Saudi FDA GMP Inspection Overview

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Outlines

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- Inspection Qualification
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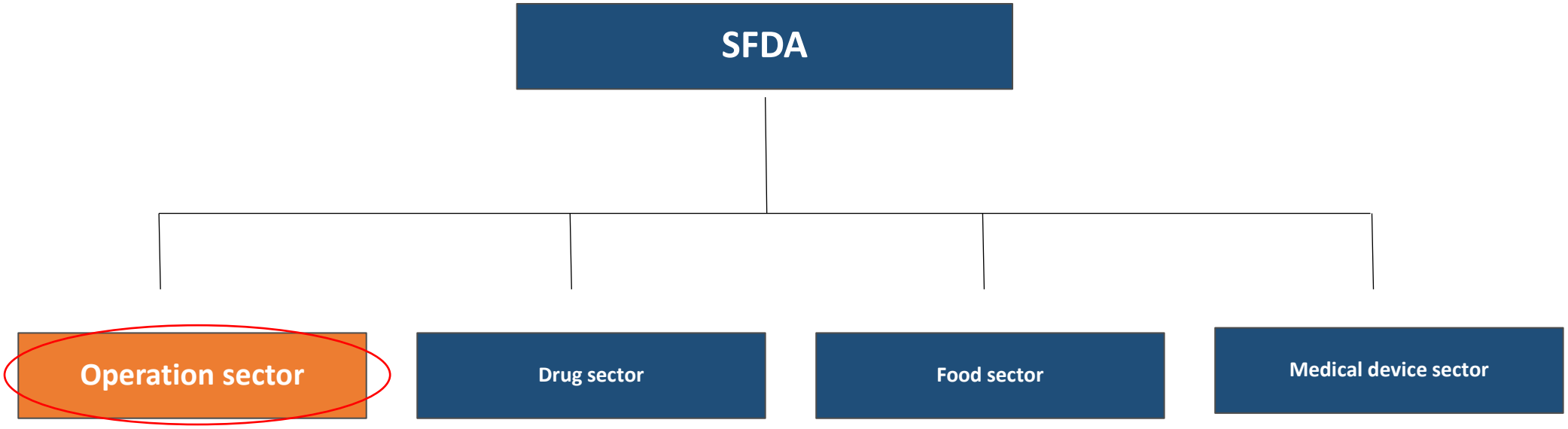
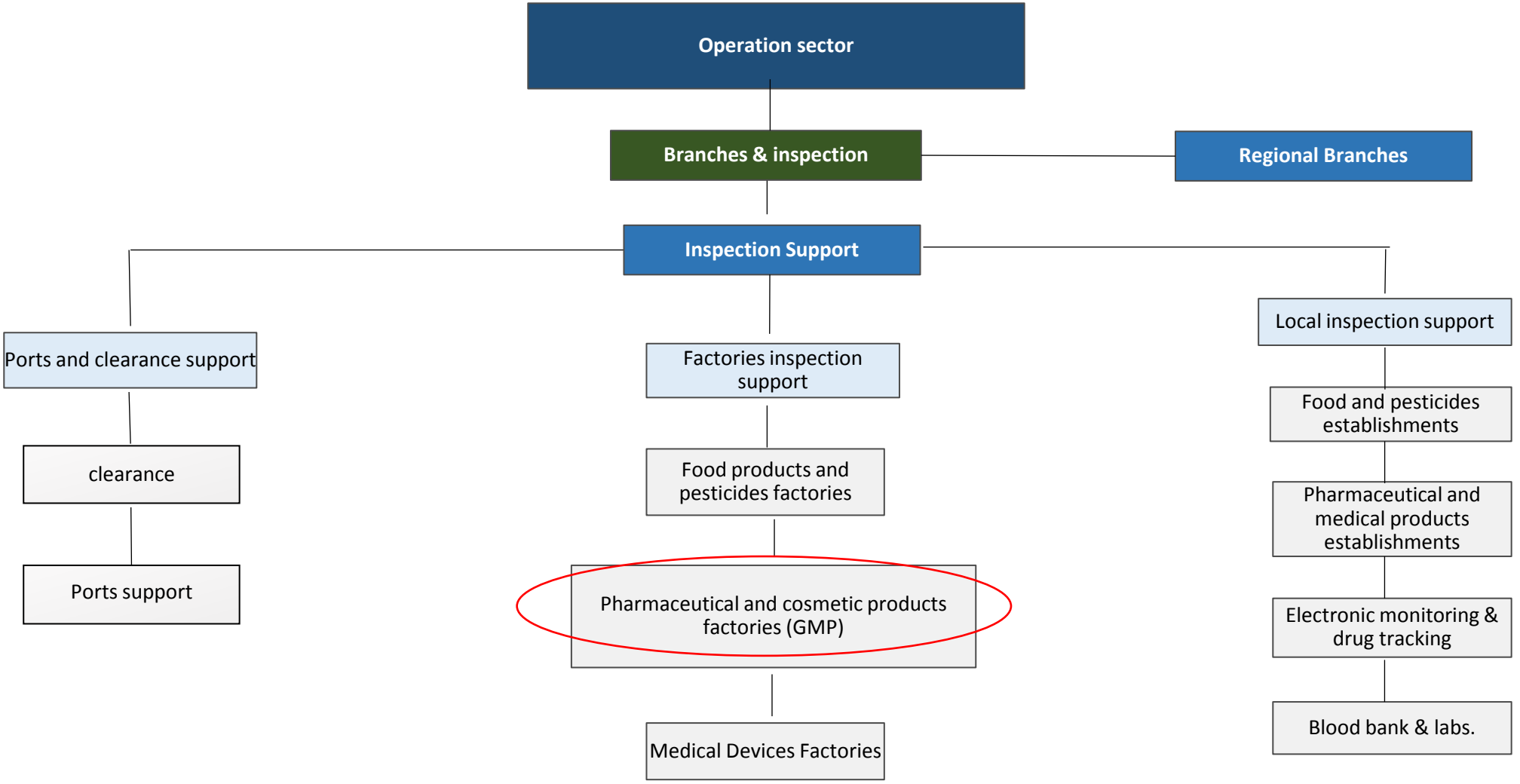
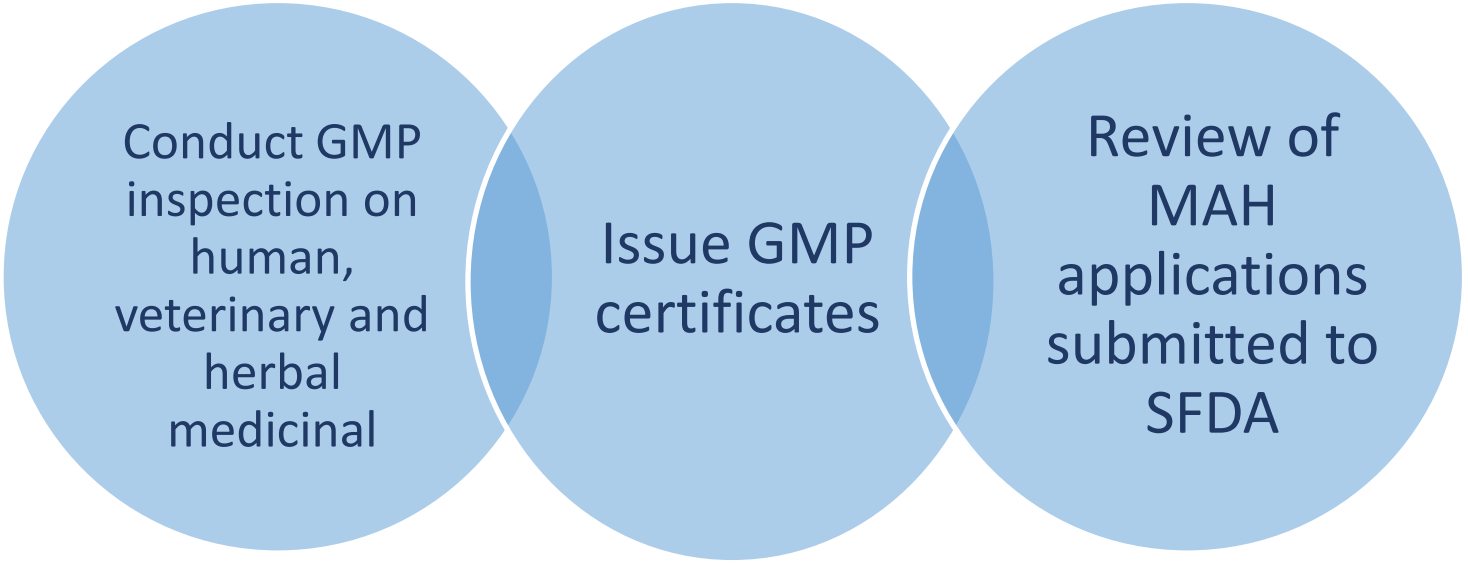

SFDA
Operation sector
Drug sector
Food sector
Medical device sector

Inspection Support Executive Directorate

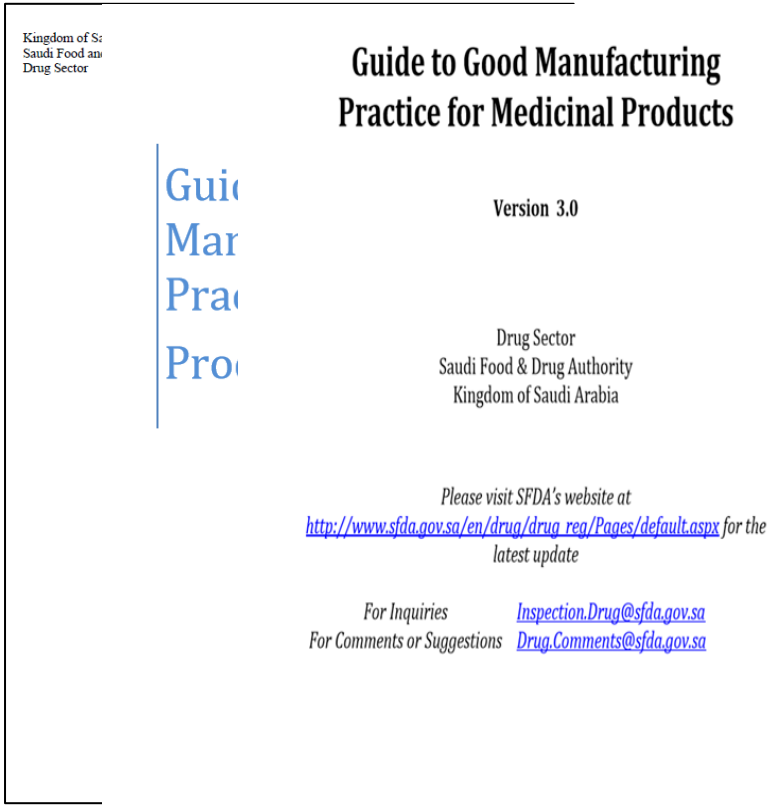


What does the SFDA GMP section do?



SFDA GMP Guideline

- After two years from establishment of SFDA in 2003, the first GMP guideline (version 1.0) was published as draft version
- In 2011, SFDA is adopting PIC/S guideline
- Latest GMP guideline (version 3.0) was published in 2018



Kingdom of Sa
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Drug Sector

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Guide to Good Manufacturing Practice for Medicinal Products

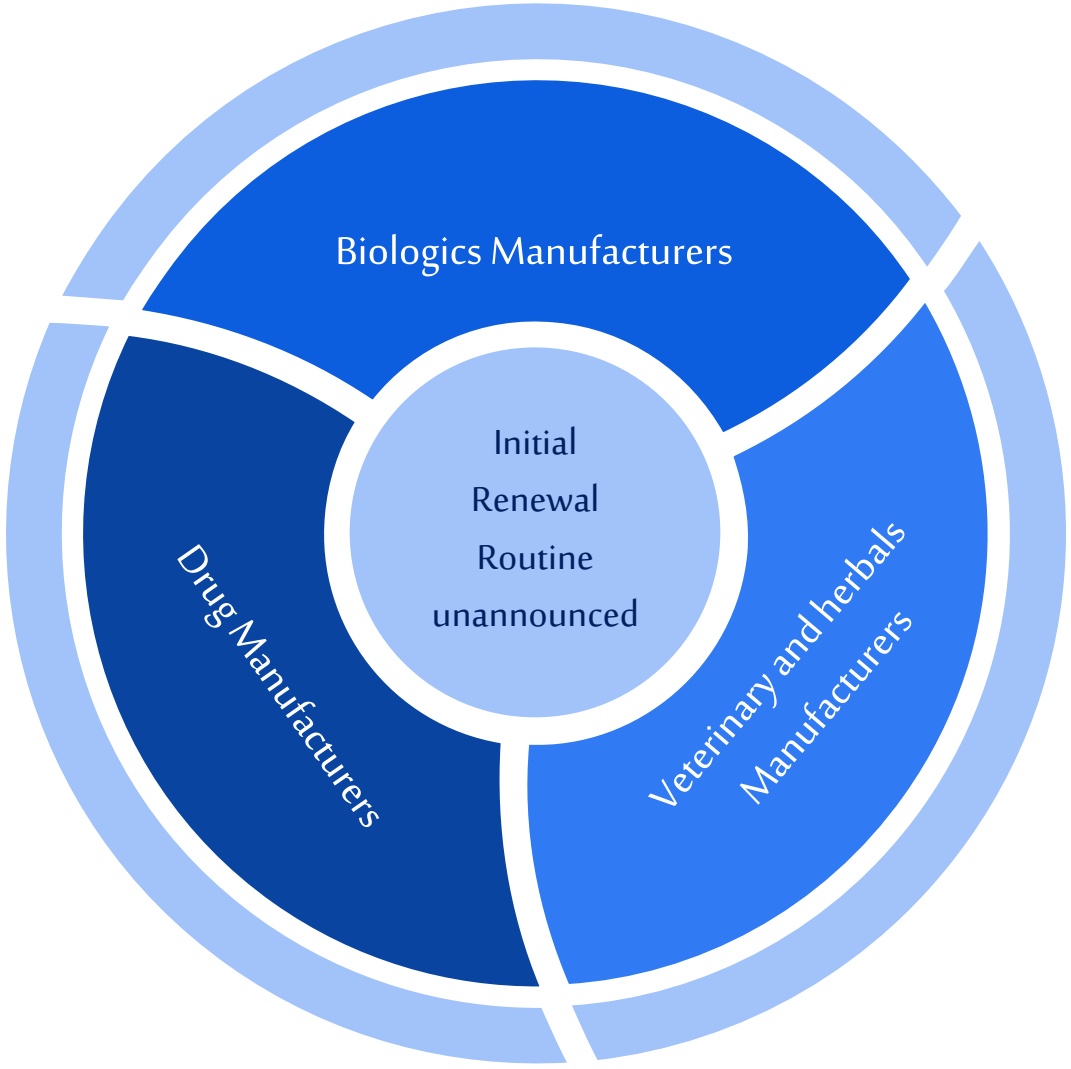
Version 3.0

Drug Sector
Saudi Food & Drug Authority
Kingdom of Saudi Arabia

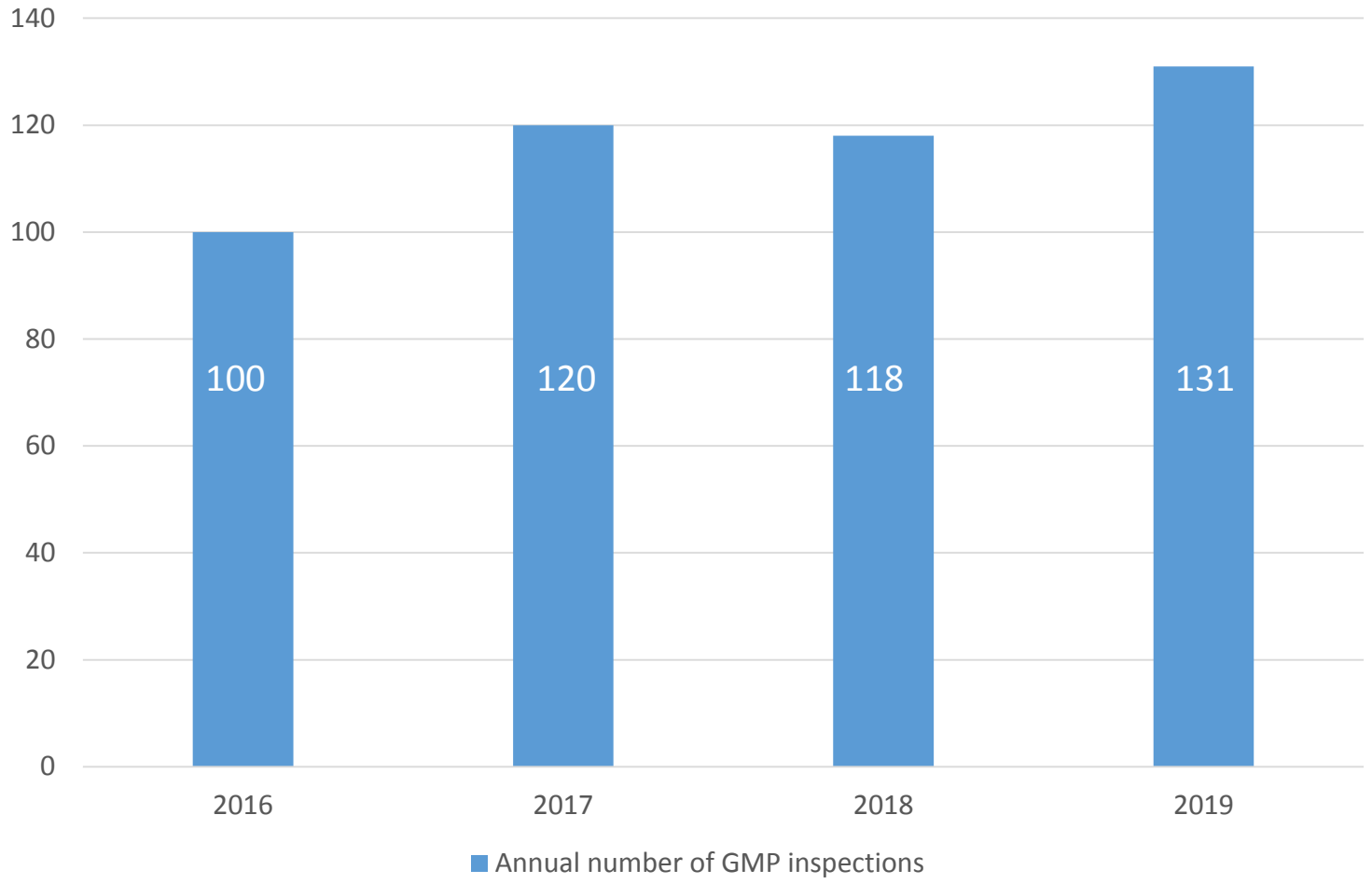
Please visit SFDA's website at
http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx for the latest update

For Inquiries *Inspection.Drug@sfda.gov.sa*
For Comments or Suggestions *Drug.Comments@sfda.gov.sa*

GMP Inspections on Medicinal Manufacturer



Annual number of GMP inspections



Overview of Pharmaceutical manufacturers in Saudi Arabia

- **There are 40 authorized manufacturer in Saudi Arabia:**
  - 33 authorized for full manufacturing distributed in all around Saudi regions.
  - 1 API manufacturer.
  - 6 Authorized for primary or secondary packaging

GMP inspection methodology:

- Risk-based approach for local manufacturers:

This approach is to prioritize the most critical sites for inspections, and to measures frequency of inspections to ensure compliance with manufacturing principles.

- Steps:
  A. Factors:
     - Site Risk Category
     - Outcome of GMP report classification
  B. Matrix table
  C. Outcome result (Risk score)

Risk-based approach for local Manufacturers

1. **Site Risk Category**

High-risk products and processes include:

- Sterile medicines, including biotechnology active pharmaceutical ingredients (apis)
- Non-sterile medicines containing antibiotics, steroids or antineoplastics
- Tissue banks with complex processing
- Cellular therapies

Medium-risk products and processes include:

- Non-sterile medicines, including herbal, unless specified as high risk
- Tissue banks with low manipulation

Low-risk products and processes include:

- Homoeopathic medicines
- Minerals, vitamins, fish oils and other supplements
- Medicinal gases
- Labelling/packaging; analysis/testing; storage

Risk-based approach for local Manufacturers

2. Outcome of GMP report classification

- **A1 Good compliance**
  (Deficiencies or non-conformities were found, which are of a relatively minor nature and/or less than 3 major deficiencies)

- **A2 Satisfactory compliance**
  (3-10 major deficiencies)

- **A3 (warning letter) Bad compliance**
  (A large number of major (more than 10) and/or few critical deficiencies not need to suspend and/or revoke

Risk-based approach for local Manufacturers

B. Matrix table:

Risk category	A1 category	A2 category	A3 category (warning letter)
	Frequency of re-audit (months)		
High	24	12	6
Medium	30	24	9
Low	36	30	12

Inspectors qualification

- There are more than 30 qualified GMP inspectors.
- All inspector with bachelor degree in (80% Pharmacy, 5% microbiologist, 15% Medical laboratory)
- 30% of inspectors are master degree holders.
- Inspection teams are usually consist of at least 2-3 inspectors.
- It is the responsibility of inspection head to appoint inspectors to inspect the manufacturing sites (team leader and members) based on manufacturer type (Product) , inspector experience and availability.

Inspectors qualification

There are 3 types of training for inspectors in SFDA:

1- Applied Training program at Local manufacturers:

- The foundation training program is designed to provide new inspectors with basic information about GMP. It is carried out with cooperation with local manufacturers. The duration of these courses is 4 months.

2- In house Continues Training program:

Example of courses:	
Pharmaceutical Water Systems	**Effective Pharmaceutical Audits and Self-Inspections**
GMP for Biological and Biotechnology Products	**Aseptic process and Sterilization**
HVAC qualification	**Computer System validation and Data Integrity**

Inspectors Qualification

3- Cooperation with International Firms and company as:

A- Cooperation with global centers for training and research in biopharmaceutical manufacturing

- Tailored programs for SFDA inspectors on biopharmaceutical manufacturing

B- Universities

- **E.g. :** Qualified person program: a program that customized for SFDA Inspectors It provided a series of modules providing theoretical and practical knowledge.

C- Cooperation with major pharmaceutical firms and multinational companies for training on advanced production technology

Deficiency Data Trend 2018

The data deficiencies report distribute the observations into 7 categories (quality management, Personnel, Premises & Equipment, Production, Quality Control, Materials Management & Validation).

Deficiency Data Trend 2018

Overview of GMP Inspections Carried Out

- 118 GMP inspections carried out in 2018,
- 84 resulted in Major or Critical Deficiencies.
- out of the 84 inspections (with Major/Critical deficiencies)
  - 20 were in the Saudi Arabia
  - 64 were overseas

- 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. While 71% were observed in the other areas

Deficiency Data Trend 2018

- **Criticals**

– 83 Critical deficiencies raised

– 22% of all 118 inspections raised Critical deficiencies

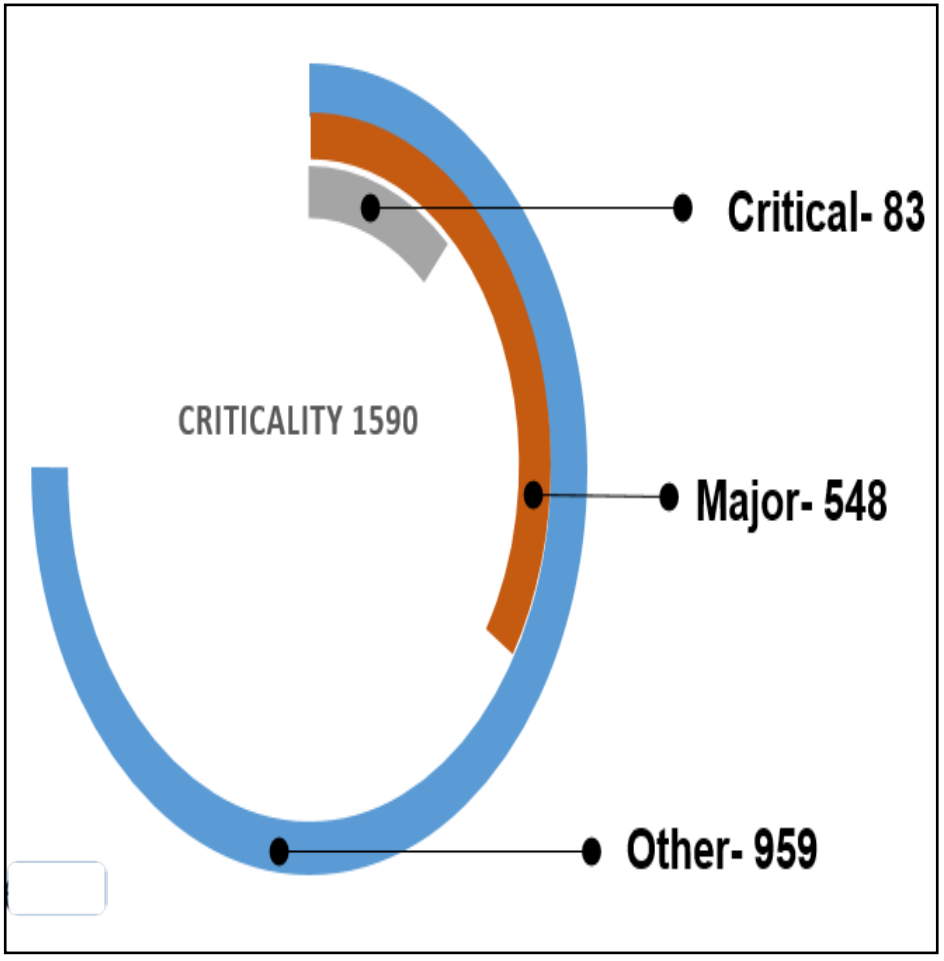
– A maximum of 10 Critical deficiencies were raised on a site.

- **Majors**

– 548 Major deficiencies raised

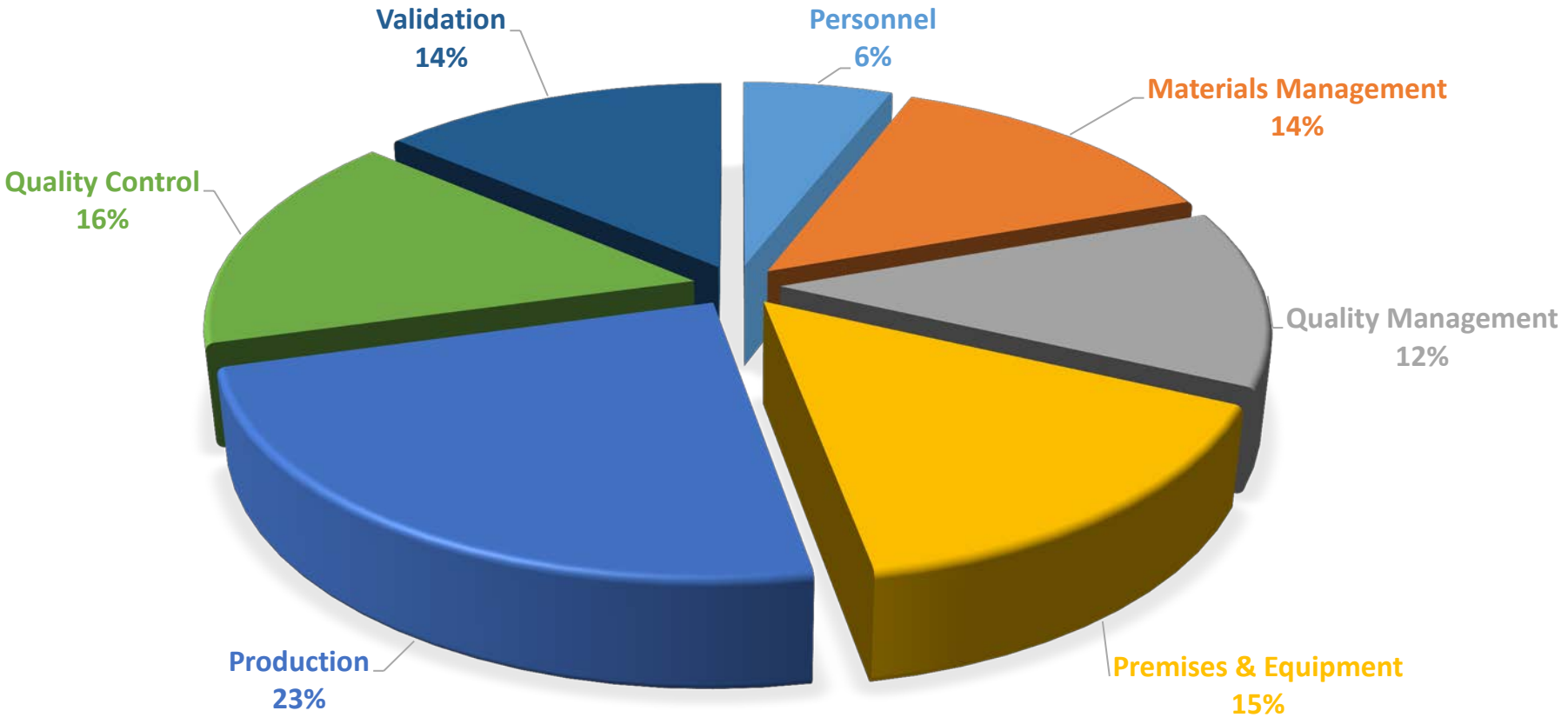
– 49% of all 118 inspections raised Major deficiencies

– A maximum of 30 Major deficiencies were raised on a site.



Deficiency Data Trend 2018

Detail of Site Types with Other/Major/Critical Deficiencies



Summary

- GMP Inspection section at SFDA is responsible for GMP inspection of local and international medicinal products industries.
- SFDA GMP guideline is adopted from PICS GMP guidelines.
- SFDA GMP inspections are conducted based on risk approach.
- Intensive training programs are carried out for GMP inspectors to ensure highest qualifications.
- Inspections results are under continuous review and evaluation.

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Saudi Food & Drug Authority

Thank you for your kind attention.