THE 1ST INDONESIA-JAPAN SYMPOSIUM ON: ENSURING QUALITY, SAFETY, EFFICACY THROUGH INTEGRITY SUPPLY CHAIN

Opening Address

by

The Head of The National Agency of Drug and Food Control Republic of Indonesia

CONTROL OF DRUG AND FOOD BY NATIONAL AGENCY OF DRUG AND FOOD CONTROL

Development Step	Approval of Marketing Authorization	Production Step	Distribution Step	Administration/ Usage
• Protect the right and safety of clinical trial subjects • Increase compliance to regulation • Evaluation of Clinical Trial Protocol and Audit of Clinical Trial based on GCP	• Evaluation of pre-clinic and clinical data to support efficacy and safety • Evaluation of quality data • Evaluation of side effects /safety profile • Consistency of quality standard for 3 consecutive batches/lots (vaccine) • Profile of usage	• Pre-production GMP certification • Inspection/ audit for GMP compliance	• Inspection in accordance with GDP • Investigation for legality	• Quality Monitoring • MESO/KIPI (Pharmacovigilance)

POLICY DIRECTION OF NADFC:
STRENGTHENING DRUG CONTROL REGULATORY SYSTEM
INCREASE CAPACITY OF NADFC MANAGEMENT

STRATEGY 3: :
Increase Post-Market Control of Drug Product

STRATEGY 4: :
Consolidation of regulation and standard in Drug Control

STRATEGY 6: :
Strengthening of Institution

- Increase of Pharmacovigilance in pharmaceutical industry and healthcare institution
- Updating GDP Guidelines
- Increasing competency, professionalism of the staffs in the field of distribution control

IMPLEMENTATION OF PV BY PI/MAH

PI/MAH

MANDATORY TO PERFORM PVAND REPORT TO AUTHORITY

NEW REGULATION

- ✓ **MoH Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, Article No. 9**
- ✓ **Head of NADFC Regulation No. HK.03.1.23.12.11.10690 of 2011 on Implementation of Pharmacovigilance for Pharmaceutical Industry (Enacted in 5 January 2012)**

TO STRENGTHEN THE DIRECTION OF AND TO HAVE BETTER STRUCTURED PV SYSTEM IN INDONESIA, WITH OPTIMALIZATION OF THE ROLES AND RESPONSIBILITIES OF PI/MAH TO ENSURE DRUG SAFETY

PHARMACOVIGILANCE FRAME WORK: STEPWISE IMPLEMENTATION OF PHARMACOVIGILANCE BY INDUSTRY

2011-2012

- ✓ **Enacted and Launched Head of NADFC Regulation on PV Implementation for PI/MAH, incl. PV Technical GL**
- ✓ **Training PV**
- ✓ **Coordination and Communication Forum for PV**
- ✓ **Development of Tools for Monitoring PV Implementation**

2013

- ✓ **Dissemination and Workshop of PV Technical Guidelines and Tools for Monitoring PV Implementation**
- ✓ **Piloting for PV Inspection /Monitoring PV Implementation**
- ✓ **PV Symposium (Joint Symposium with Japan)**

2014

- ✓ **Piloting for PV Inspection /Monitoring PV Implementation**
- ✓ **Evaluate possibility of Changing Reporting Format into E2B (ICH standardized format)**
- ✓ **Development of Analysis system for Signaling/Upgrading Data Base System**

2015-….

- ✓ **PV Inspection /Monitoring PV Implementation**
- ✓ **Upgrading Reporting Format into E2B (ICH standardized format)**
- ✓ **PV Training**
- ✓ **Review PV Technical Guidelines**
- ✓ **Pilot Test for Analysis system for Signaling/Upgrading Data Base System**

GDP ROADMAP

2003 - 2008

- GDP Guideline 2003 edition
- Technical Direction on GDP implementation
- GDP Inspection

2009

- Tools mapping Developed
- Training for GDP inspector
- GDP Inspection

2010 - 2012

- Training for GDP inspector
- Mapping dissemination
- Mapping on GDP implementation
  5% (2010), 15% (2011), 30% (2012)
- GDP Certification
  2% (2011), 10% (2012)
- **Technical Guidelines on GDP 2012 edition**
- GDP Inspection

2013 - 2014

- Training for GDP inspector
- Technical Guidelines on GDP dissemination
- Mapping on GDP implementation
  45% (2013), 60% (2014)
- GDP Certification
  25% (2013), 45% (2014)
- GDP Inspection

2015

- Training for GDP inspector (continue)
- Technical Guidelines on GDP dissemination (continue)
- Mapping on GDP implementation (continue)
- GDP Certification (continue)
- GDP Inspection