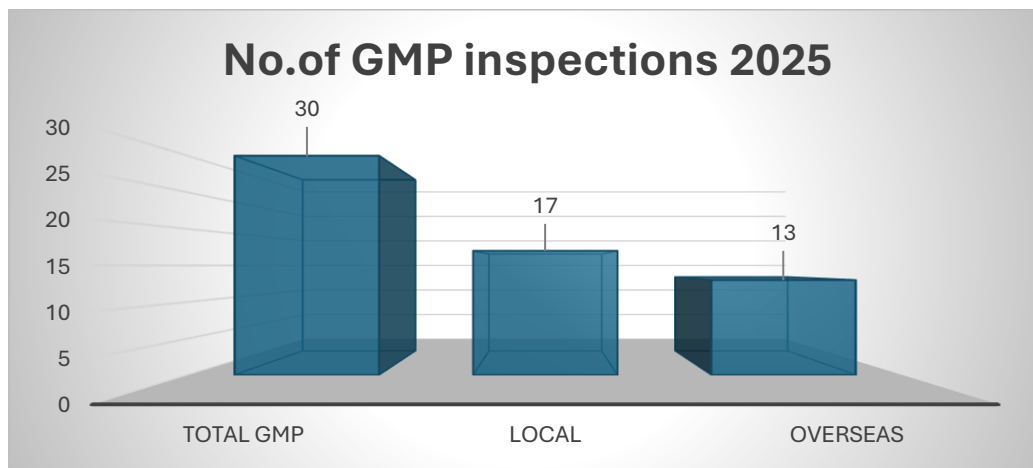


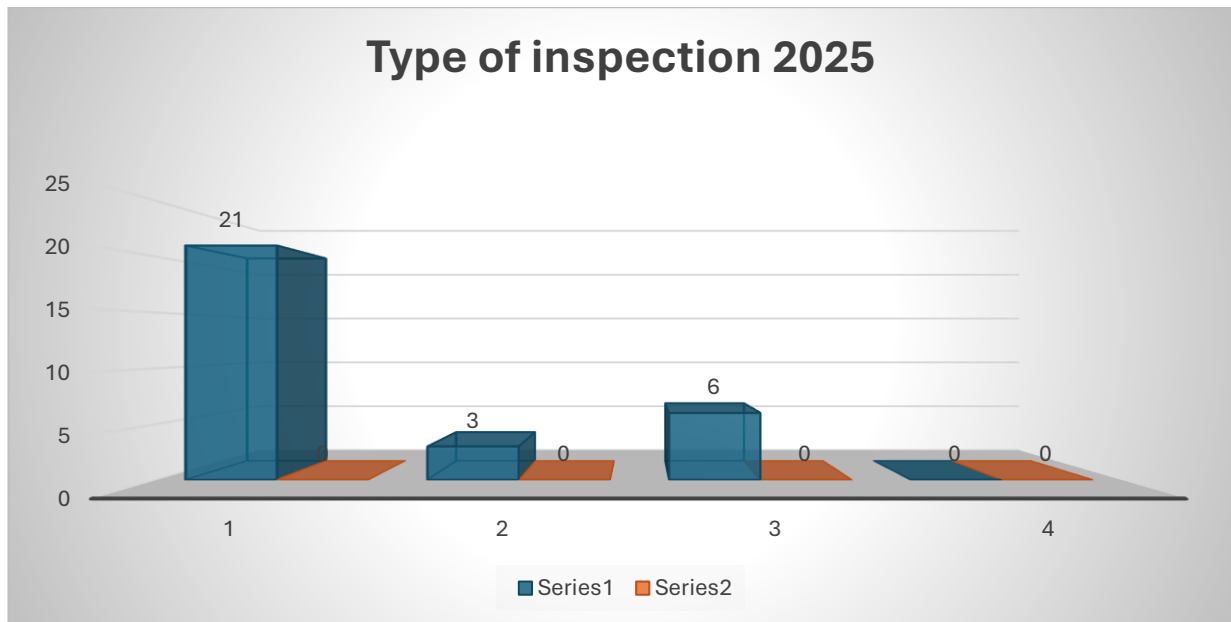
Collective Analysis of GMP Inspection Observations Data report/ 2025

Executive summary:

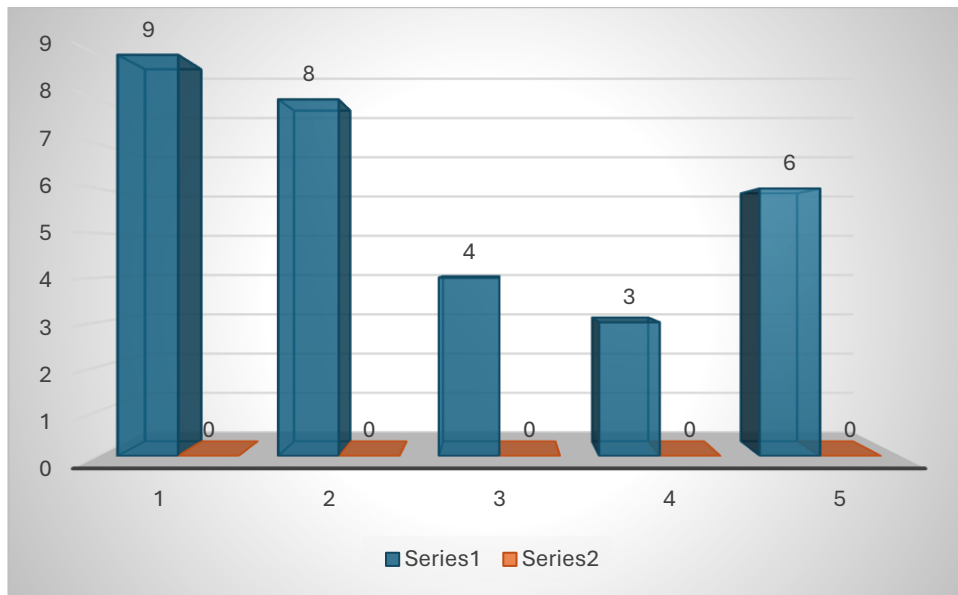
- Total no. of GMP inspections: **30 Inspection**
- No. of Local GMP inspections: **17 Inspection**
- No. of overseas GMP inspections: **13 Inspection**



- **Types of inspections:**
 - Routine inspections, **21 Inspection**
 - For-cause inspection, **3 Inspection**
 - Follow-up inspections, **6 Inspection**
 - Virtual inspection, **0 Inspection**



- **Types of inspections for purpose of inspection:**
 - No. of Routine inspections for registered biological products (**9 Inspection**),
 - No. of Routine inspection for new registered biologicals (**8 Inspection**),
 - No. of Routine inspection for post approval changes (**4 Inspection**),
 - No. of For-cause inspection (**3 inspection**),
 - No. of Follow up inspection (**6 Inspection**),



Types of inspections according to Purpose of Inspection

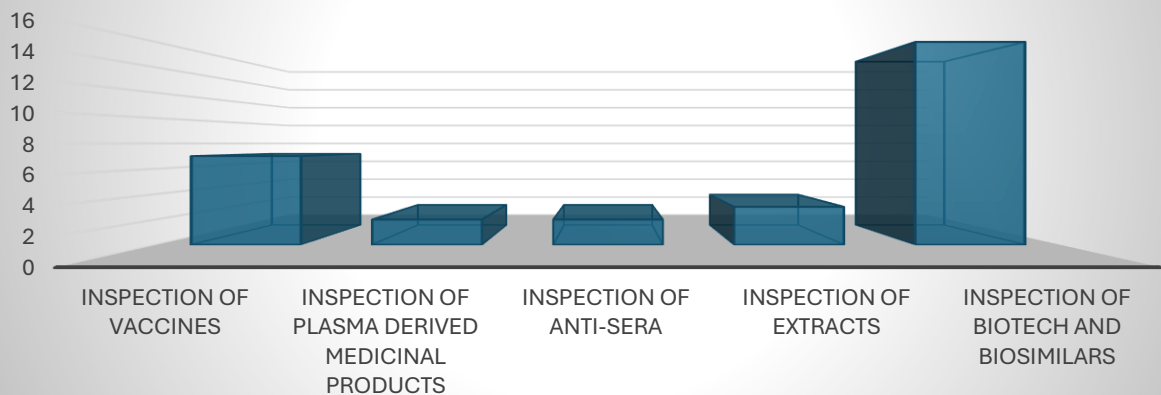
- *Type of inspection according to the Biological products type:*
 - No. of inspection of vaccines (**7 Inspection**),
 - No. of inspection of anti-sera (**2 inspection**),
 - No. of inspection of plasma derived medicinal products (**2 inspection**),
 - No. of inspection of extracts (**3 inspection**),
 - No. of inspection of Biotech and biosimilars (**16 Inspection**)



Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Inspection
on Pharmaceutical Institutions
G.A. of factories inspection

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للتفتيش
على المؤسسات الصيدلانية
إ.ع. التفتيش على المصانع

Inspection according to the Biological Products Type



Overview section:

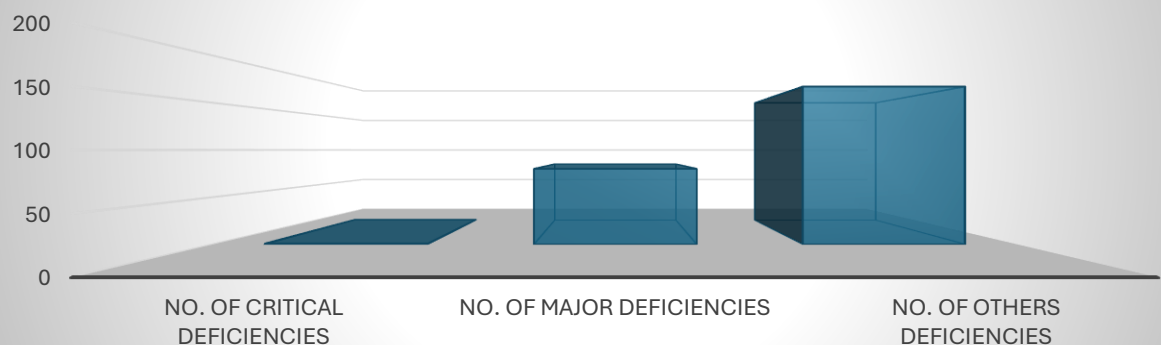
A) Total no. of deficiencies:

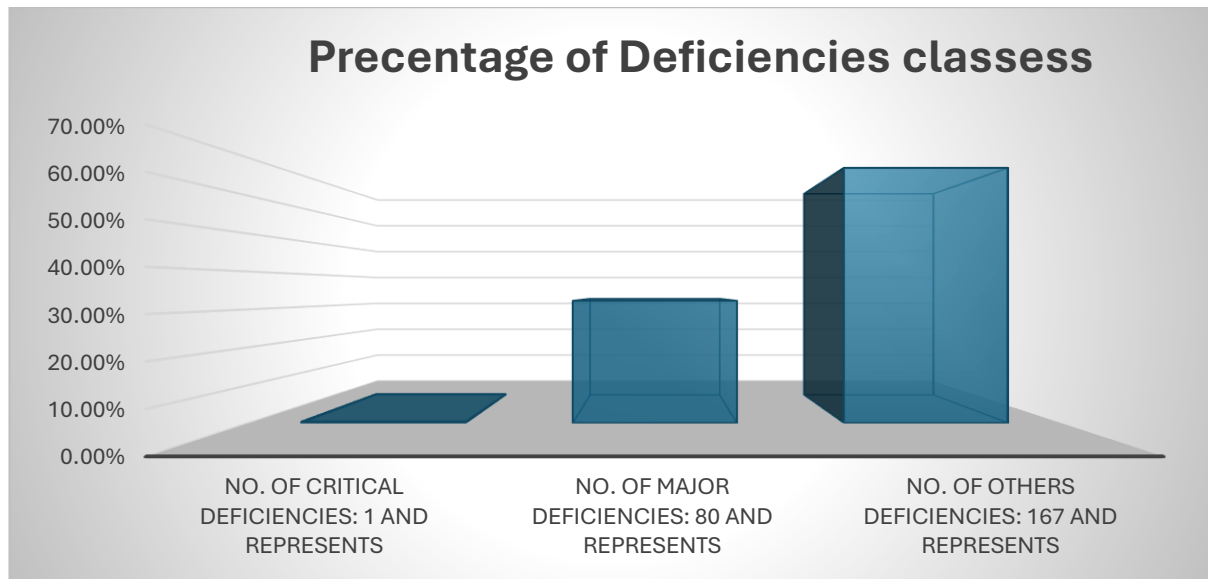
No. of critical deficiencies: **1 and represents 0.40 %**

No. of major deficiencies: **80 and represents 32.26 %**

No. of others deficiencies: **167 and represents 67.33 %**

Classification of Total Deficiencies

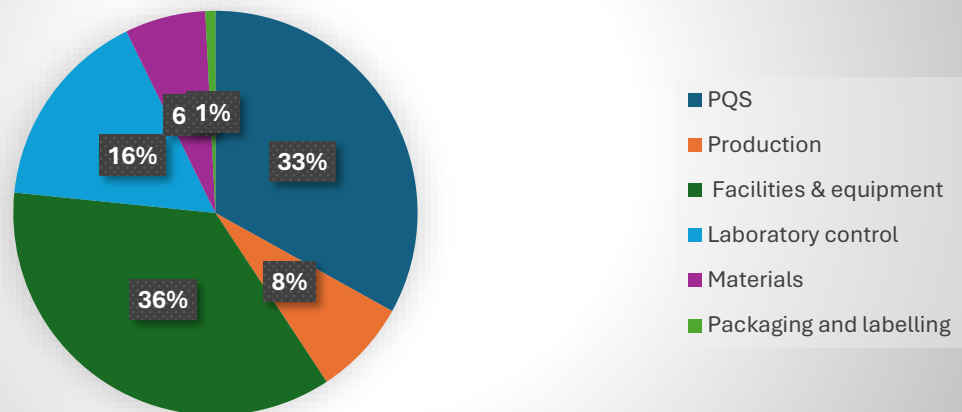




B) Number of deficiencies per GMP system

1. Pharmaceutical Quality system: **82 deficiencies**
2. Production system: **19 deficiencies**
3. Facilities and equipment system: **89 deficiencies**
4. laboratory control system: **40 deficiencies**
5. Materials System: **16 deficiencies**
6. Packaging and labelling system: **2 deficiencies**

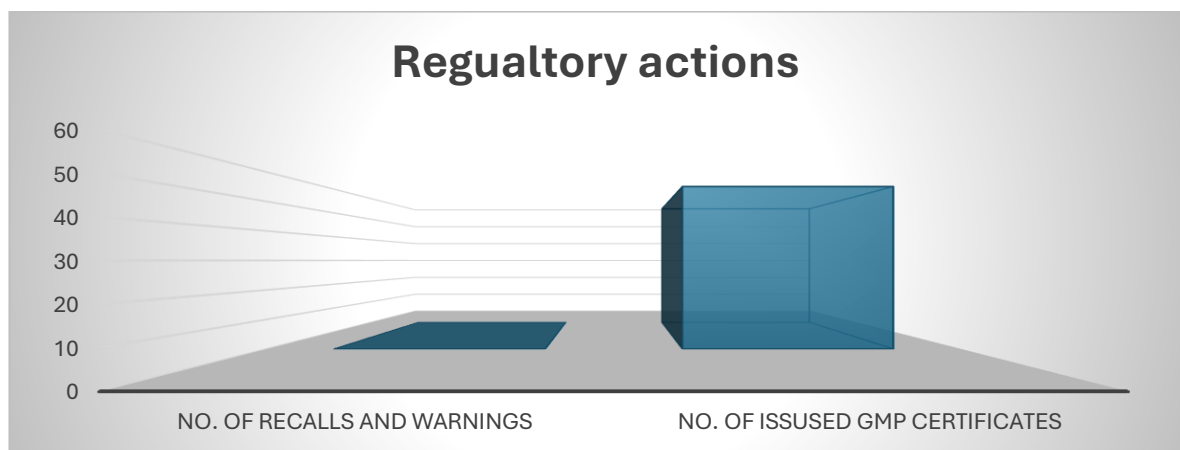
Distribution of Deficiencies Per GMP System



C) No. of issued GMP Certificates: 55

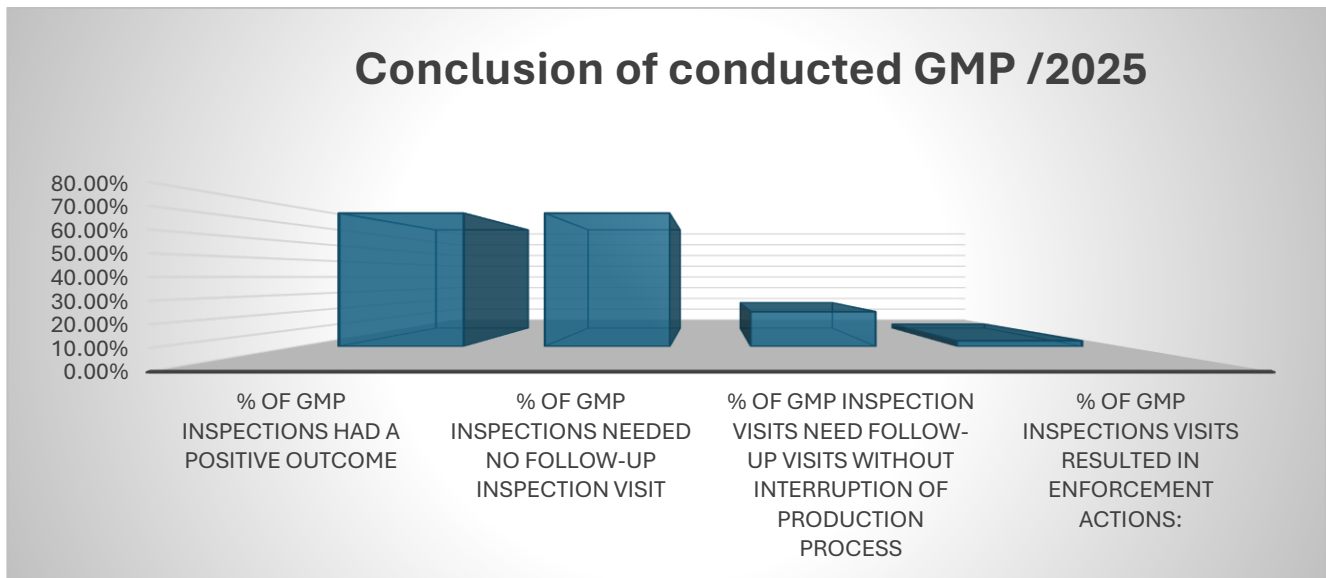
D) No. of recalls and warnings: 0

Regulatory actions



Conclusion:

1. % of GMP inspections had a positive outcome: **76.7%**
2. % of GMP inspections needed no follow-up inspection visit: **76.7%**
3. % of GMP inspection visits need follow-up visits without interruption of production process: **20 %**
4. % of GMP inspections visits resulted in enforcement actions: **3.3 %**



Prepared by:
Position: **Periodic inspection
follow-up unit manager**

Reviewed by:
Position: **BPI administration manager**

Approved by:
Position: **GM of Factories
inspection GA**

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Sig./date:

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Sig./date: