MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

SID& GP

BADAN POM

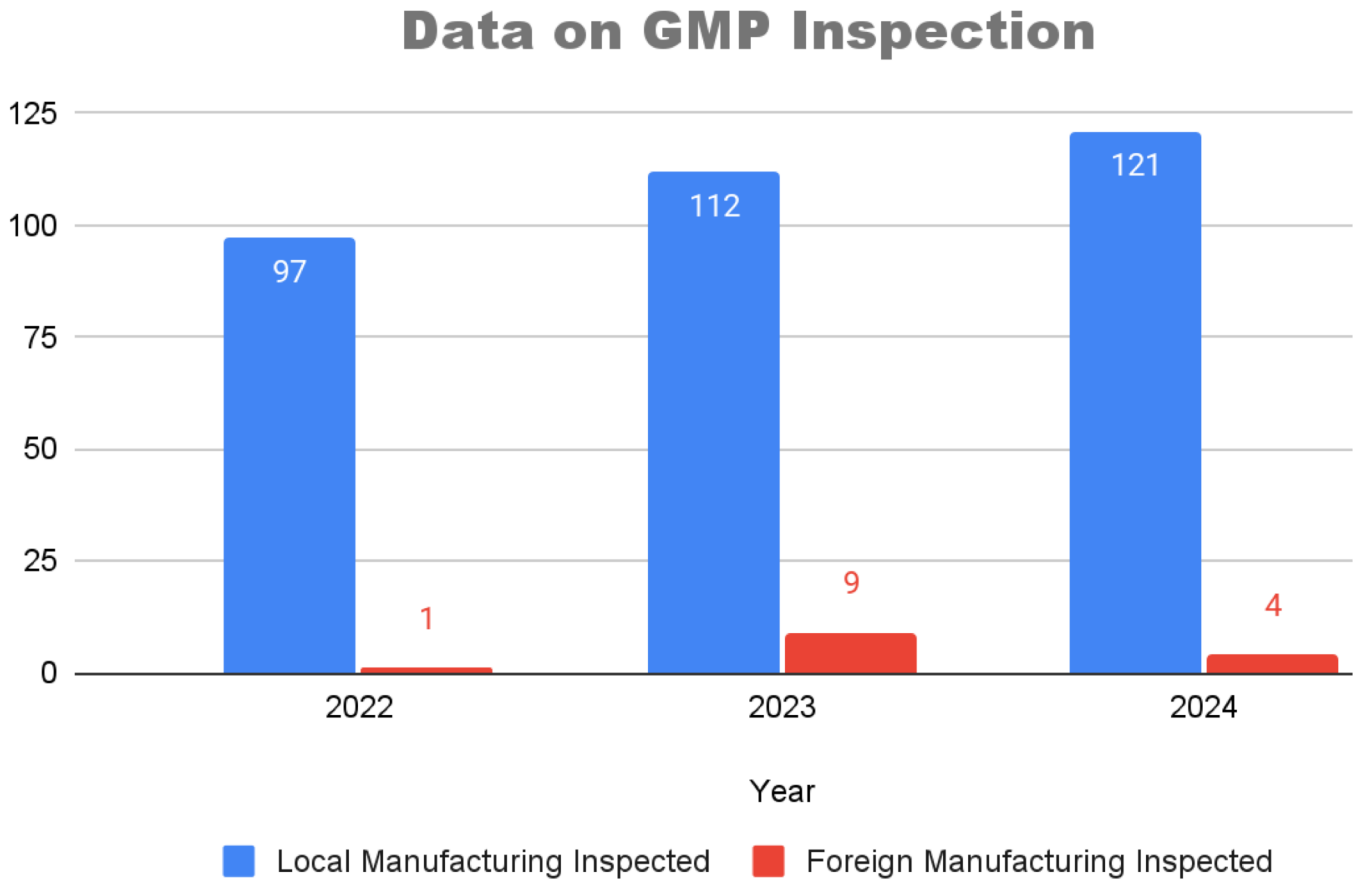
GMP

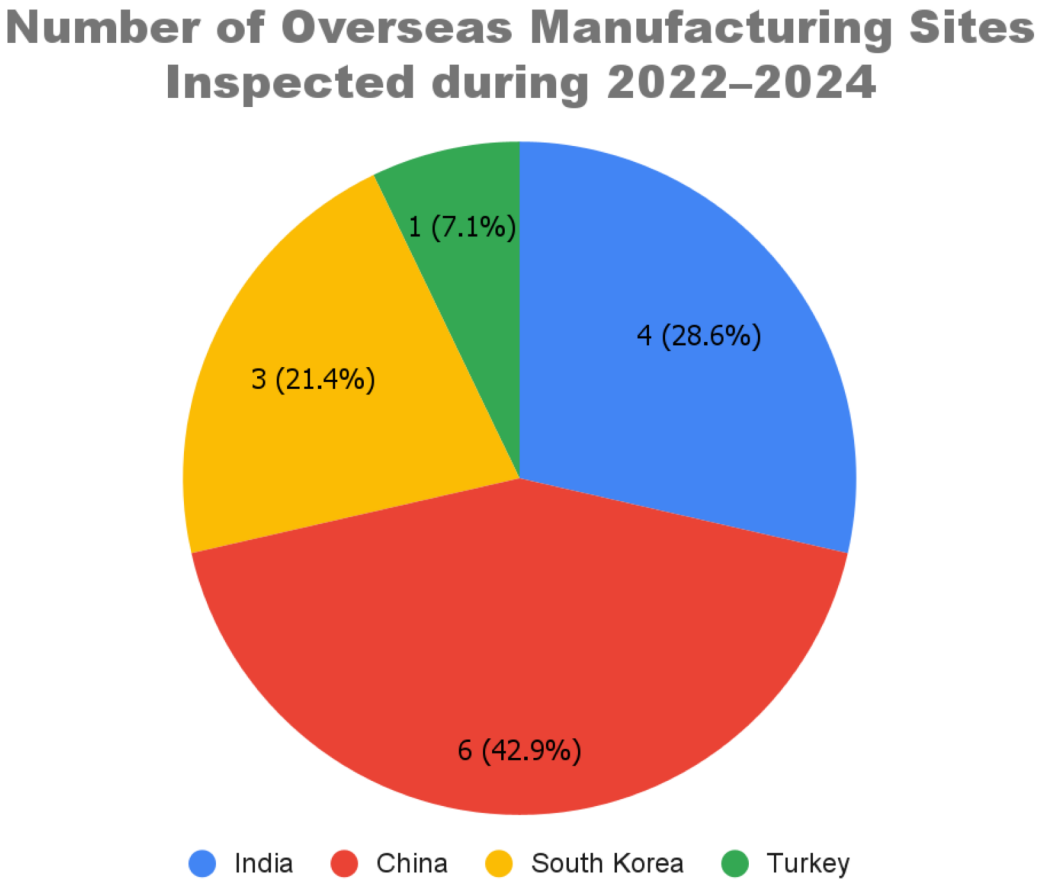
10th PAN-RUSSIAN GMP CONFERENCE

OVERVIEW OF GMP INSPECTION DEFICIENCIES

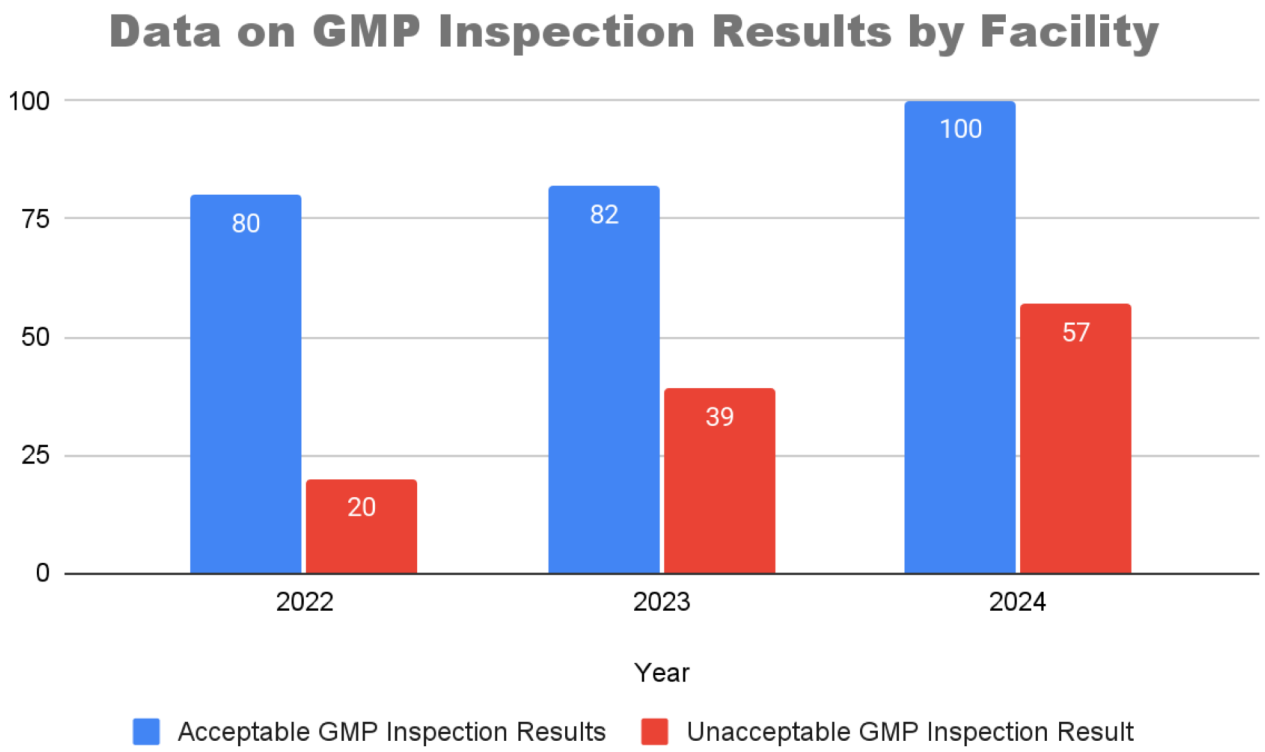
Directorate of Drugs, Narcotics, Psychotropics, and Precursors Production Control
Indonesian FDA (BPOM RI)

Number of Conducted GMP Inspections





Data on GMP Inspections

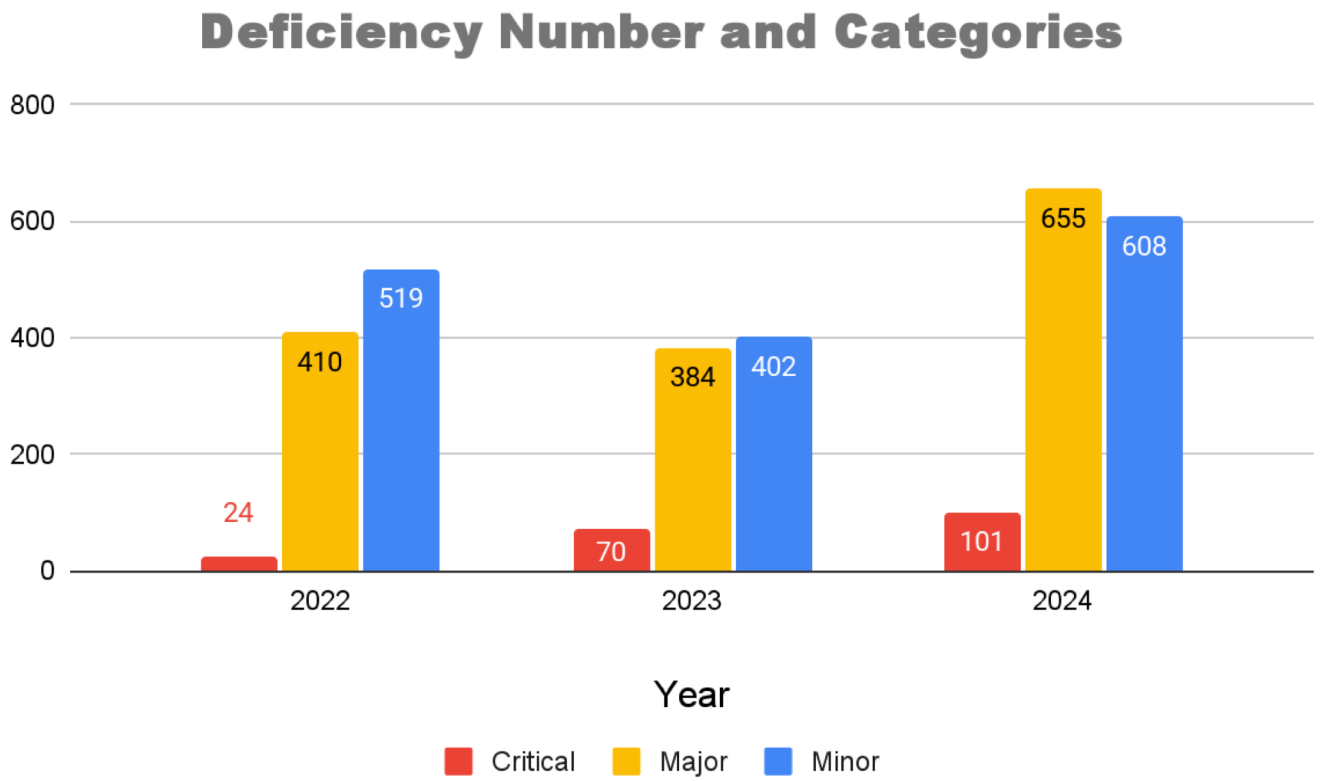


Number of GMP Certificates Refused and Revoked in 2022–2024

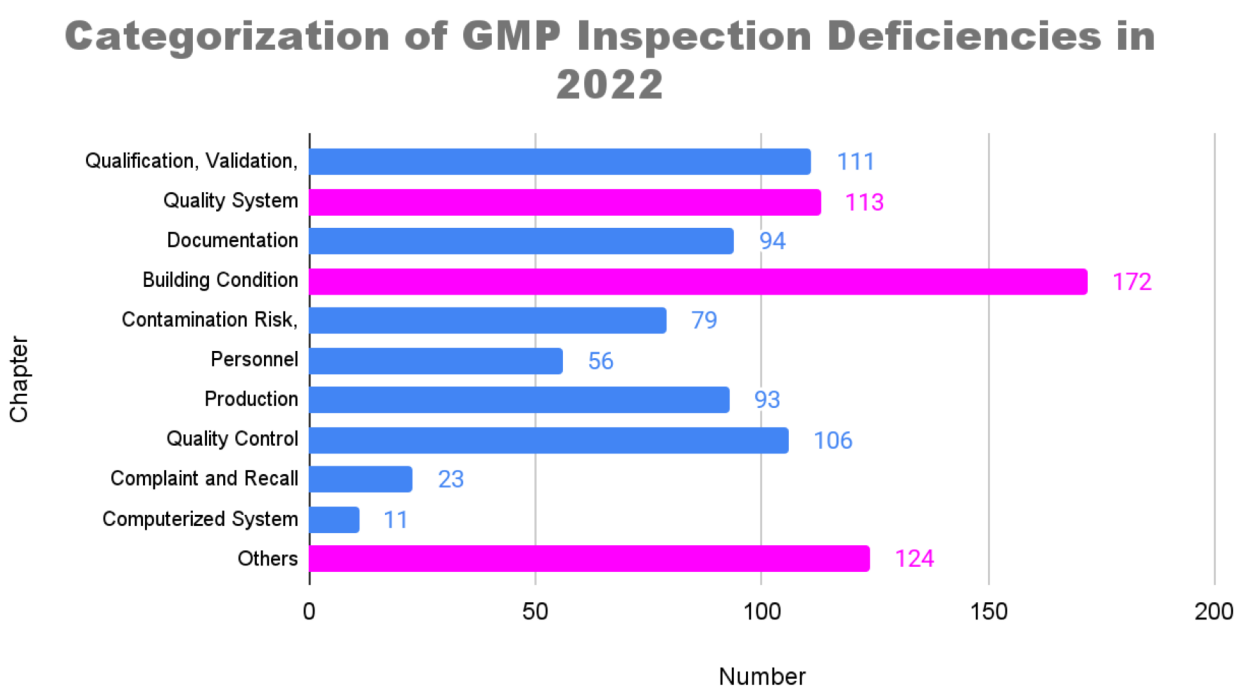
GMP Certification	2022	2023	2024
Number of GMP Certification Refused	2	0	4
Number of GMP Certification Revoked	6	0	1

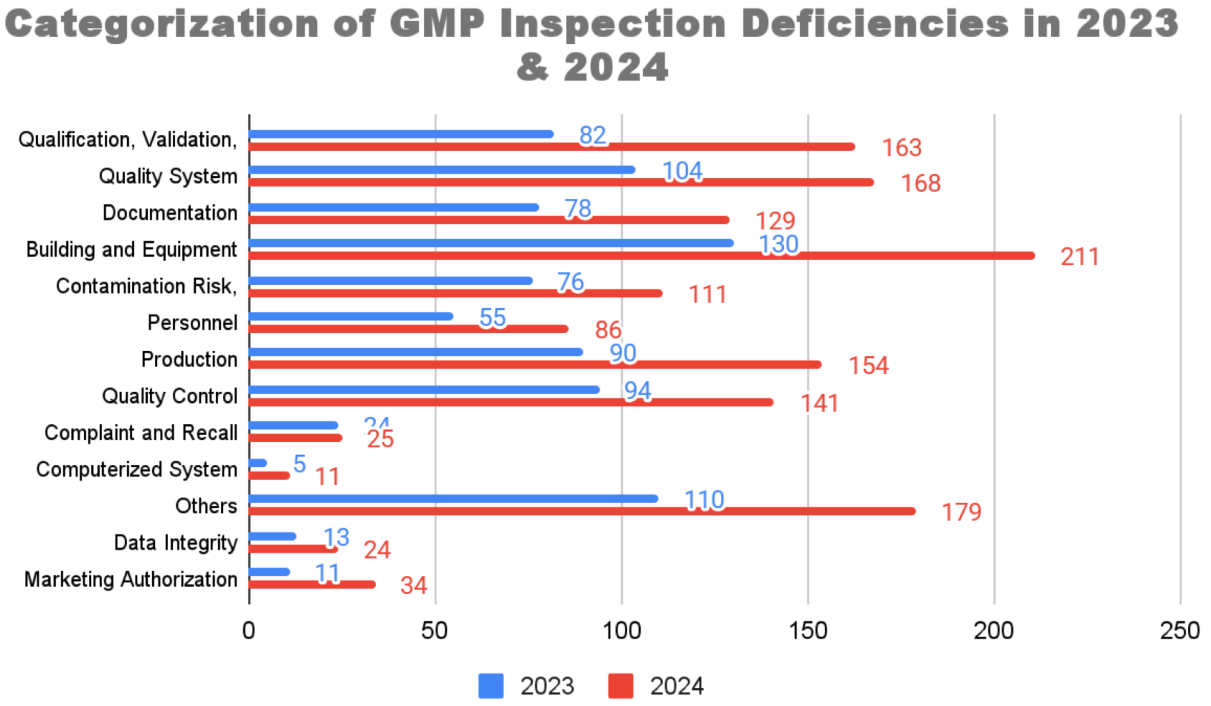
Data on GMP Inspection Deficiencies

The classification of deficiencies is regulated under the **Indonesian FDA Regulation Number 19 of 2025** concerning Amendment to the **Indonesian FDA Regulation Number 9 of 2024** on Guidelines for Follow-Up Actions to the Surveillance Results of Medicines, Pharmaceutical Ingredients, Narcotics, Psychotropics, Precursors, and Addictive Substances, which refers to **PIC/S PI 040-1 (2019) on *PIC/S Guidance on Classification of GMP Deficiencies***



Data on GMP Inspections





Examples of Critical Deficiencies

Quality System

CAPA system ineffective, with repeated findings from the previous inspection not corrected.

Production

Production activities were not able to ensure the quality of sterile products and consistent compliance with established requirements.

Building and Facility

Inadequate design and maintenance of buildings, facilities, and equipment, posing a contamination risk and lacking consistent compliance with current regulatory requirements.

Quality Control

Quality control and analytical method validation were inadequate to ensure compliance with specifications and/or that testing was performed using appropriate methods.

Qualification, Validation, Calibration

Non-compliant calibration, qualification, and validation processes, with equipment still in use and production ongoing.

Contamination RIsk

Potential contamination/ cross-contamination and inadequate containment of penicillin and cephalosporins.


THANK
YOU!