



GMP Programme on Blood Establishments in Indonesia

Bayu Wibisono

Badan Pengawas Obat dan Makanan
Republic of Indonesia



BADAN POM RI

Outline

INTRODUCTION

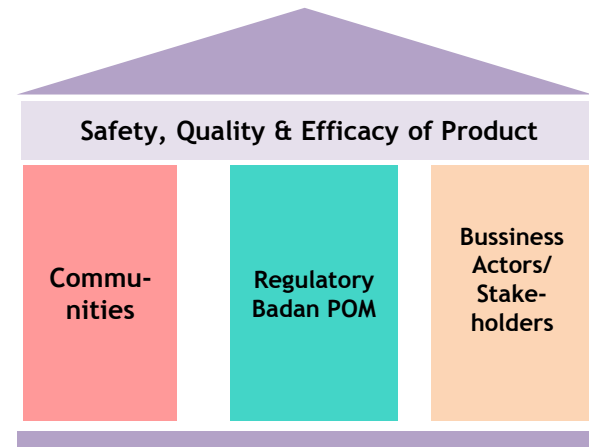
**GMP IMPLEMENTATION
ON BLOOD ESTABLISHMENTS**

CHALLENGES

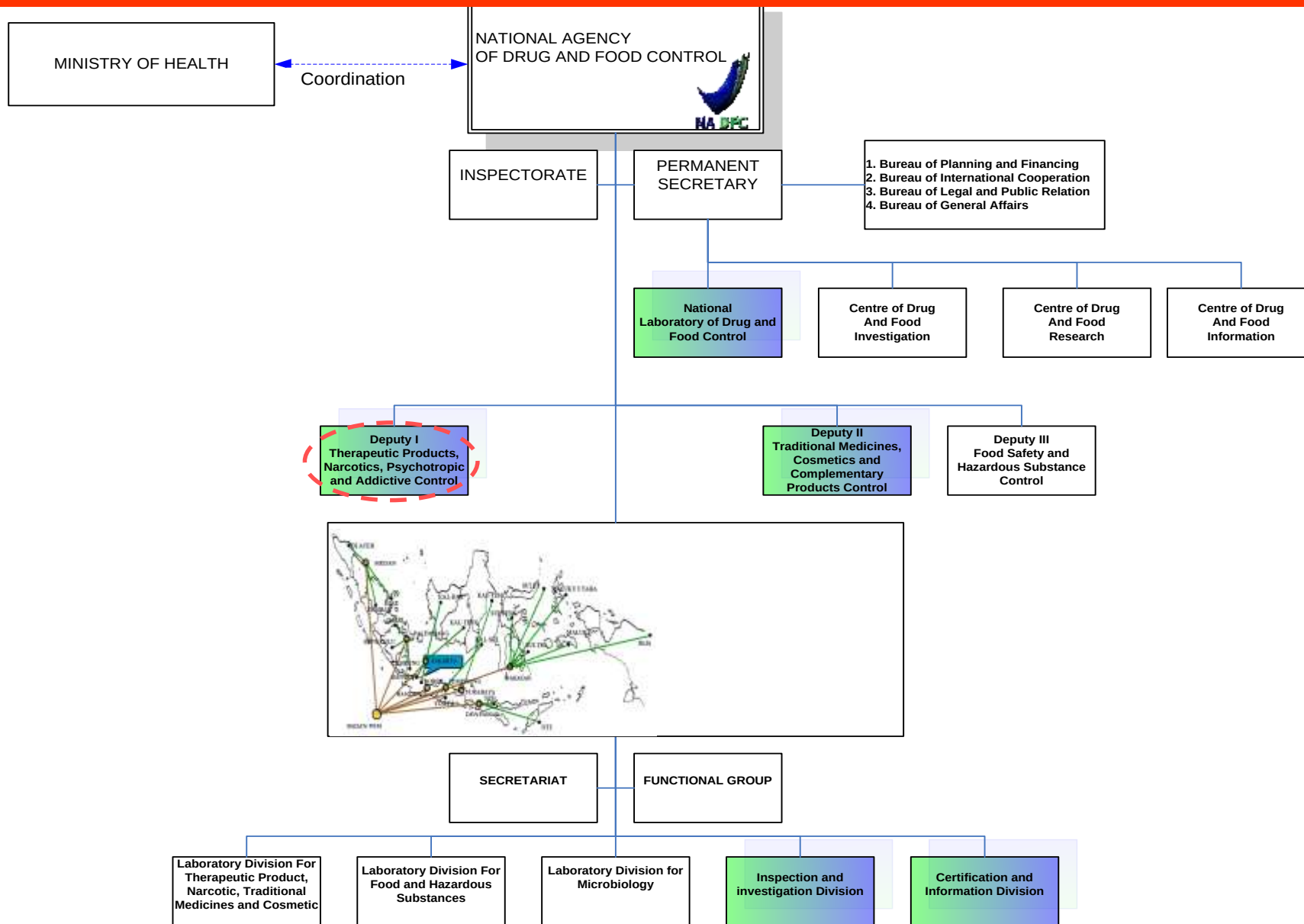
CONCLUSION



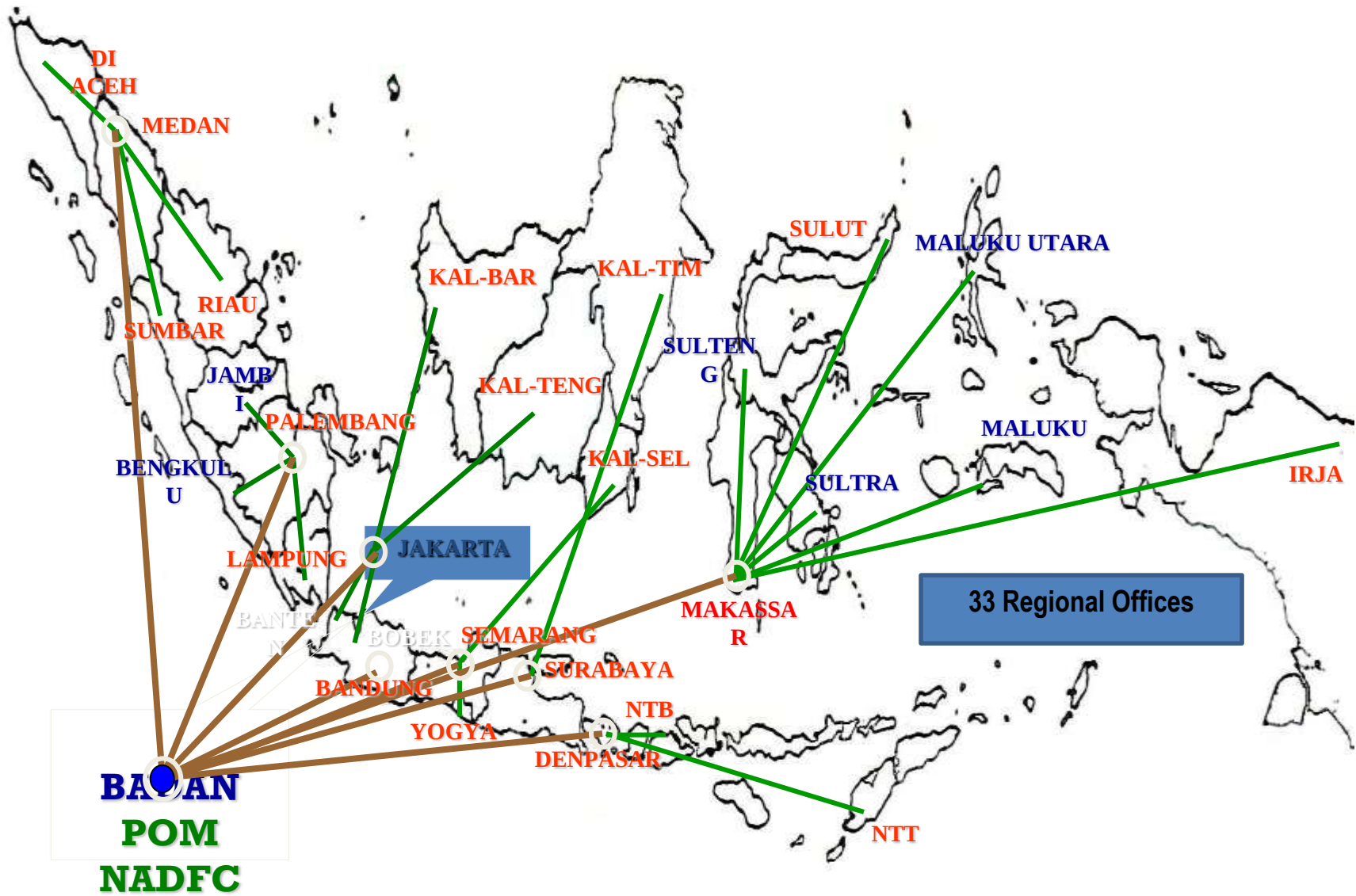
- BPOM is the government agency responsible for drug and food control in Indonesia.
- BPOM conducts a comprehensive and systematic full-spectrum drug and food control system :
 - ✓ Standardization
 - ✓ Pre-market evaluation
 - ✓ Post-market surveillance (sampling & lab testing)
 - ✓ Inspection of GMP & GDP Implementation
 - ✓ Labelling & advertising surveillance
 - ✓ Investigation & law enforcement
 - ✓ Community empowerment
- BPOM always strengthens cooperation, coordination, and synergy with stakeholders and communities to carry out effective implementation of drug & food control



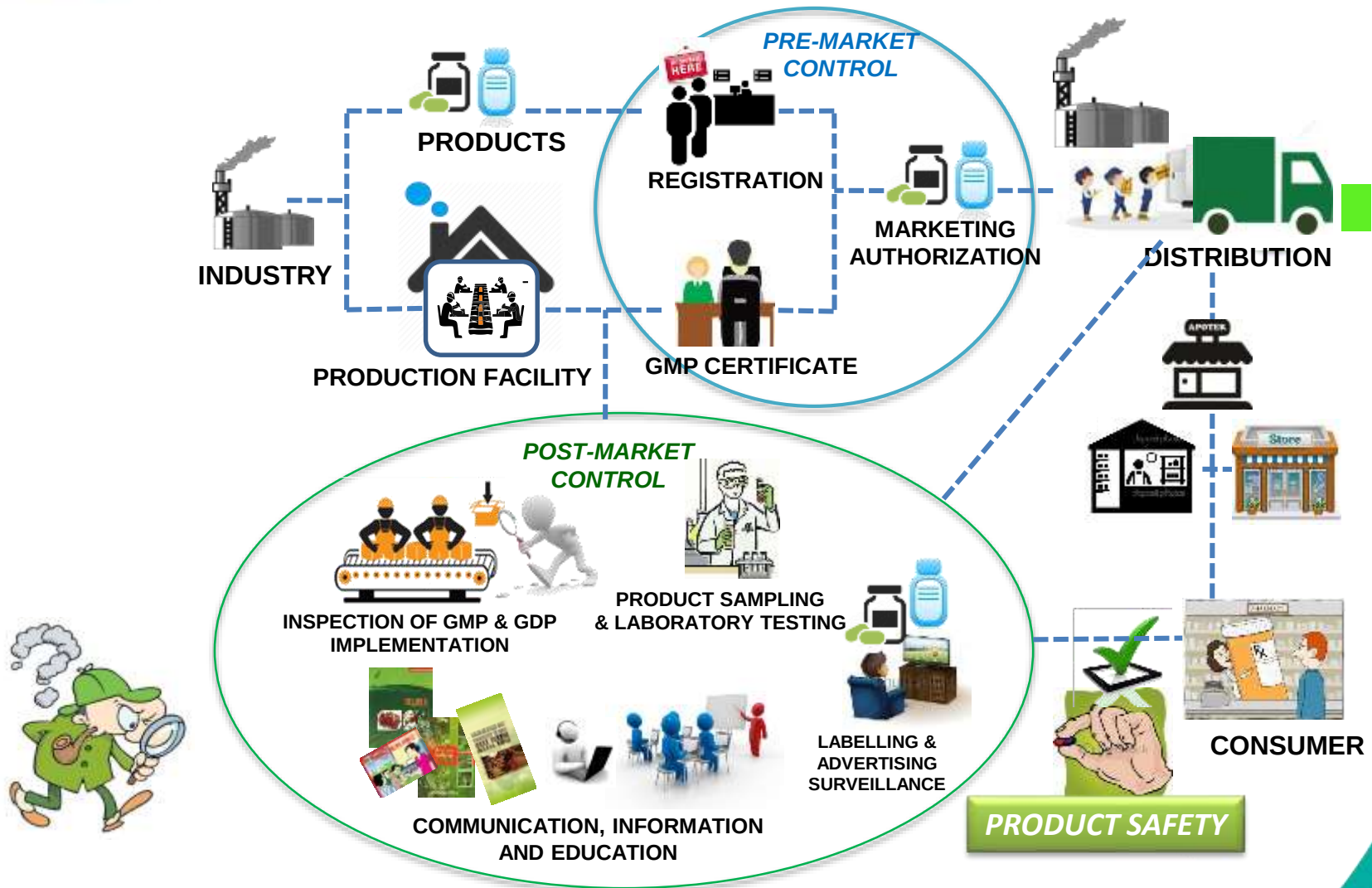
ORGANIZATION STRUCTURE OF BADAN POM



NATIONAL NETWORKING OF DRUG AND FOOD CONTROL SYSTEM



BPOM'S FUNCTION ON DRUG CONTROL



BPOM'S LEGAL BASIS ON BLOOD SUPERVISION

**Health Law
No.36/2009**

Blood services are run by Blood Transfusion Unit (BTU) either under government or IRC

**Government Regulation
No. 7/2011**
Pelayanan Darah

Government is responsible for fulfilling the need, access, quality and data management of blood service

MOH Decree 83/2014
UTD, BDRS, dan Jejaring
Pelayanan Transfusi Darah

BPOM is responsible for quality of blood

MOH Decree 72/2015
Fraksionasi Plasma

- Blood Establishment and fractionator plant should comply the GMP standards.
- GMP supervision is conducted by BPOM

MOH Decree 91/2015
Standar Pelayanan
Transfusi Darah

- BPOM can take administrative action for National Standard violation
- Some aspect of the National Standard are refer to GMP Guideline for Blood Establishment

GMP IMPLEMENTATION ON BLOOD ESTABLISHMENTS



SITUATION OF BLOOD ESTABLISHMENT IN INDONESIA

Indonesia has 414 Blood Transfusion Units (BTUs) :

- 221 IRC BTUs
- 193 Government BTU (MoH, 2017)

Most of Blood Establishments are run by nonprofit organization



Total donation :
4,6 million bags of blood and blood components (MoH, 2015)

Population :
± 250 million people

Potential plasma source

Problems :

- The BTUs are distributed in 34 provinces → Varies condition and quality between BTUs
- Blood products or plasma which do not meet the quality requirements → risk of disease transmission
- High waste of poor quality plasma (± 60.000 L/year) → high cost, plasma potential is not utilized
- Cost effective of blood services is very low due to limited access to technology
- All plasma derivative products in Indonesia are imported → expensive

Strategy to Increase Blood Safety and Quality

Indonesia
South Africa

WHA 63.12 (WHO, 2010)
“Availability, Safety, & Quality
of Blood Products”

OBJECTIVES

Increase the **availability, safety, quality and accesibility** of blood products

Encourage the developing country to use its own plasma as raw material for plasma fractionation



STRATEGY

Blood Establishment

Plasma apheresis Centre

GMP Implementation



Plasma source for fractionation

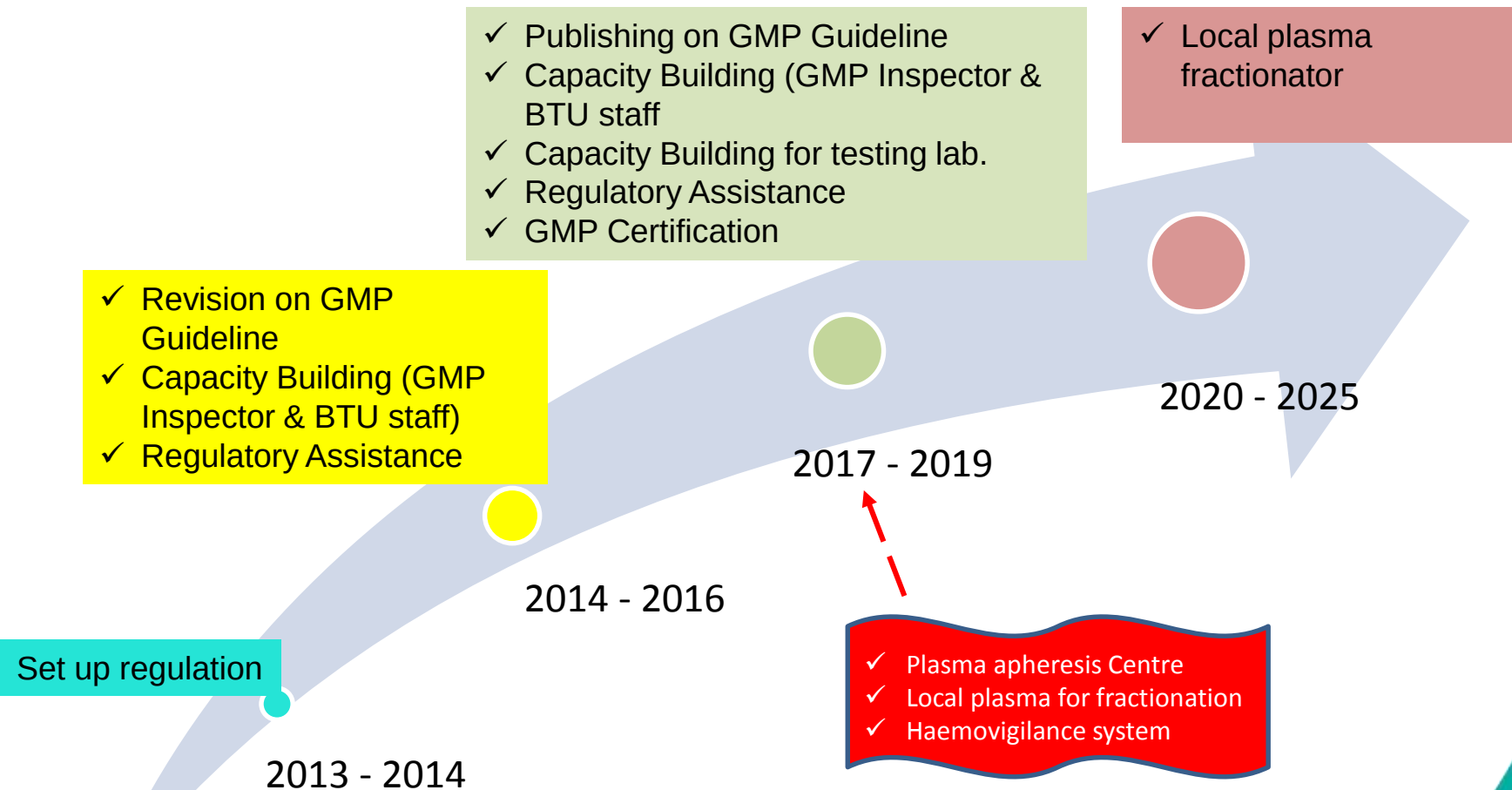


Establishing Local
Plasma Fractionator

Presidential
Instruction
#6/2016

Badan POM has a
role in the
supervision of
GMP Compliance

ROADMAP for GMP Implementation



2013**2014****2015****2016****2017 (Plan)****Updating Regulation**

- Regulation meeting with GMP expert to revised the existing Indonesian GMP for Blood Establishment.
- Public consultation of the draft guideline

- Guideline Finalization;
- Certification scheme to include Blood Transfusion Unit;
- Dissemination of the guideline in west region (Jakarta) and central region (Bandung)

- Dissemination of the guideline in east region (Makassar)
- Publishing the GMP Guideline and Operational Manual

GMP Regulatory Assistance

5 IRC BTUs:
IRC Central BTU,
Bandung, DKI Jakarta,
Surakarta, Surabaya

6 IRC BTUs:
DKI Jakarta, Bandung,
Surakarta, Surabaya,
Semarang, Prov. Bali

7 IRC BTUs:
Kota Cirebon, Kab.
Bekasi, Makassar,
Lampung, Pekanbaru,
Bandung, IRC Central
(UTDP)

- 5 IRC BTUs:
Padang, Sidoarjo,
Banjarmasin, Banyumas,
Malang
- GMP certification 4 IRC
BTU :
DKI Jakarta, Surabaya,
Bandung, Semarang

Capacity Building

- Seminar on Blood and Regulation Control (Collaboration with WHO)

- Blood Testing and Risk Assessment as Part of GMP in Blood Establishment (WHO)
- Enforcement and Implementation of Good Manufacturing Practices for Blood Establishments (WHO)

- Basic GMP Training
- GMP Training on BE
- Assesment of GMP Implementation on Surabaya IRC BTU by WHO

- GMP Training

- GMP Training on BE

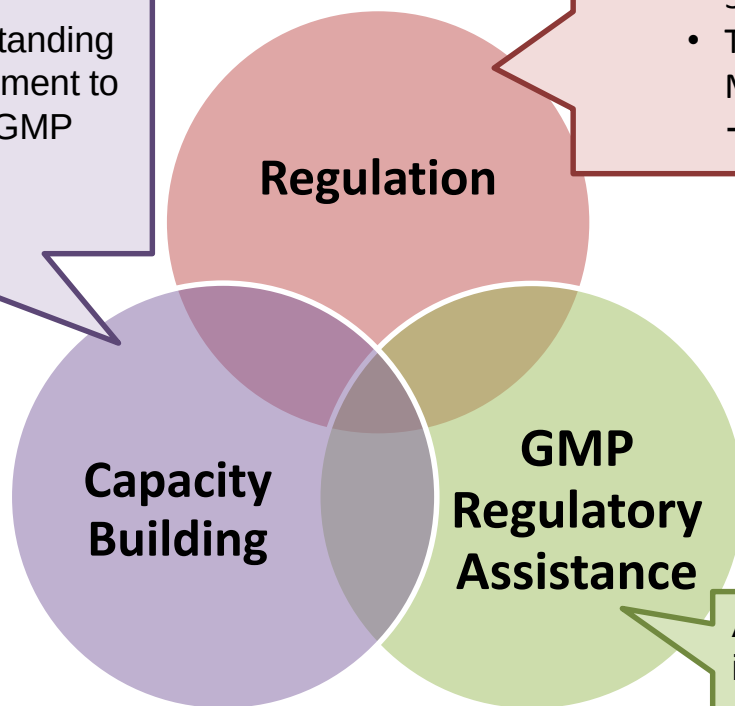


ENHANCING GMP COMPLIANCE

BADAN POM RI

WHAT HAVE DONE & STILL CONTINUE

- Training/workshop that involving the BTU's personnels and GMP inspectors
- Aim to increase the understanding of GMP for Blood Establishment to the BTU's personnels and GMP inspectors
- same perception on GMP



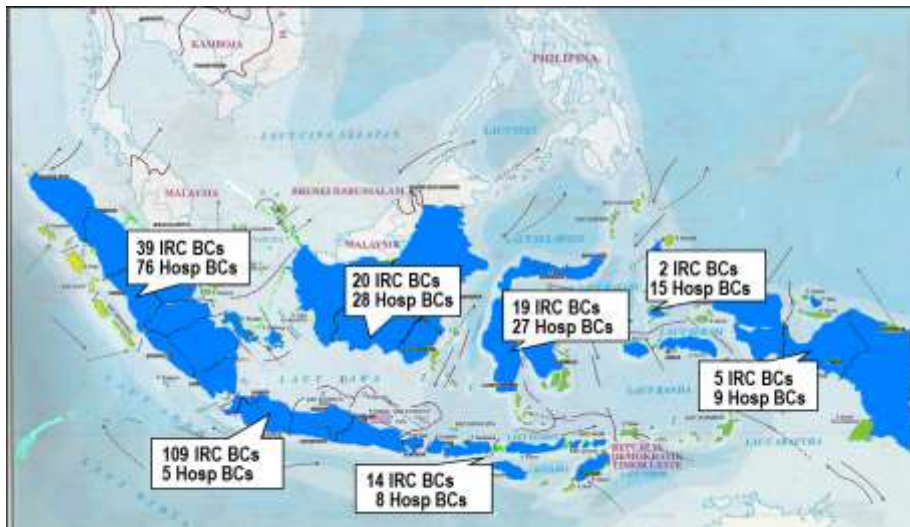
- Certification scheme
- Indonesian Blood Guideline:
 - GMP for Blood Establishment (ref: WHO Annex 4, TRS 961 (2011) & PIC/S PE 005-3 (2007)
 - Technical Guidance/ Operational Manual of GMP for Blood Establishment
→ specific guideline explanation

Aims to identify the GMP implementation gap in BTUs, and giving assistance to fulfill GMP standards.

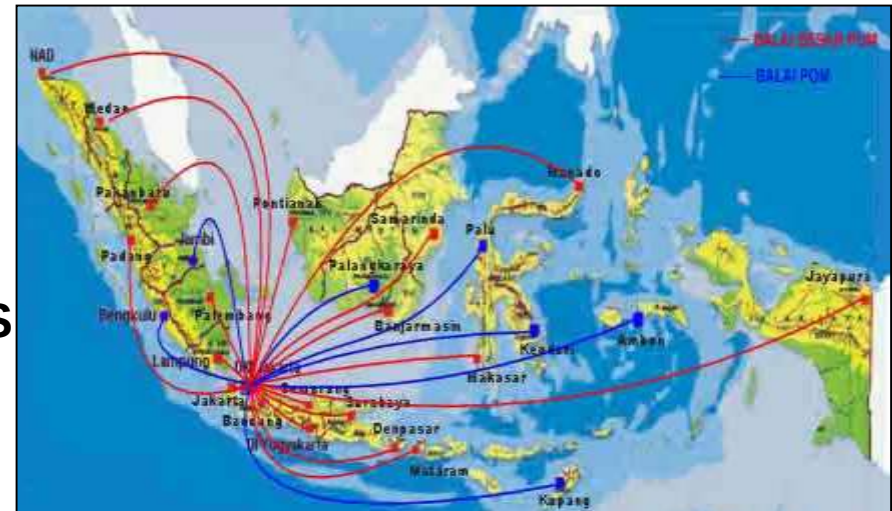
CHALLENGES



Blood Establishment VS GMP Inspector



VS



- BPOM has **33 regional offices** in **34 provinces**
- Total GMP inspectors are **114 persons**.
- The GMP inspectors **only available in central office** and **9 regional office** → Not all of the inspector familiar with blood facilities.

- Possibilities that the BTUs were not reached by inspection system/catchment areas of BPOM inspectors
- Inspectors from 24 Regional Offices have not been trained on GMP aspects : Basic knowledge on GMP aspect is not sufficient → need special inspectors trained in GMP, QMS, and familiar with blood service & facilities.

Activities Conducted on 2013 – 2016 (1)



**WHO Seminar on Blood Regulation and Control
Jakarta, 22-23 Agustus 2013**



**WHO Workshop on Blood Testing and Risk Assessment
as part of GMP in Blood Establishment
Jakarta, 9-12 June 2014**



Activities Conducted on 2013 – 2016 (2)



WHO Assessment of GMP Implementation on Surabaya BTU (11 – 14 Agustus 2015)



Basic GMP Training (involving BPOM & BTU personnel)



Training on GMP for Blood Establishment (Desember 2015)

Activities Conducted on 2013 – 2016 (3)



Public Consultation on Draft GMP for Blood Establishment (Jakarta, 21 December 2015)

Activity 2013 – 2016 (4)



Advanced GMP Training (May 2016)



Dissemination of GMP for Blood Establishment (Bandung, 11 – 12 August 2016)



Dissemination of GMP for Blood Establishment (Surabaya, 30 – 31 Agustus 2016)

SUMMARY

- Badan POM is the government agency responsible for drug and food control in Indonesia. Blood products along with other pharmaceuticals are included as commodities under the supervision of Badan POM
- GMP in blood establishments is one of the key issues for a successful plasma fractionation program.
- Role of BPOM on Promoting GMP Compliance :
 - Updating Regulation as guideline for implementing GMP in BTUs
 - Capacity Building of GMP Inspector & BTU's Personnels
 - GMP regulatory assistance & Certification.
- Increasing the capacity building both for GMP and BTU staff in relation with GMP for Blood Establishment.
- Need close cooperation between RA, MoH and IRC in improving the quality of blood products





Thank you

