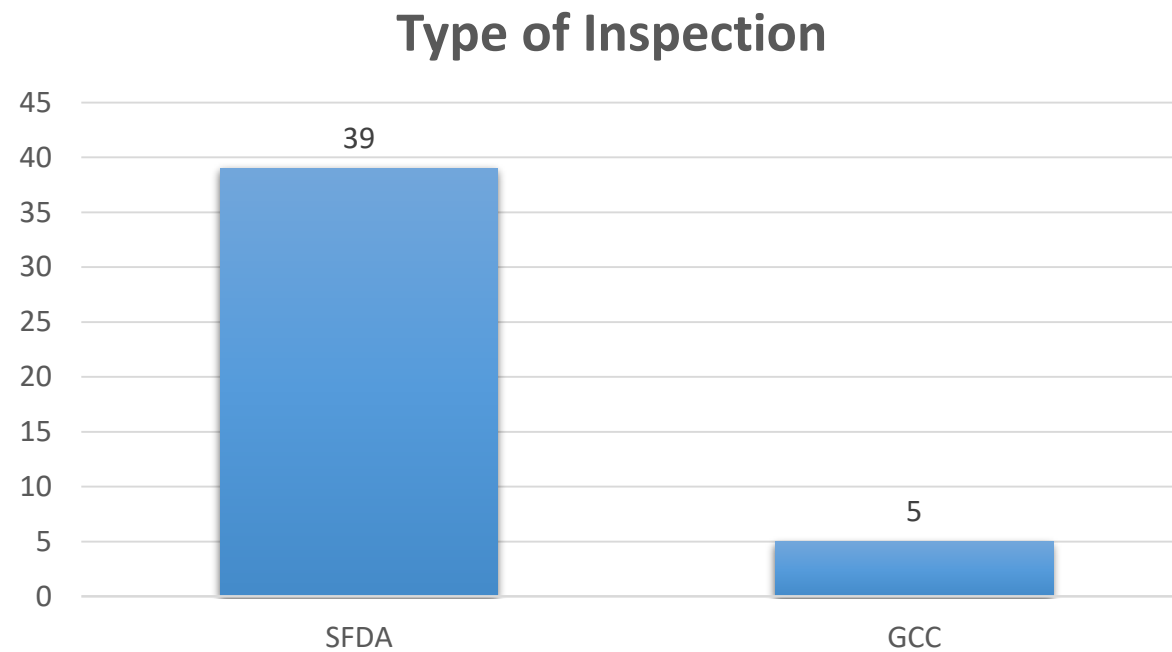
- 237 Major deficiencies raised
- 34% of all 689 inspections raised Major deficiencies

Other :

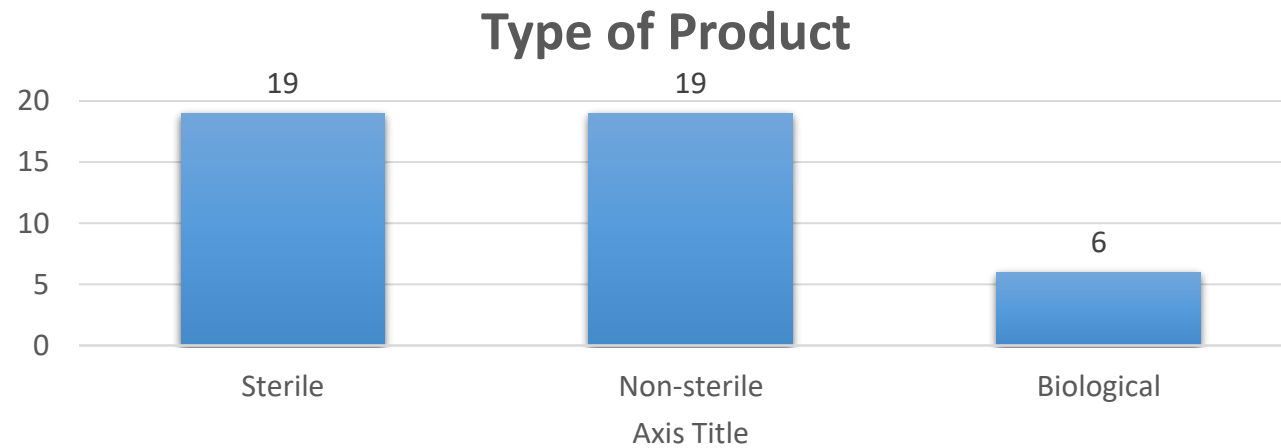
- 427 Major deficiencies raised
- 62 % of all 689 inspections raised Major deficiencies



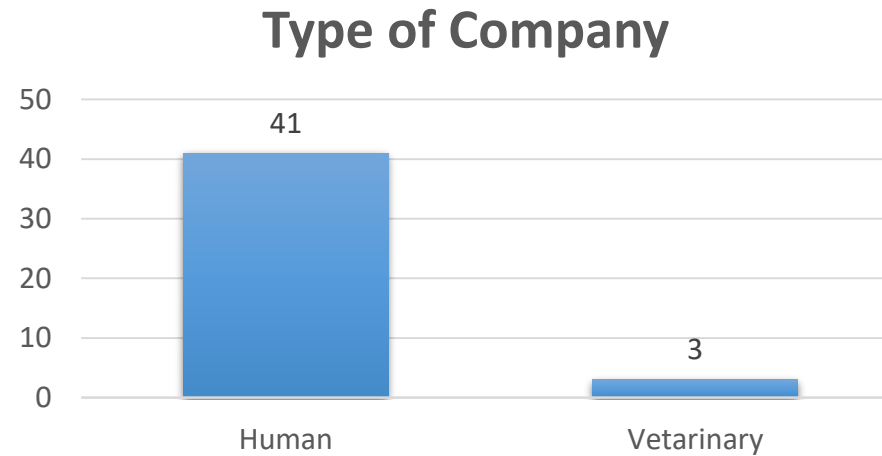
Type of Inspection



Type of Product



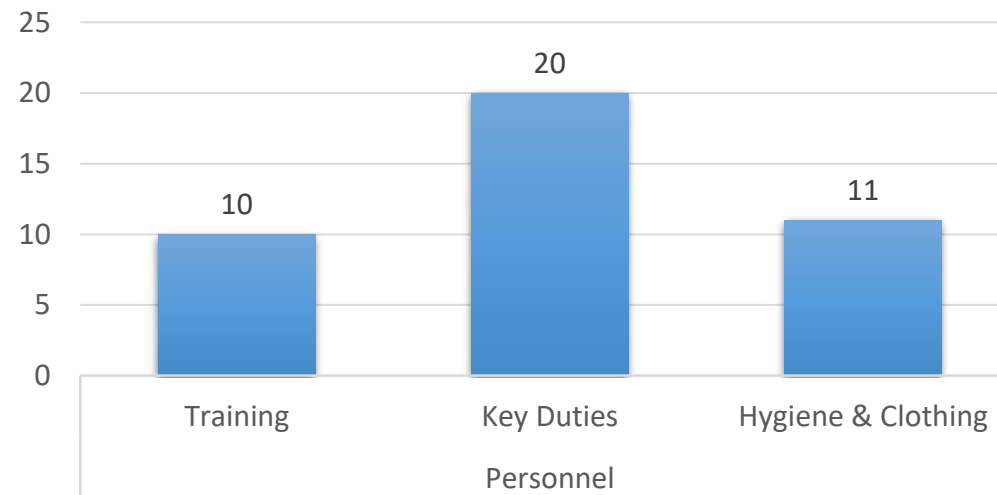
Overseas Inspections Review according to Type of Company



Most Common Findings for Sites according to systems

Personnel

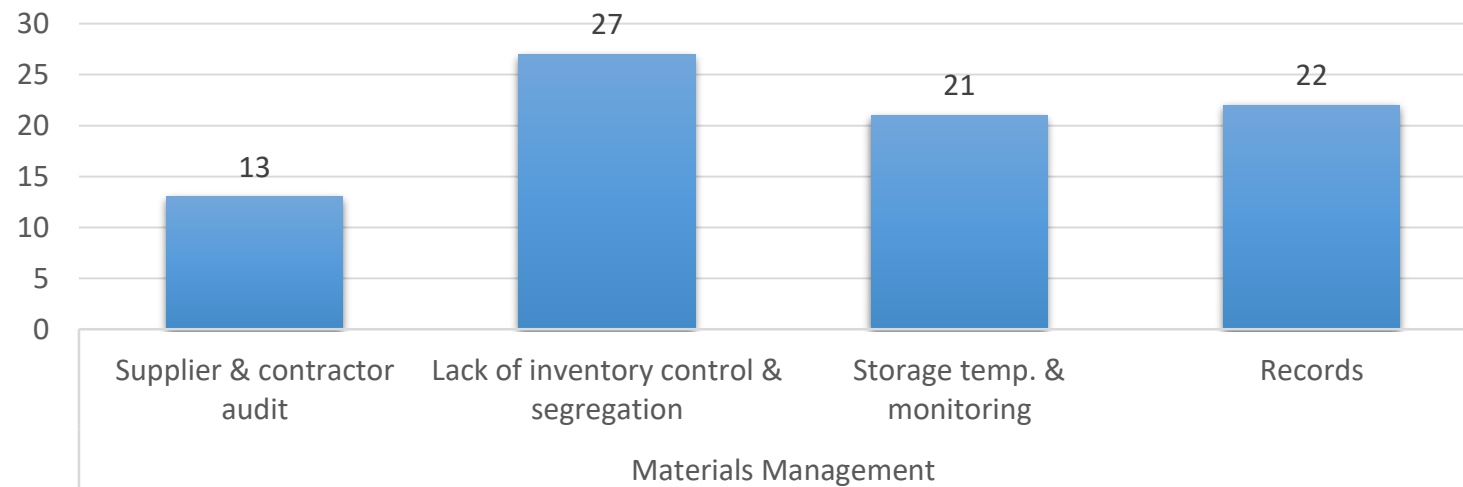
Personnel 41



Most Common Findings for Sites according to systems

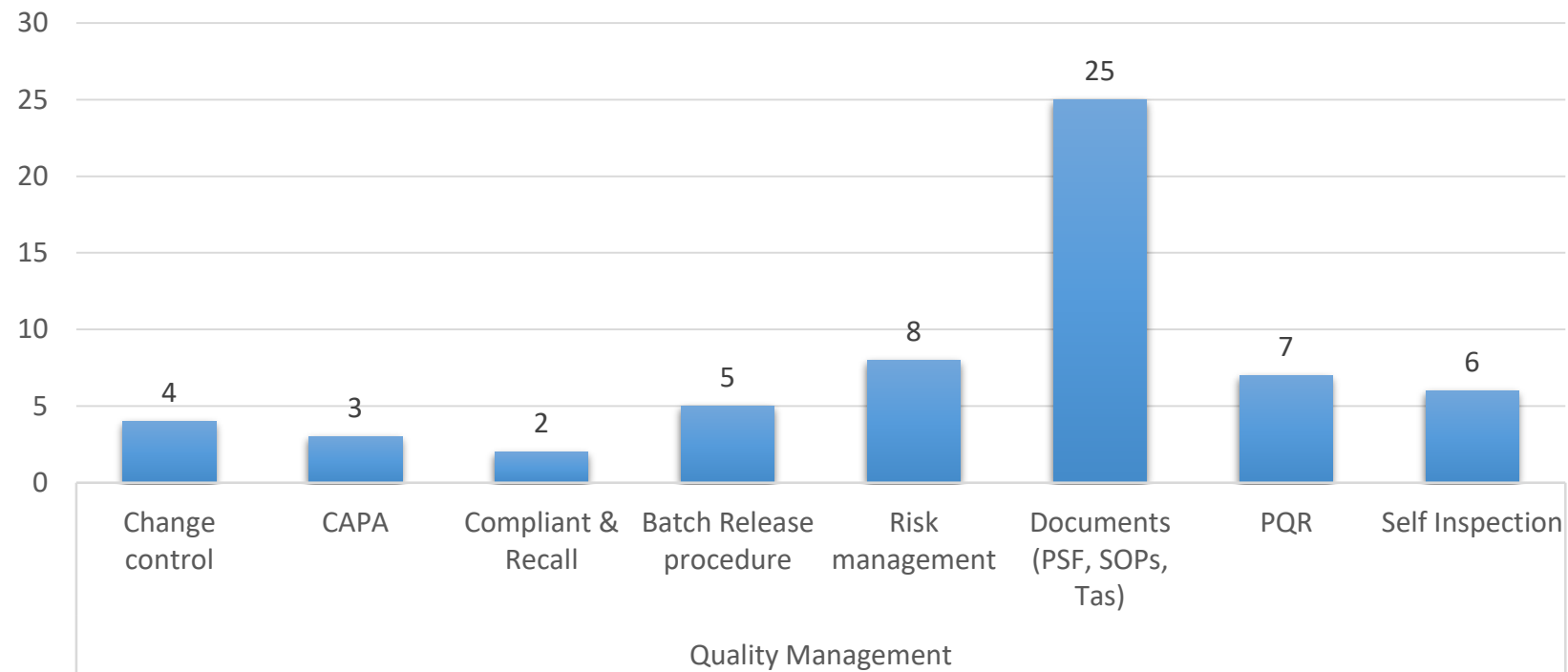
Material Management

Materials Management 83



Most Common Findings for Sites according to systems

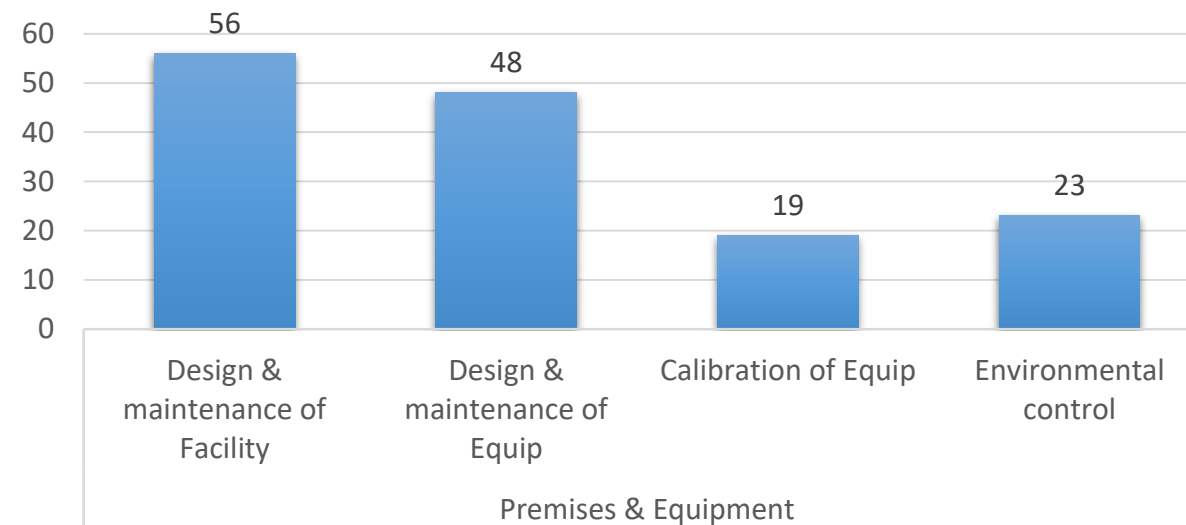
Quality Management 60



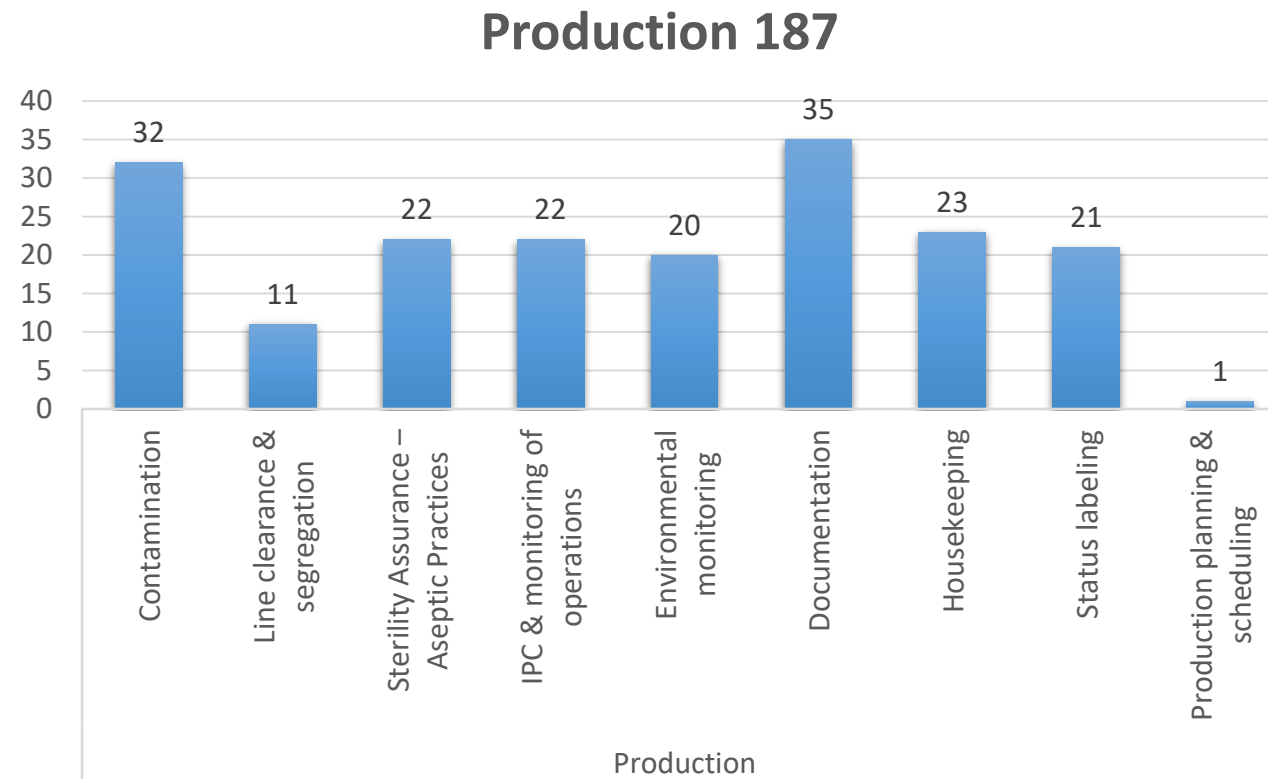
Most Common Findings for Sites according to systems

Premises & Equipment

Premises & Equipment 146



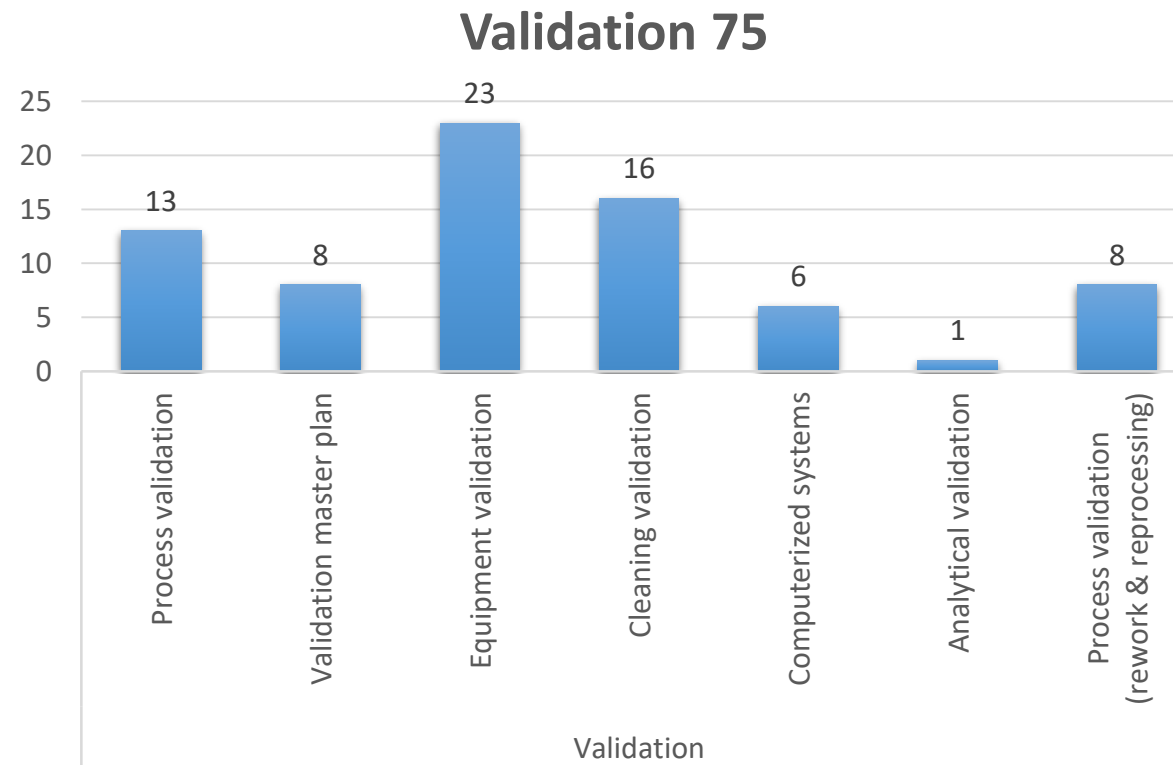
Most Common Findings for Sites according to systems



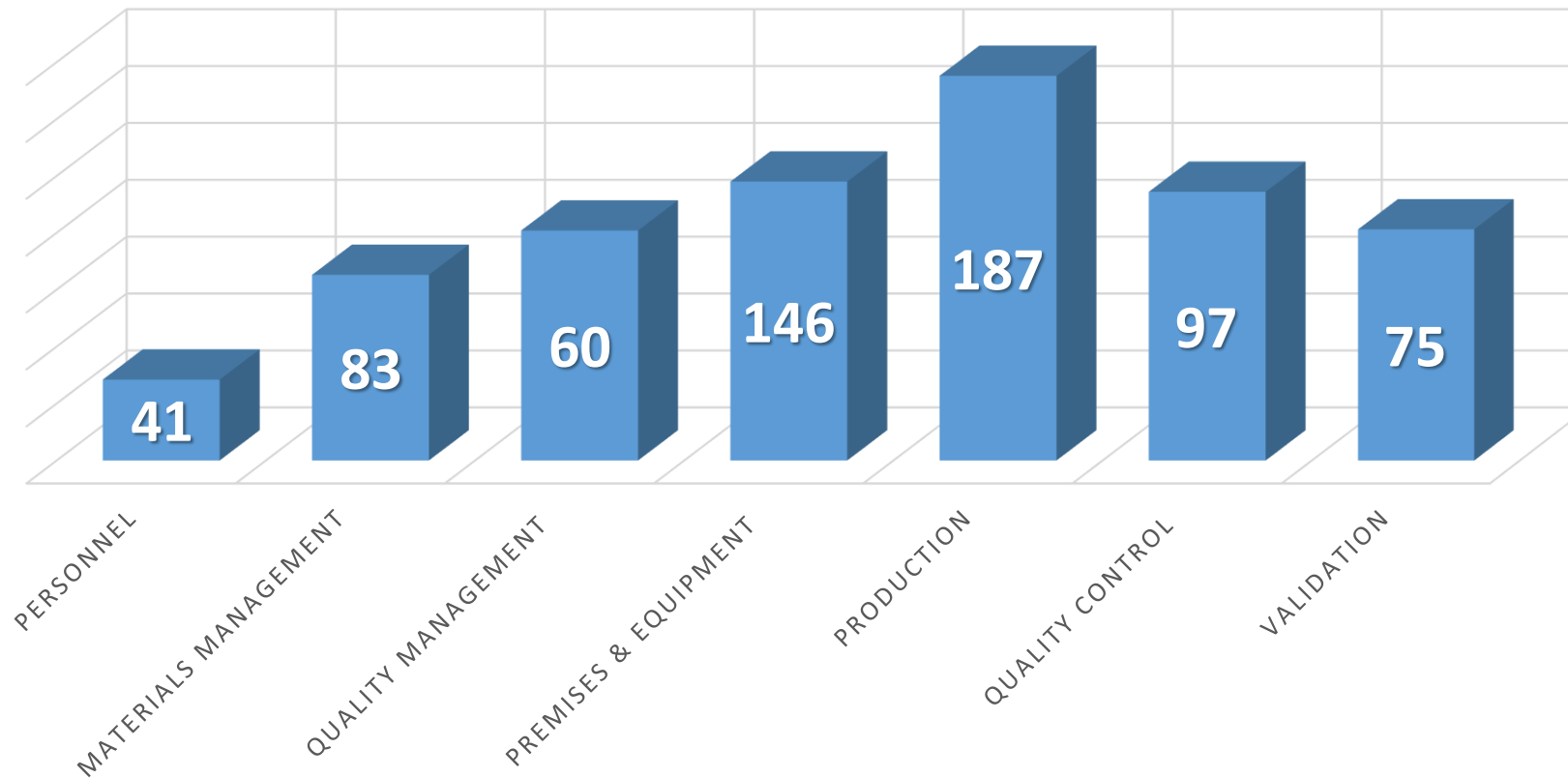
Most Common Findings for Sites according to systems



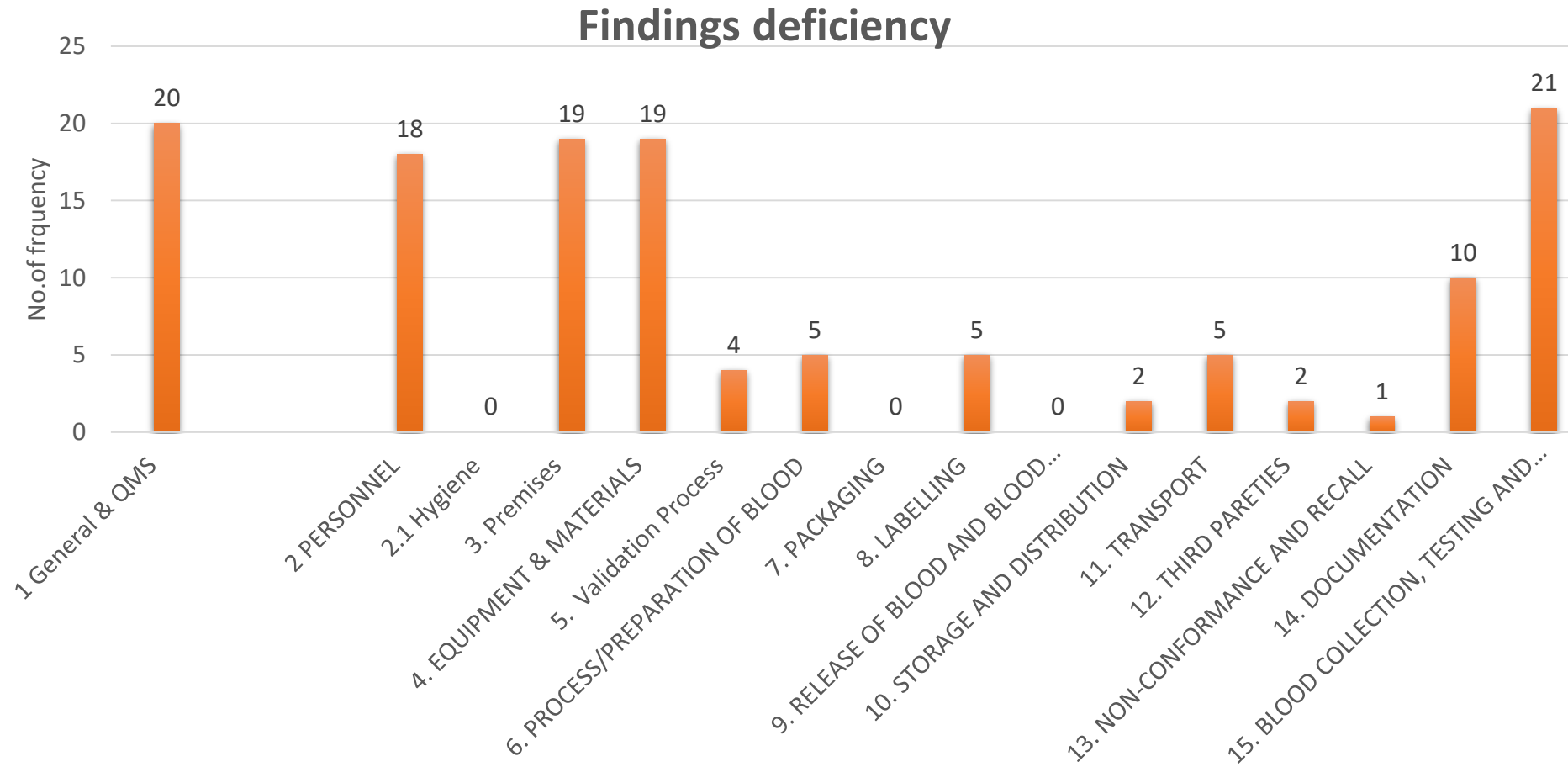
Most Common Findings for Sites according to systems



Most Common Findings for Sites according to systems

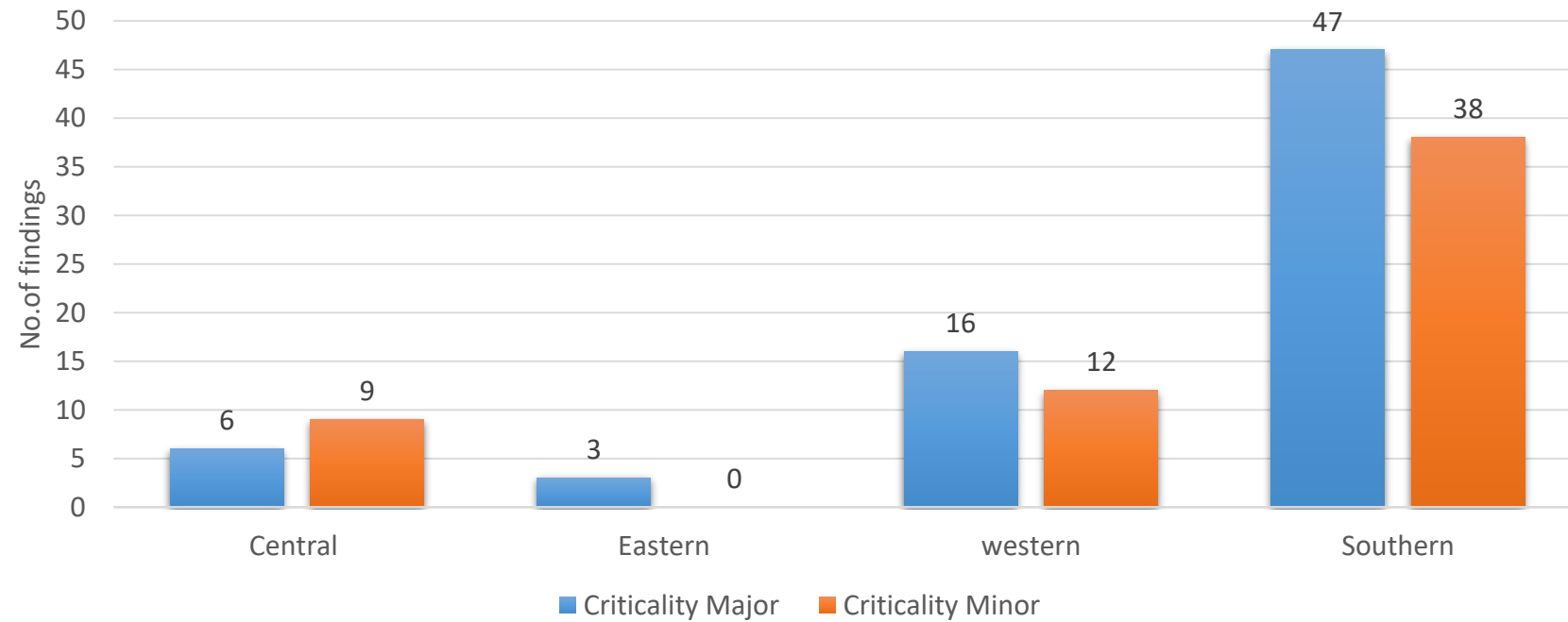


2- Blood banks most common findings



Blood banks

Criticality Distribution Based on Region



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Thank you