DRUG QUALITY MANAGEMENT REGULATIONS IN VIETNAM

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OUTLINE

1. DRUG QUALITY MANAGEMENT SYSTEM
2. REGULATIONS
3. GOOG PRACTICES IMPLEMENTATION

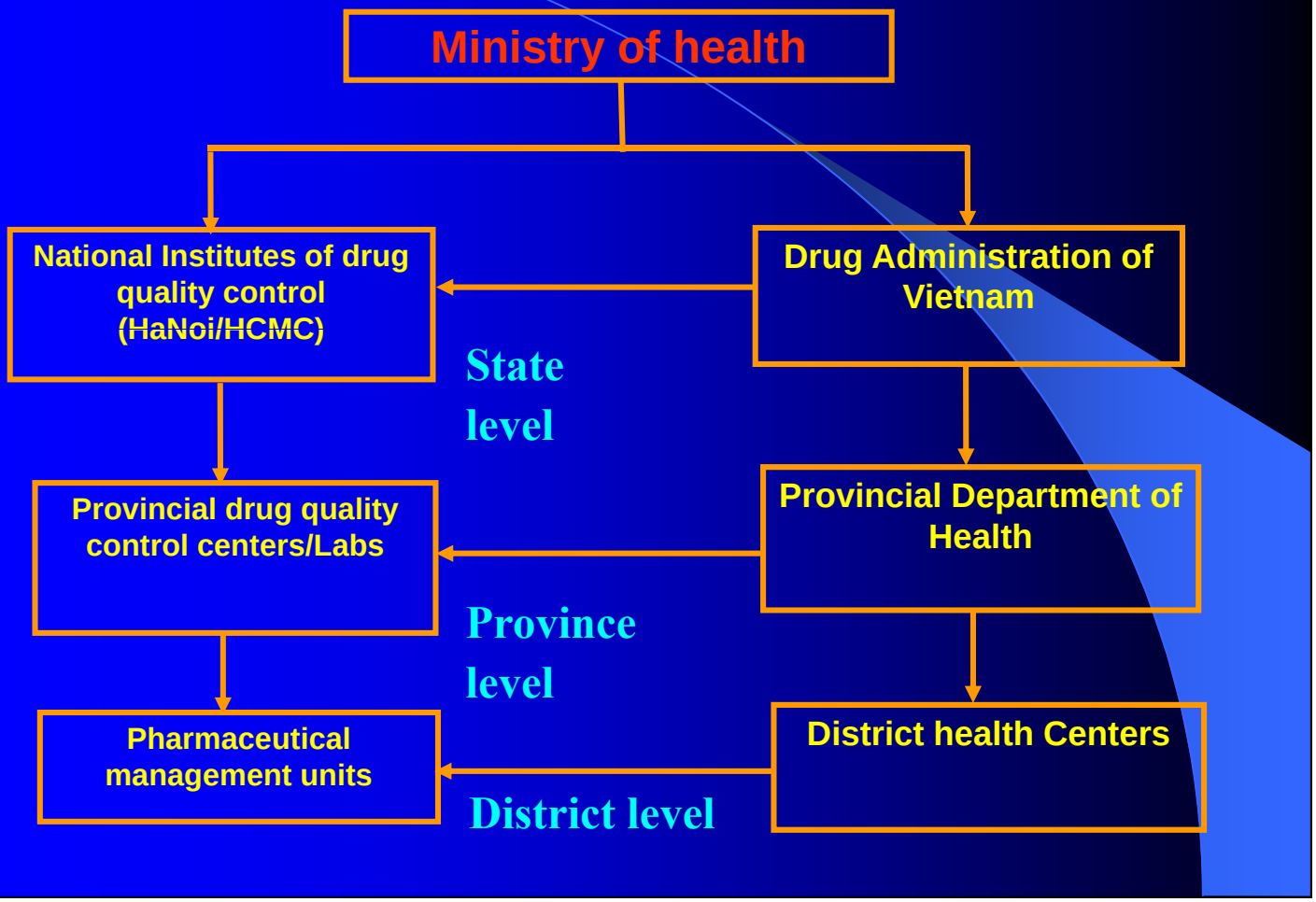
Part 1
DRUG QUALITY MANAGEMENT SYSTEM

DRUGS QUALITY MONITORING NETWORK (1)

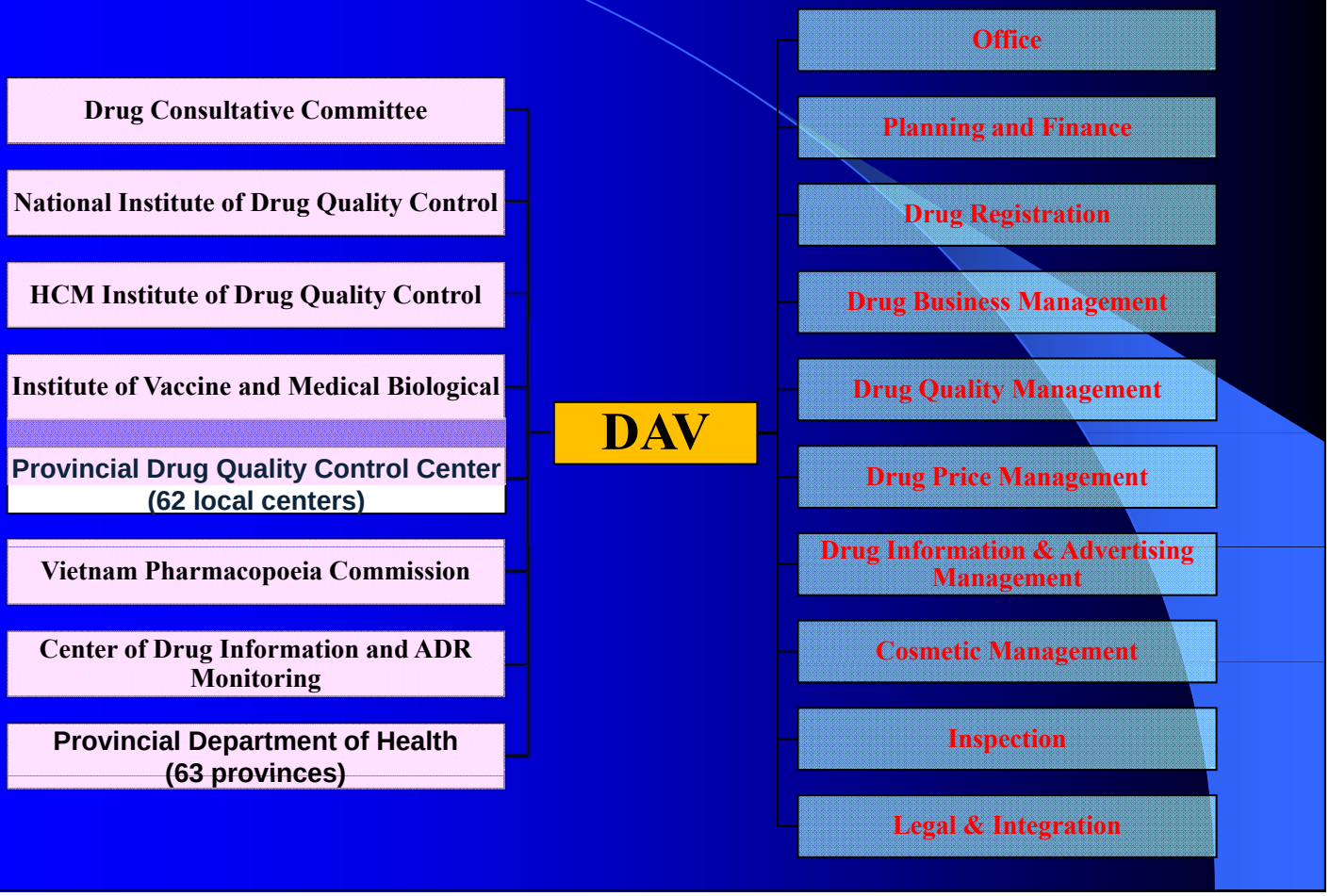
MINISTRY OF HEALTH

Institutes of Drug Quality Control	Drug Administration of Vietnam (DAV)	Pharmaceutical Inspectorates
▪ Drug sampling and testing ▪ Review Registration dossier (Quality Parts).	▪ Policies and regulations making ▪ GMP, GLP, GSP licensing ▪ Marketing Authorization ▪ Price and Advertising control ▪ Monitoring the drug quality ▪ Taking the samples ▪ Drug Substandard/Counterfeit Recalling	▪ Carry out the inspection ▪ Taking the samples ▪ Punishing the violations

DRUG QUALITY MONITORING NETWORK (2)



DRUG MANAGEMENT SYSTEM



DRUG QUALITY CONTROL SYSTEMS

1. Government laboratories
- Central: NIDQC, IDQC-HCM, NICVB
- Provincial: QC centers
2. Private Laboratories
3. QC Department of Pharmaceutical manufacturers

Responsibilities of regulatory authority

- Policies
- Legislation/Regulations
- Technical guidelines
- Pre-Marketing Approval (Evaluation/Assessment)
- Post-Marketing Surveillance
  - Market Monitoring
  - Sampling
  - Testing
- Inspection/Audit
  - Factories
  - Wholesalers
  - Pharmacies
  - Laboratories
  - Exporter / Importer
- Other responsibilities

Part 2
REGULATIONS

LEGISLATION

1. Pharmaceutical Law
2. Standards and Technical Regulations Law
3. Product and Goods Quality Law
4. Decree No. 176/2013/ND-CP on the administrative punishment in health sector
5. Circular No. 09/2010/TT-BYT guiding management of Drug Quality
6. Circular No. 04/2010/TT-BYT on Drug Sampling
7. Circular No. 06/2016/TT-BYT on the labeling
8. Circular No 08/2010/TT-BYT guiding to report BA/BE study for drug registration
9. Circular No. 44/2014/TT-BYT on Drug registration.

DRUG SAFETY MANAGEMENT
Strategic Policies

NATIONAL POLICY ON DRUGS
(The Government Resolution No.37/CP dated June 20, 1996)

General goals:

1. **To ensure the continuous supply of quality drugs to people**
2. **To ensure rational and effective drugs use**

NATIONAL DRUG POLICY (1996)

1. **Specific policies:** Essential drugs: rational and safe use of Drugs and minimize risk caused by non-compliance with Regulation on prescribing, sale, use of drugs.
2. **Pharmaceutical Developing Strategy to 2010:** By the end of 2010, all manufacturers, quality control labs, suppliers, importers and exporters should be meet the **GMP, GLP,GDP,GPP, GSP**

DRUG SAFETY MANAGEMENT
Strategic Policies (2014)

Decision No. 68/QD-TTg of The Prime Minister Approving

THE NATIONAL STRATEGY ON DEVELOPMENT OF THE VIETNAM PHARMACEUTICAL INDUSTRY UP TO 2020, WITH A VISION TOWARD 2030
(dated 10 January 2014)

I. DEVELOPMENT VIEWPOINT

1. **To use medicines rationally, safely and effectively; to push up operation of clinical pharmacy and pharmacovigilance.**
2. **To manage strictly, effectively stages from production, export, import, preservation, circulation, di stribution to usage of medicines.**

II. OBJECTIVES

1. General objectives

- Ensure medicine usage to be safe and rational.

2. Specific objectives up to 2020:

- To strive to attain 40% generic drugs produced domestically and imported with circulation registration number already assessed bioequivalence and bioavailability.
- 100% of medicines-trading establishments under the drug distribution system meet good practice standard, 50% of testing establishments and 100% of establishments of examining and verifying medical biological products and vaccines meet good practice standards (GPS).

3. Objectives oriented by 2030:

- System of drug quality control, drug distribution, clinical pharmacy, drug information shall be equal to the advanced countries in region.

DRUG QUALITY MANAGEMENT

Pre-Marketing Control:

1. Drug Registration review

- ❖ Administration Parts
- Quality Parts: Formula, Manufacturing Process, Specifications, Stability Study.
- Clinical Parts

2. Operation licence certification:

- ❖ GPs complied: GMP, GLP, GSP, GDP, GSP,...
- ❖ 100% imported batches must be tested before supplying to the market: Started from 2013.
- Applied for the Manufacturers which have had substandard products.
- The testing must meet the registered specification.

DRUG QUALITY MANAGEMENT

Post Marketing Control:

1. Pharmaceutical Manufacturers:

- ❖ Drug Self-control during drug circulation in the market and all quality-related issues must be reported to Drug authorities.

2. Drug Authority:

- ❖ Randomised sampling in the market and testing by 2 national institutes of Drug quality control and 62 Provincial Labs.
- ❖ Oversight of implemetating regulations on drug quality, GPs...
- ❖ Inspection of drug manufaturers, traders...

DRUG QUALITY SPECIFICATION

1 Drug Specifications:

- Vietnam's pharmacopoeia issued by MOH,
- Foreign pharmacopoeias recognized by MOH: USP, BP, EP, International Pharmacopoeia, JP.

2 In-house Specifications:

- Developed by Manufacturer
- not lower than corresponding national Specifications/ recognized Foreign Pharmacopoeia

DRUG RECALL

- Not of right categories due to mistakes in the course of dispensation and delivery;
- Fail to meet:
  - the registered quality Specifications;
  - drug labeling requirements;
  - Packaging materials and package forms requirements;
- Not be registered products (MA or Import license).
- Having notifications of drug recall issued by manufacturers or Vietnam/Foreign Drug Authorities.

DRUG RECALL

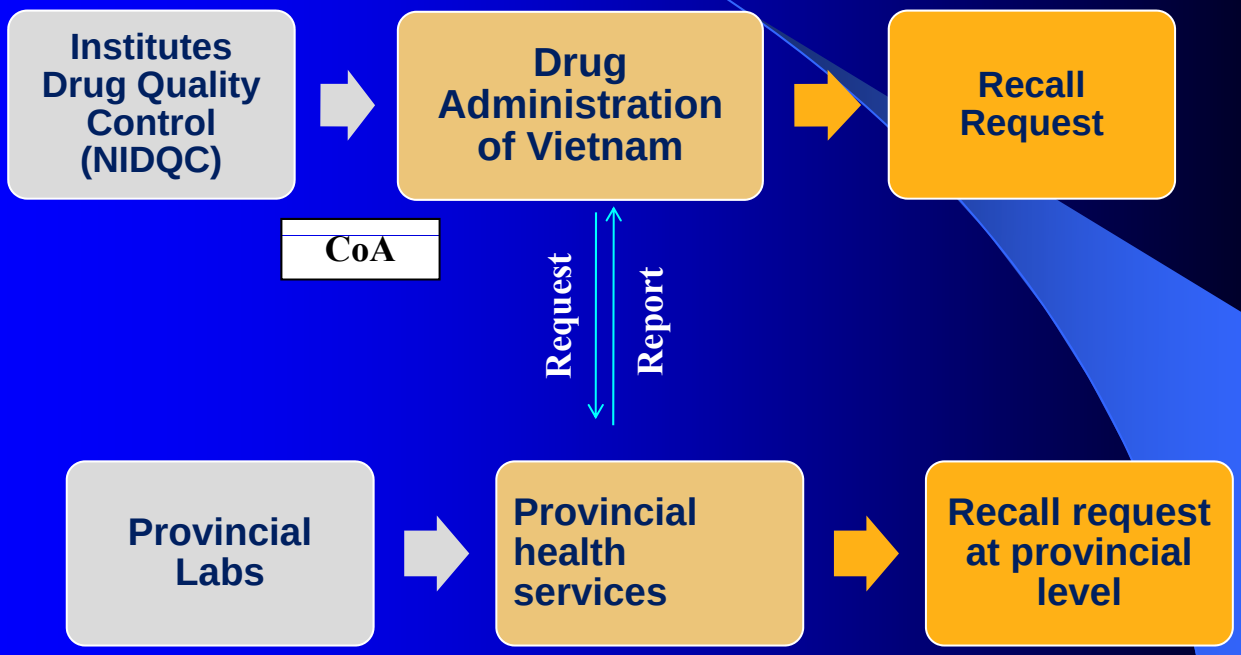
Quality Violation:

- **Level 1:** Life threatening Violation which can lead to severe injuries or human death -> Urgently sent to license holders, manufacturers, medicine traders, using hospital pharmacies; publicized in the mass media.
- **Level 2:** Violations which have bad affect the therapeutic effect and safety of drug users/patients -> Suspension notification be sent to license holders, manufacturers and medicine traders.
- **Level 3:** Violations which do not affect or slightly affect the therapeutic effect and safety of users/patients -> Suspension notification be sent to entities as level 2, except pharmacies.

HANDLING OF RECALLED DRUG

1. Substandard/Label regulation Violations: recycled or destroyed
2. Other cases: destroyed

DRUG RECALL PROCEDURE



DRUG RECALLING RESPONSIBILIES

Recall urgently

Importers

- To be responsible for Drug Recalling
- Handling of recalled drugs

Manufacturers

Wholesalers

- To be involed in drug recalling procedure
- To receive recalled drugs from Retailers

- To recall drug and send to suppliers

Retailers

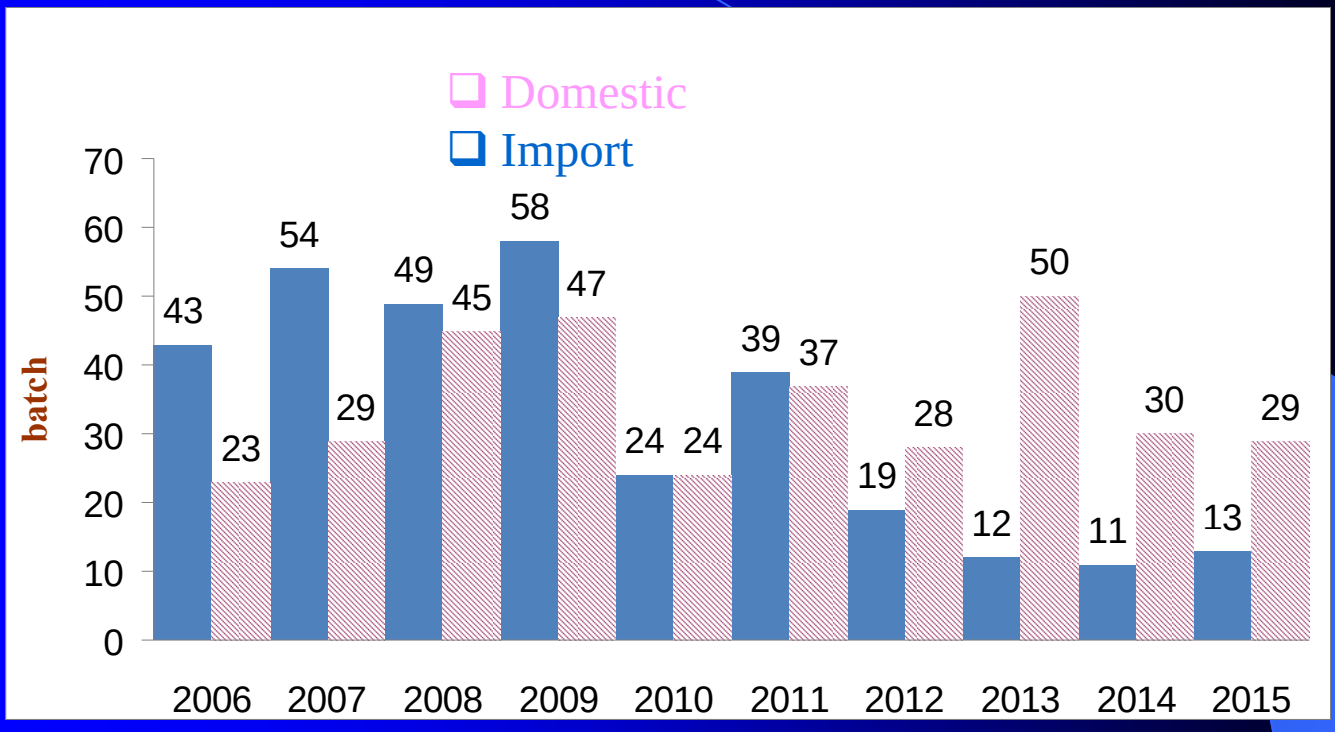
Drug Recalling Documents:

- Drug recalling Reports
- Drug recalling Evidence

DRUG QUALITY MONITORING IN THE MARKET

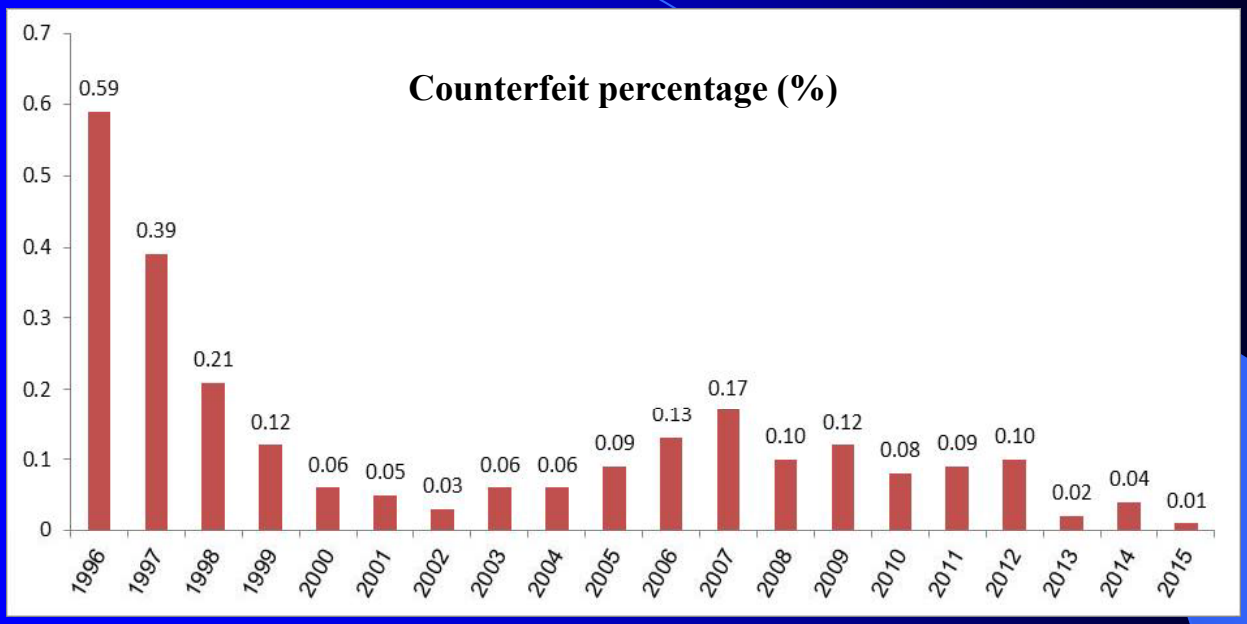
Year	Number of samples	Number of substandard samples	Percentage of substandard (%)
2006	29.819	947	3,18
2007	25.460	839	3.30
2008	25.320	744	2,94
2009	31.542	1051	3,33
2010	32.313	1008	3,12
2011	33.508	940	2,81
2012	32.621	1.008	3,09
2013	39.853	1.004	2,52
2014	40.245	967	2,40
2015	38.627	749	2,00

NUMBER OF BATCHES RECALLED BY DAV



2012: 47 batches
2013: 62 batches
2014: 41 batches
2015: 42 batches

SITUATION OF COUNTERFEIT



(Counterfeit percentage based on quatity of samples)

Vietnam: low percentage counterfeit drug

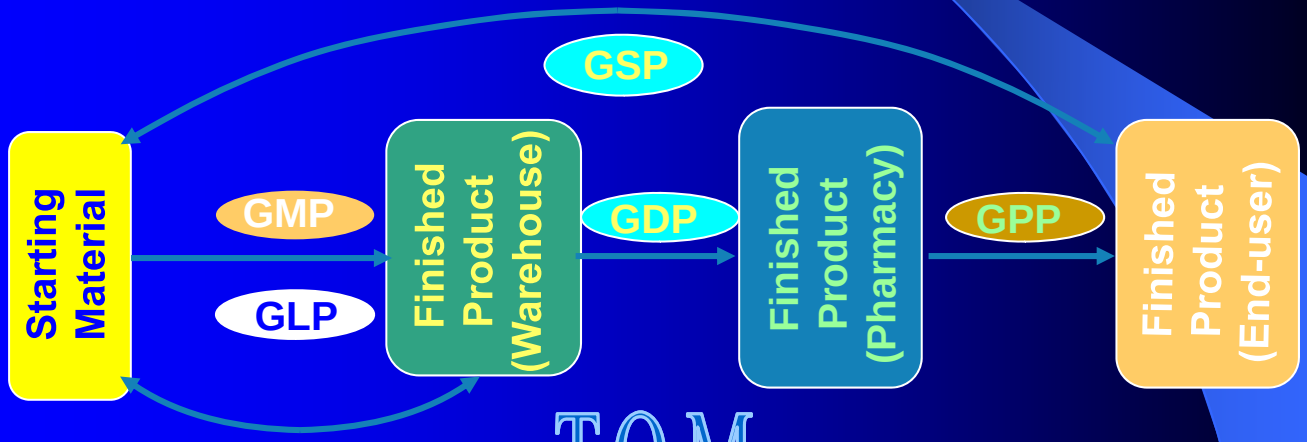
Part 3

GOOD PRACTICES IMPLEMENTATION

Comprehensive quality control

Comprehensive quality control strategy:

Synchronic investment : GMP, GLP, GSP, GDP, GPP

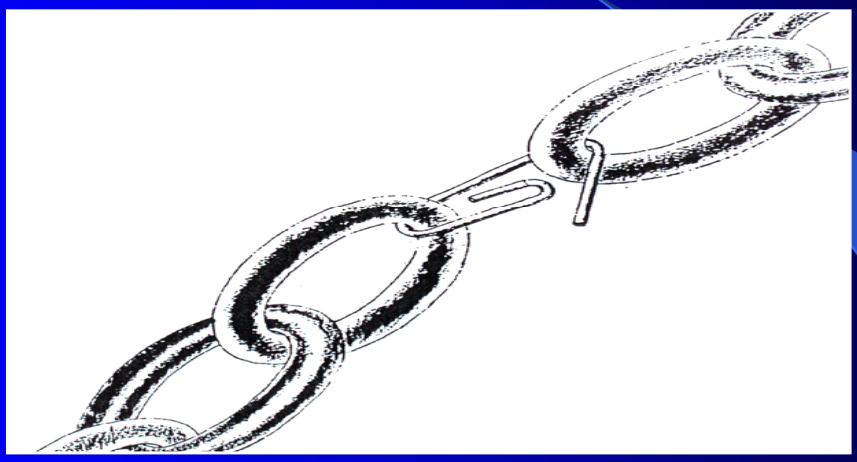


T.Q.M

Toltal Quality Management

Total quality management

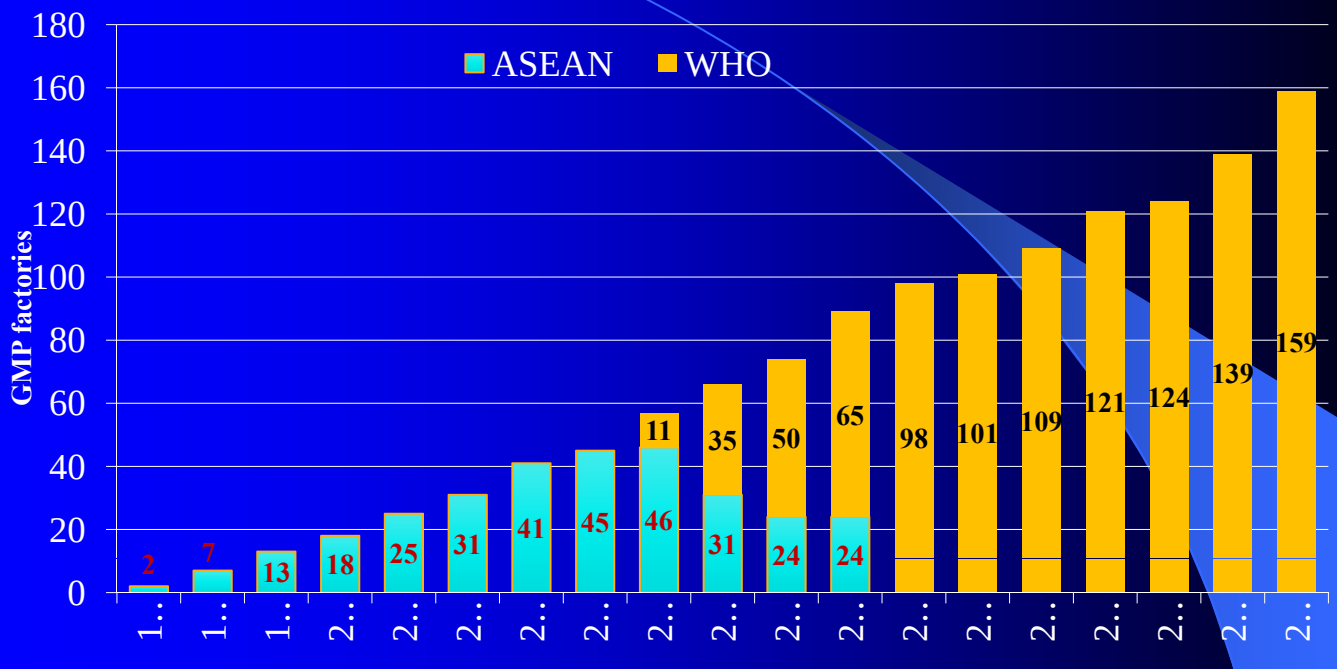
Toltal Quality Management



GPs IMPLEMENTATION IN VIETNAM

1996	2000	2001	2004	2007	2018 - 2020 (estimated)
GMP-ASEAN	GLP	GSP	WHO-GMP	GDP GPP	**ASEAN listed &**
Manufacturer	Laboratories	Storage Logistics	Manufacturer	Wholesalers Pharmacies	**GMP-PICs** Manufacturer

Number of GMP factories



- **ASEAN-GMP: since 1996**
- **WHO-GMP: since 2004**
- **PIC/s: establishing**

MRA ASEAN

- 2009 - Mutual Recognition Agreement on GMP Inspection has been signed among ASEAN countries.
- 2018: to be listed in Asean Inspection services.

PLAN FOR PIC/S-GMP

- 2017: submitt pre- assessment dossier
- Implementation PIC/s QMS framework
- 2020: to become a member of PICS.

PIC/S-GMP: PREPARATION PROCESS

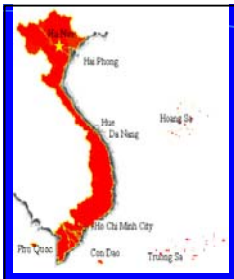
- Strengthening QMS
- Regulation activities for PIC/S guidance and roadmap
- Improving inspector skills through abroad/coach GMP training
- Promoting experience sharing activities with other national regulatory inspectorates (ASEAN, Cuba,..)

PHARMACEUTICAL LAW 2016

New policies:

▪When registering an imported drug or pharmaceutical material in Vietnam, foreign manufacturer must assess the fulfillment of GMP requirements as the following ways:

- Assessing GMP manufacturer documents;
- Mutual recognition (ex: Manufacturers inspected by listed ASEAN inspectorate…);
- On site Inspection.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THANK YOU