IX PAN-RUSSIAN GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

REGULATORY RELIANCE: BENEFITS AND PITFALLS

INTERNASIONAL EXPERIENCE

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Indonesian FDA (BPOM RI)

INDONESIAN FDA (BPOM) PROFILE

BADAN POM

- Drugs
- Traditional Medicines
- Cosmetics
- Health Supplement
- Processed Foods

Catchment Areas

1 central office

76 regional/district offices

Legal Basis

- Presidential Decree No. 80/2017 regarding Badan Pengawas Obat dan Makanan (THE INDONESIAN FDA)
- Presidential Instruction No. 3/2017 regarding Improvement of Drug and Food Control Effectiveness

Indonesian FDA's

Full spectrum of Drug Control

Pre-Market		Post Market
Drug Dev. & Establishment of Facilities	Marketing Authorisations (MA)	Post Market Surveillance and Control
IND Regulatory System	Medicine Evaluation	Regulatory Inspections – GMP & GDP
Clinical Trial Authorisation		Post Market Sampling & Testing
GCP Inspection		Lot Release (Vaccines & Biologicals)
GMP Certification		Label & Adv Control / PV

Indonesian FDA in International Organization

PIC/S Membership

- Indonesian FDA becomes member of PIC/S since 2012 and was the 41st member at that time
- PIC/S currently consists of 58 Participating Authorities originating from around the world (Europe, Africa, Americas, Asia, and Australia)

ACCSQ-PPWG

- develop harmonization schemes of pharmaceuticals' regulations of the ASEAN member countries to complement and facilitate the objective of ASEAN Free Trade Area (AFTA).
- In GMP sector, we have Sectoral MRA on GMP Inspection which aims to facilitate the movement of medicinal product in ASEAN through the mutual exchange and recognition of GMP inspection reports and certificates

Acknowledgement WHO to The Indonesian FDA

BADAN POM

World Health Organization

ISO 9001:2015

Maturity Level 3&4 for vaccine

Full spectrum of Vaccine Oversight

PREMARKET

- Vaccine Development & Establishment of Manufacturing Facilities
  - IND Regulatory System
  - GMP Certification
  - Clinical Trial Authorisation
  - GCP Inspection
- Marketing Authorisations (MA)
  - Vaccine Evaluation System for MA

POSTMARKET

- Post Market Surveillance and Control
  - Lot Release (Vaccines & Biologicals)
  - Pharmacovigilance
  - Label & Advertisement Control
  - Regulatory Inspections – GMP & GDP
  - Post Market Sampling & Testing

- ✓ Good Regulatory Practices (GRP)
- ✓ Good Laboratory Practices (GLP)
- ✓ Good Clinical Practices (GCP)
- ✓ Good Manufacturing Practices (GMP)
- ✓ Good Review Practices (GRev)
- ✓ Good Distribution Practices (GDP)
- ✓ Quality Management System (QMS)

RELIANCE FOR GMP ASSESSMENT OF IMPORTED DRUG MANUFACTURER

Indonesia Experience

GMP compliance of Imported Drug Manufacturer

4 level of assessment

1. **Preliminary Evaluation of GMP Compliance of Imported Drug**
2. **Desktop Inspection**
3. **On Site Inspection**
4. **CAPA Evaluation**

BPOM Regulation No. 7 Year 2019

RISK-BASED ASSESSMENT

Asean MRA for GMP Inspection Of Manufacturer of Medicinal Product

specifically for chemical drug products

PIC/S

Imported drug manufacturers that are regularly inspected by ASEAN NRAs are exempt from on-site inspections, while those inspected regularly by PIC/S member countries have a lower risk of undergoing on-site inspections

GMP Assessment of Imported Drug Manufacturer

BADAN POM

GMP Inspectorate Unit

Imported Medicinal Product

Registration process (dossier application)

Desktop inspection needed?

YES

Does inspection needed?

YES

PIC/S

OVERSEAS INSPECTION (pre-market)

NO

NO

Closed CAPA!!

Issuance of recommendation letter of GMP compliance

OVERSEAS INSPECTION (post-market)

Based on RISK ASSESSMENT

APPROVED

Marketing Authorization

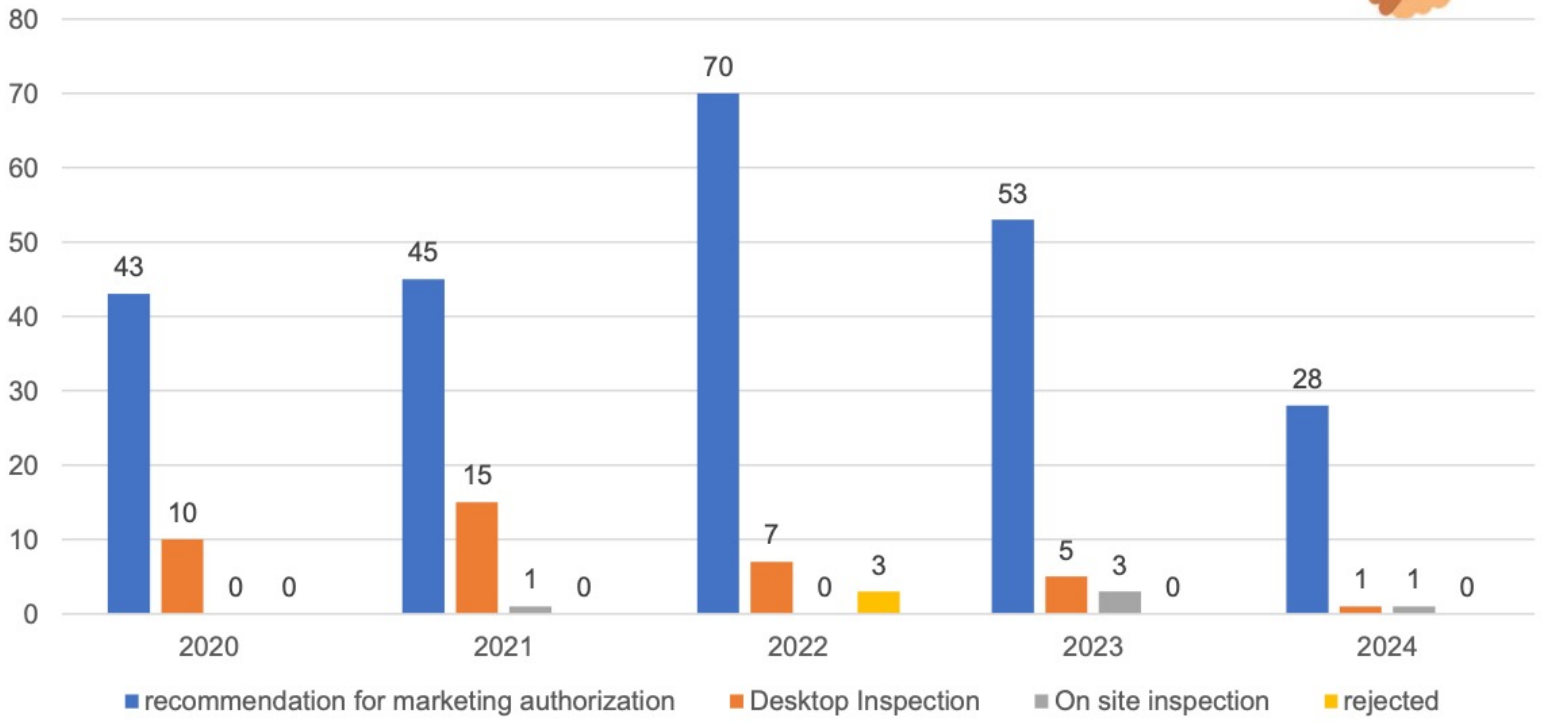
Registration Unit

RELIANCE FOR GMP ASSESSMENT OF IMPORTED DRUG MANUFACTURER

Indonesia Experience

Indonesia's GMP compliance assessment of Imported Drug Manufacturers from ASEAN & PIC/S member country

2020 - 2024



Manufacturers assessed were primarily from PIC/S member countries such as Germany, Spain, France, USA, Canada, Italy, Japan, Korea, and others. There were also manufacturers from ASEAN countries like Thailand, Singapore, and Malaysia.

On-site inspections were conducted for manufacturers whose final assessment results indicated high risk, such as those producing sterile products or biotechnology products.

Benefit & Pitfalls of Reliance

BENEFITS

Efficiency in Regulatory Processes

Resource Optimization

Accelerated Access to Medicines

strengthen relationship between regulators

PITFALLS

Incomplete or Inaccurate Information

Varied Interpretation of Standards

Classification of the findings


THANK
YOU!

ORGANIZERS

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

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