GMP COMPLIANCE ASSESSMENT IN INDONESIA

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OUTLINE

1. Brief Profile of Badan POM
2. Legal Basis of Drug Registration and GMP Compliance
3. Regulatory Framework on Ensuring S, Q, E of Medicine
4. Registration Process for Imported Medicine
5. Badan POM in improving efficiency of GMP compliance review
6. Summary
Our Vision

• Safe Food and Medicine to Improve Public Health and National Competitiveness.

Our Mission

• Intensifying Risk-based Drug and Food Control System to protect public health
• Encouraging Self Reliance of Business Actors in ensuring Drug and Food Safety and strengthening partnership with stakeholders
• Enhancing NADFC institutional capacity.
Legal Basis of Drug Registration and GMP Compliance

- Law No.36 of 2009 on Health
- Government Regulation No. 72 of 1998 on Safety of Pharmaceutical and Medical Devices
- MoH Decree No.1010/MenKes/Per/XI/2008 on Drug Registration
- MoH Decree No.1799 of 2010 on Pharmaceutical Industry
- Head of Badan POM Decree No. HK.04.1.33.12.11.09937 of 2011 on GMP Certification
- Head of Badan POM Decree No. HK 03.1.33.12.12.8195 of 2012 on Implementation of GMP Guideline
- Head of Badan POM Decree No. HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedure for Drug Registration
Regulatory Framework on Ensuring S, Q, E of Medicine

PRE-MARKET CONTROL
- Marketing Authorization
- GMP Certification

POST-MARKET CONTROL
- Inspection of production & distribution facility
- Product sampling & lab testing
- Information service
- Monitoring of advertisement and product label

INDUSTRY
- Production facility

Distribution
- Costumer
National Networking of GMP Inspection System

- NORTH SUMATERA: 6 industries
- SOUTH SUMATERA: 1 industry
- BANTEN: 25 industries
- WEST JAVA: 78 industries
- JAKARTA: 35 industries
- EAST JAVA: 41 industries
- YOGYAKARTA: 41 industries
- CENTRAL JAVA: 23 industries
- WEST SUMATERA: 1 industry
- SOUTH SUMATERA: 1 industry
- NORTH SUMATERA: 6 industries
- GMP INSPECTORATES: 21 industries
- Pharmaceutical Industries: 9 inspectorates
History of GMP Code and Technical Guideline 2006-now

- Good Manufacturing Practice Ed 2006
- GMP for Active Pharmaceutical Ingredient 2009
- 1st Supplement to National GMP Code 2010
- Operational Manual 2006
- Operational Manual GMP 2013

NADFC became PIC/S’ 41st participating authority

2009

2010

2012

2013

2017

- Drafting the GMP Guideline for Blood Establishment
- Revising GMP Annexes for Biological Medicinal Substances & Products
Registration Process for Imported Medicine (1)

Consideration for foreign inspection

**Risk Based Assessment:**

- Manufacturer never been inspected by Badan POM
- Last inspection done > 2 years
- Production facility of product(s) applied are different facilities where ever been inspected
- Manufacturer does not hold any MA of the same product type and dosage form as applied
- There is a history of the recall / rapid alerts due to non compliance to GMP
- The results of previous inspections by Badan POM / other NRA

**FOLLOW UP ON CRITICAL FINDINGS OF POST-MARKET INSPECTION**

- Prohibition of supply
- Tight monitoring of distribution
- Unfinished CAPA within a month $\rightarrow$ Recall of all batches & suspension of MA $\rightarrow$ unfinished CAPA for the next following month $\rightarrow$ withdrawal of MA

**Post-market**

- alleged cases of S, Q, E
- Renewal of MA; and/or
- surveillance based on risk assessment
Registration Process for Imported Medicine (2)

1. Imported Medicinal Product
2. Registration process (dossier application)
3. Evaluation of GMP Documents
4. Does inspection needed?
   - NO: Issuance of letter of recommendations of GMP compliance
   - YES: FOREIGN INSPECTION
5. Marketing Authorization
6. Registration Unit
7. GMP Inspectorate Unit

Registration Unit

Marketing Authorization

satisfied
Registration Process for Imported Medicine (3)

Pre-market

FOREIGN INSPECTION

GBA

CAPA Evaluation

comply
does not comply

Letter of recommendations of GMP compliance (to registration unit)

APPLICATION DENIED

Marketing Authorization

Badan POM does not issue any GMP Certificate for Foreign Manufacturer considering the inspection is product-based inspection
Pre Inspection Docs:
1. VMP
2. Qualification of Critical Equipments
3. Qualification of HVAC System
4. Qualification of Water System
5. Process Validation
6. Cleaning Validation
7. Media Fill Validation (where applicable)
8. Analytical Method Validation
9. Release procedure of finished product
10. SOP for Recall
11. SOP for Change Control
12. SOP for Deviation handling
13. SOP for Complaint Handling

Previous NADFC Foreign GMP Inspection Scheme

APPLICANTS

SMF

PRE-INSPECTION DOCUMENTS

Evaluation Result

Need Additional Doc

Evaluation

Foreign Inspection

CAPA submission

BADAN POM CAPA Evaluation

Acceptable?

Recommendation Letter of GMP Compliance

Inspection report
Badan POM in improving efficiency of GMP compliance review

**Simplification of the documents to be evaluated**

- Site Master File → will be used for planning & conducting GMP Inspection
- Pre-inspection documents (simplified)
- Shortened timeline for evaluation

**Simplification of review process**

- Performing initial screening on the doc(s) completeness
- Consultation & discussion on the result of review/ additional data required
Current NADFC Foreign GMP Inspection Scheme

APPLICANTS

- SMF
- PQR
- GMP Inspection Report from PIC/s PA
- GMP Certificate

Need On Site Verification

PRE-INSPECTION DOCUMENTS

- Evaluation Result

Foreign Inspection

CAPA submission

BADAN POM CAPA Evaluation

Pre Inspection Docs (simplified):
1. VMP
2. Protocol and report of validation of media fill (where applicable)
3. Trend analysis of environmental monitoring
4. Release procedure of finished product
5. History of recalls and defects product

Acceptable?

Yes

Recommendation Letter of GMP Compliance

No
Badan POM commits to **support harmonisation and simplification** of drug evaluation including GMP review in order to **accelerate the launch of new drugs** without compromising the S, Q, E of the product.

Both of domestic and foreign manufacturer **must comply with the regulation** on drug registration and GMP compliance.

**On-site inspection** to foreign manufacturer regarding the MA application will be based on risk assessment.

Domestic and foreign manufacturer are **subjected to Post Market Control**, including the routine GMP inspection.
Thank You