



## **THE 2<sup>nd</sup> INDONESIA-JAPAN SYMPOSIUM ON: ENSURING AND ENHANCING QUALITY ASSURANCE of MEDICAL PRODUCTS**



**Deputy Chairman for Therapeutic Products, Narcotics, Psychotropics,  
and Addictive Substances Control**

**NADFC - INDONESIA**

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# Outline

- Quality Assurance of Medicine, Regulatory framework
- Risk Management
- Supply chain integrity and Product Recall

# Regulatory Framework on Ensuring Q,S, E of Medicine

## Quality Assurance

Q, S, E

**Documentation, Monitoring, and Evaluation**

**Pre Marketing Assessment**  
(marketing authorization/  
licensing and  
registration)

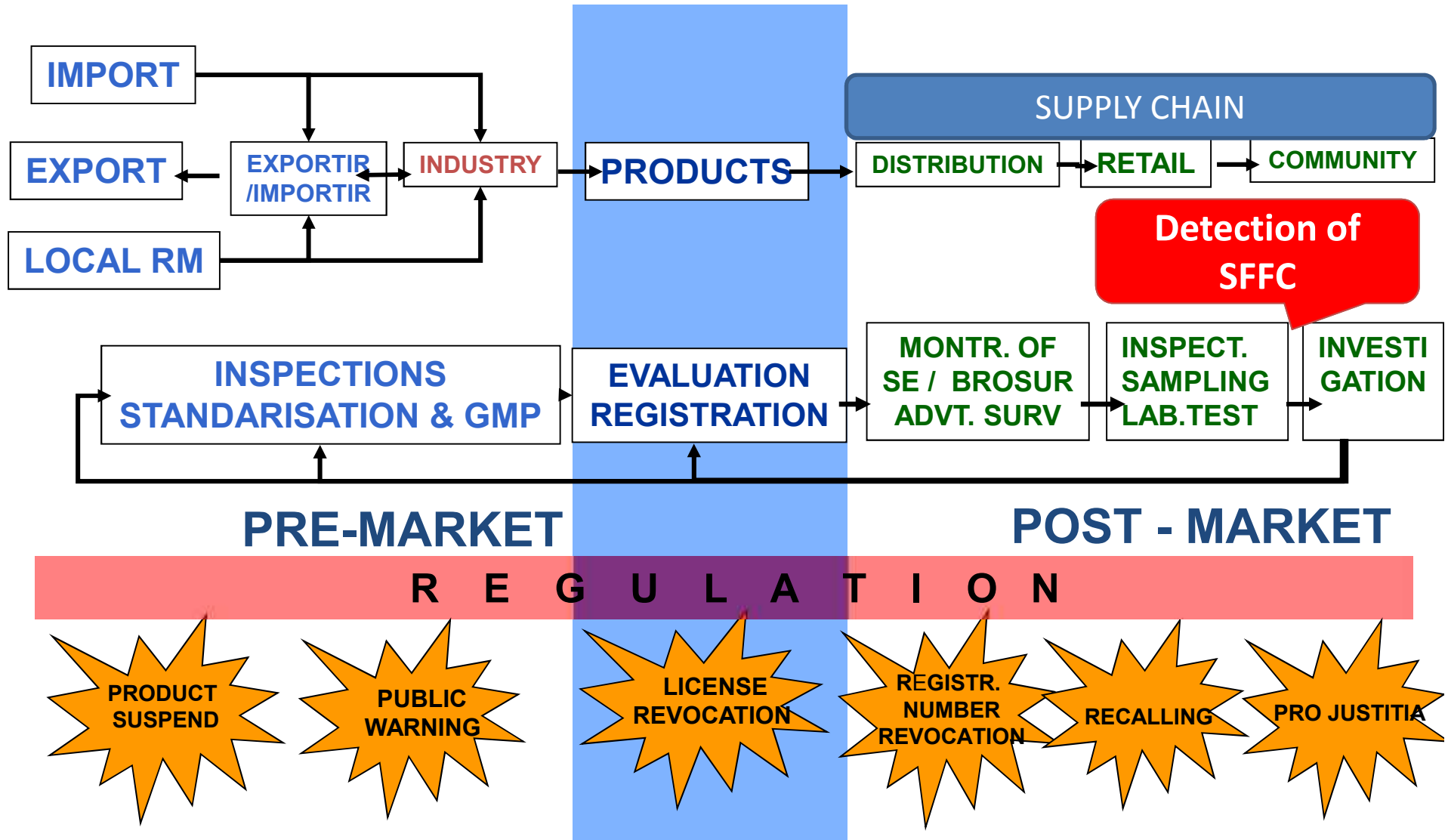
**Regulatory Elements**  
(full spectrum/  
comprehensive  
functions including,  
inspection, recall,  
central & provincial  
lab)

**Technical Elements**  
(quality  
specifications,  
Basic tests, GMP,  
GLP, GPP, GDP,  
GSP, GCP)

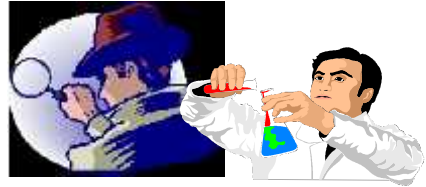
**Post-marketing surveillance**  
(for quality ,  
adverse events,  
and product  
information,  
promotion)

**Adequate legislation and law enforcement**

# DRUG CONTROL SYSTEM IN INDONESIA



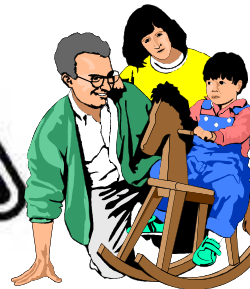
## CONTROL FUNCTIONS SYSTEM



**REGULATORS**



**STAKEHOLDERS**



**CONSUMERS**

- **NADFC ensuring Quality, Safety, Efficacy of Marketed Drug**
- **Stakeholders responsible on their products**
- **Consumers able to protect themselves from risky product**

**Risk communication is a key !**



# QUALITY ASSURANCE IN THE BUSINESS PROCESS

## NADFC Implementation of QMS



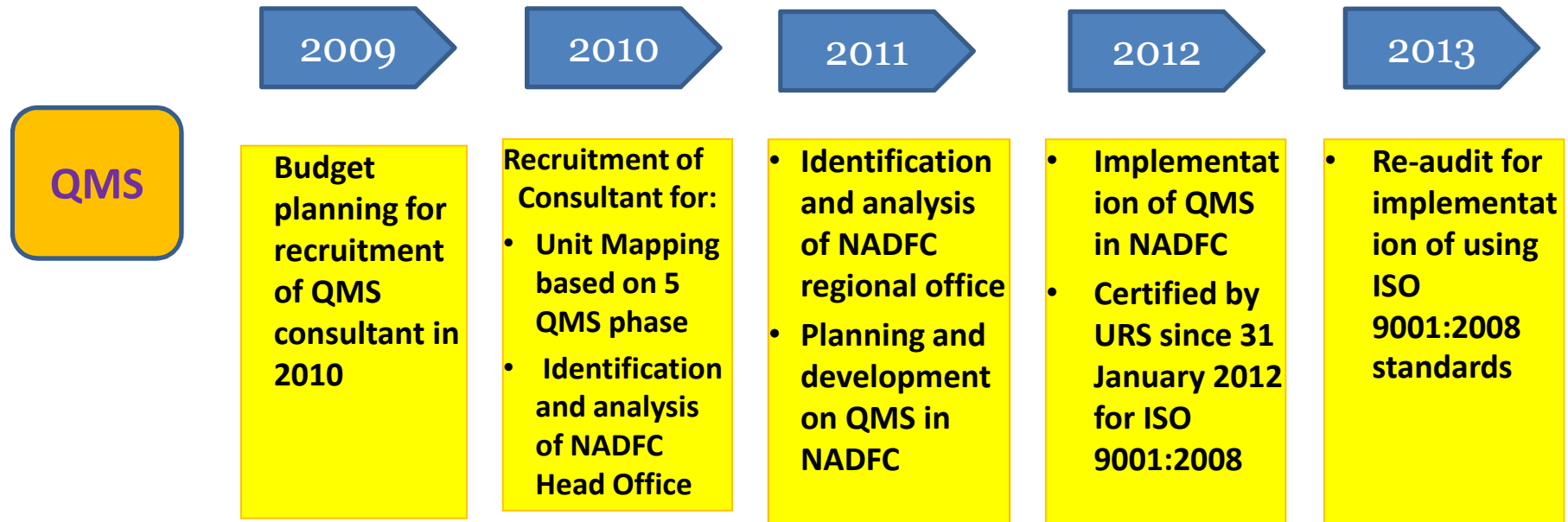


# Quality Management Principles

- A comprehensive and fundamental rule or belief,
- For leading and operating an organization
- Aimed at continually improving performance over the long term
- Focusing on customers
- Addressing the needs of all other stakeholders



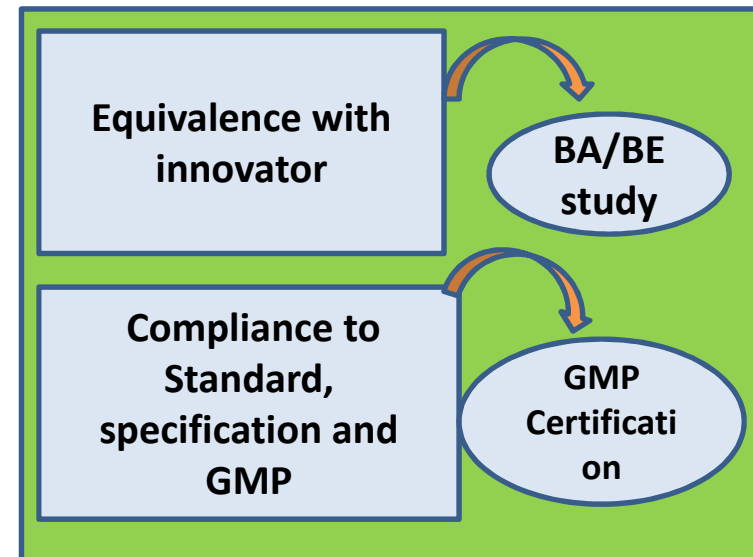
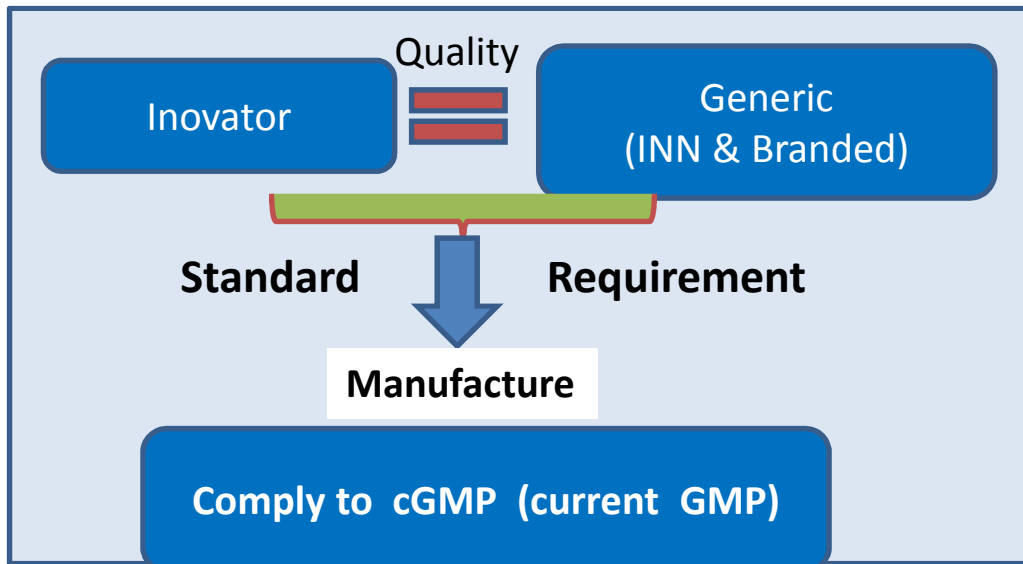
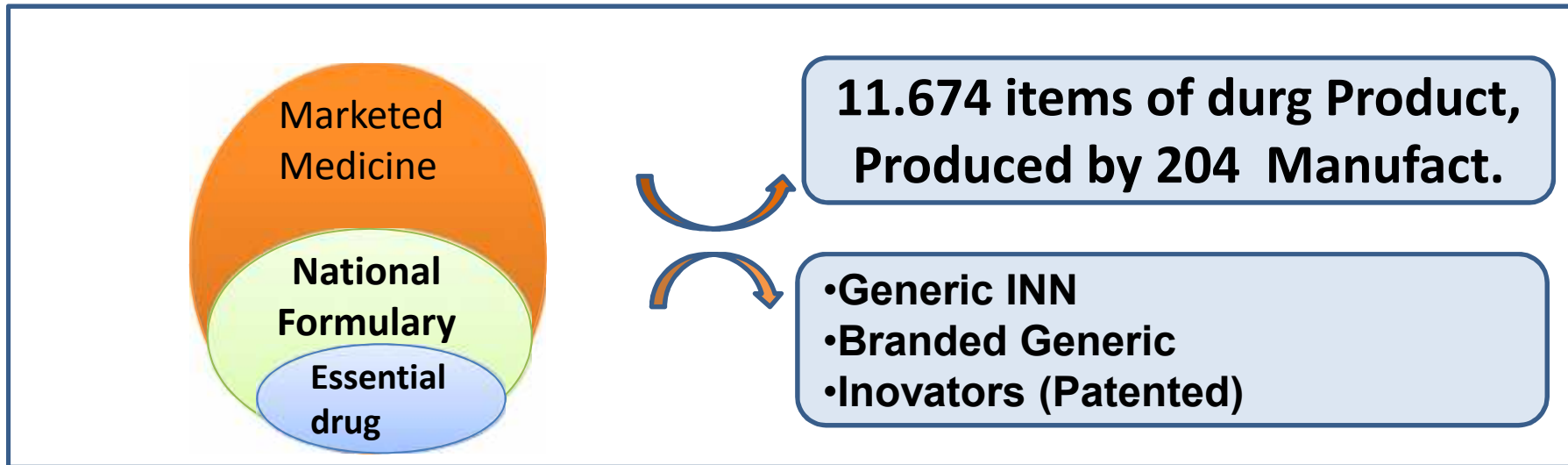
# ACHIEVEMENT in QMS UP TO 2013



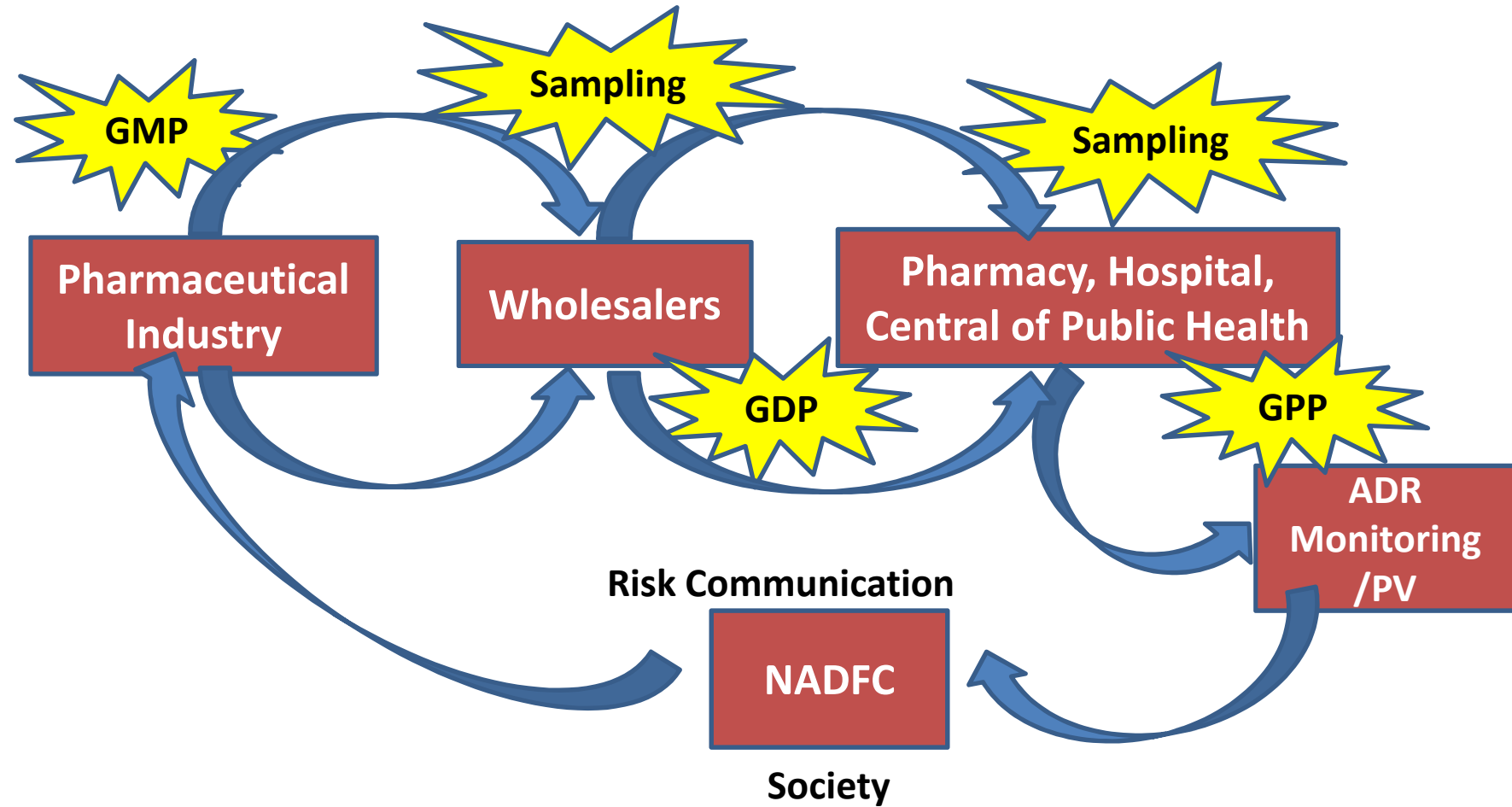
- In October 2011 QMS implemented in all level
- Audit for Certification on 5 January-28 February 2012 :
  - ✓ 24 units in NADFC
  - ✓ 30 Regional offices
- Certificate ISO 9001:2008 by United Registrar of Systems (URS), obtained on 31 January 2012 (for some units in NADFC).
- At present all units have obtained certificate ISO 9001:2008 , next audit will be based on 9001:2012



# Quality Assurance Scope and situation



# RISK BASED SURVEILANCE AND AUDIT FOR SAFETY AND QUALITY OF PRODUCT



# RISK BASED CONTROL SYSTEM

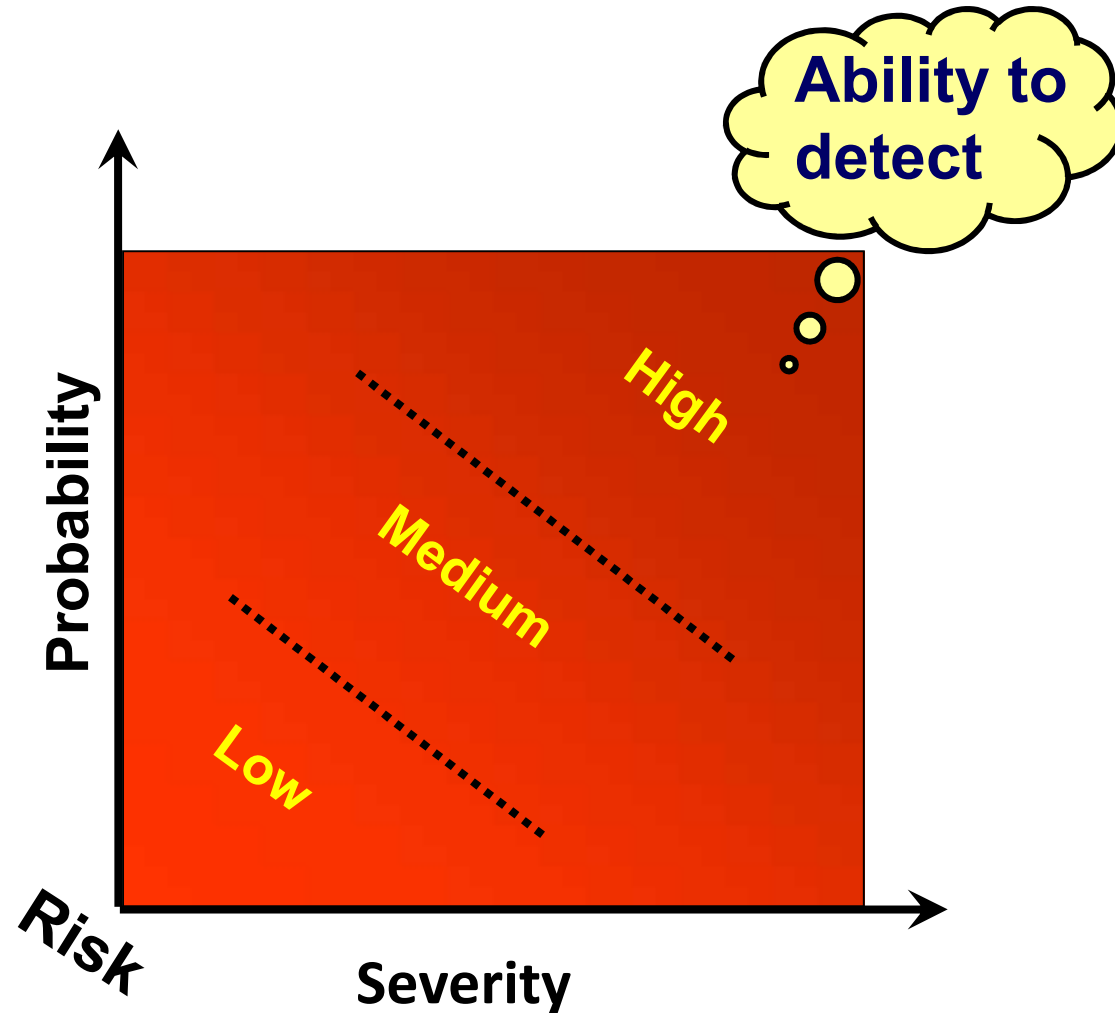
- ❖ Program planning should consider the maximum risk mitigation/elimination using real capacity and resources
  - ❖ Develop a roadmap to guide the Action and to evaluate as well to adjust the speed toward the target outcome
  - ❖ Periodic evaluation should also measure the outcome that give impact to public protection.
- ➔ **Impact assessment : analyze the achievement vs Risk managed**

# Risk assessment

Risk parameter  
to measure  
detectability



Risk ranking  
and priority to  
be mitigated



# Quality Risk Management

- This Quality Risk Management methodology is a simple tool that allows Inspectorates **to assign a relative risk rating to manufacturers** when planning the routine inspection program for those sites.
- The risk ratings that are generated using this methodology may then be used by the Inspectorate **to assign a frequency** to the routine inspections that will be performed at the various manufacturers under its supervision.
- The risk ratings that are assigned to sites **are based on an assessment of two different kinds of risk - an intrinsic risk and a compliance-related risk.**

# Type of risk

- **The intrinsic risk** estimated for a site reflects **the complexity of the site, its processes and products as well as the criticality of the products** or services provided by the site including from a supply perspective.
- The **compliance-related risk** that is estimated for the site reflects the GMP compliance status of the site immediately following the most recent routine inspection at the site. When this risk is being estimated, the classification and number of deficiencies identified at the last inspection are taken into account.

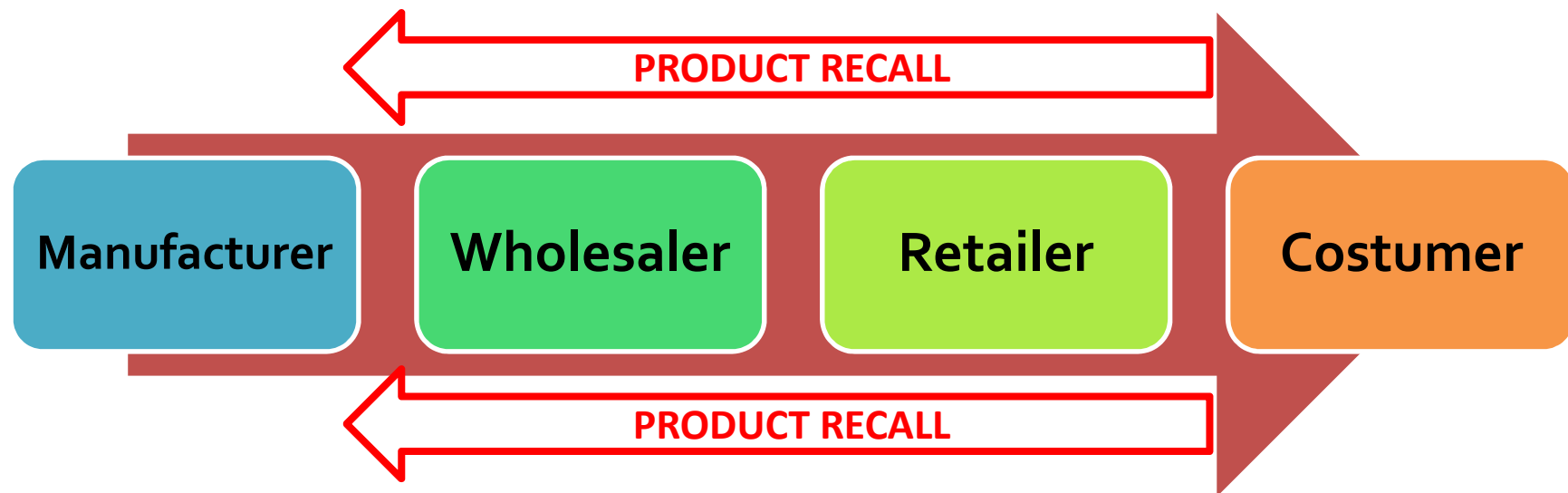
# Regulatory challenges in risk based surveillance and audit

- Number and competency of inspectors
- Level of sites compliances in the supply chains
- Variety of product and advance technology
- Support of good training system
- Support og good laboratory facility
- Dynamic global standard
- Benchmarking and networking among regulators

# Challenges of Supply Chain Integrity

Through all DISTRIBUTION CHANNELS

All the organizations that facilitate the pass through of product between its point of production and consumption



SITUATION: Archipelago of 17.000 islands; Air transport are not cover all potential economic cities; high mobility people, rivers and unattended islands could be risks of illegal trading



# Supply Chain Control



## Activities:

- Inspection to Wholesalers, Pharmacies, Hospitals, Clinics and Drug stores to ensure good distribution practices
- Sampling of product from the market as a part of Regulatory quality control
- Surveillance for early detection of illegal/counterfeit pharmaceutical products
- Investigation to track and trace back of counterfeit and illegal supplier

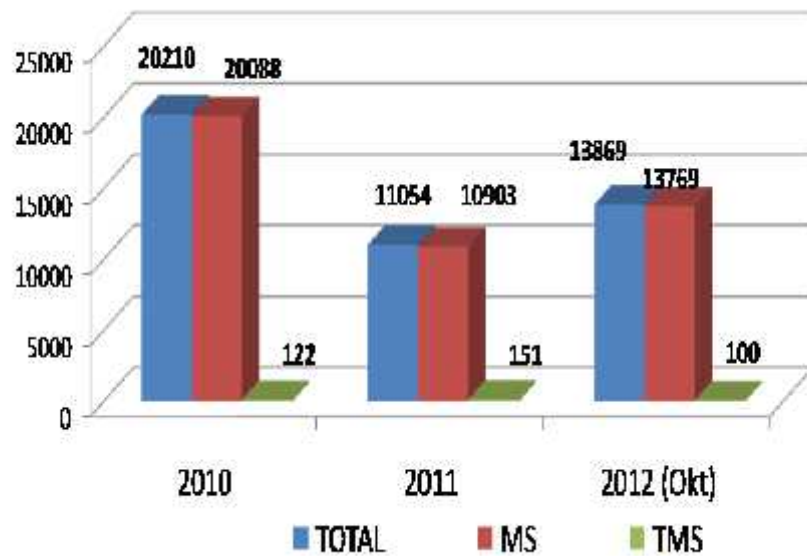
## Penalties:

- Administrative sanctions
- Withdrawn of license
- Public warnings
- Pro Justitia

Year	Discovered Counterfeit Drugs	Discovered Drugs which illegally marketed
2009	22	121
2010	10	36
2011	8	67
2012	5	96
2013	13	159

# Trend of product RECALL (items) 2010 - 2012

## Total sampled



## Total items recalled



# SUMMARY

- Quality assurance of Medicine should consider comprehensive commitment from Regulator-Product key player – Public
- Regulatory risk based Control function should be implemented in the frame work of Quality management system
- Patients or consumer will be the most protected from any risk of the product as a reason of product recall



**Thank you  
Arigato**