



# GDP Implementation: Business and Ethics

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# Anugrah Argon Medica

## “RELIABLE SOLUTION IN SELLING, DISTRIBUTION & SERVICES”

AAM provides reliable solution and significant added values to customers and business partners in Selling, Distribution and Services of Pharmaceutical Products, Medical Devices, OTC and Consumer Health Products. AAM has 3 key competitive advantages: strong market exploration, reliable supply chain solution, and knowledge organization.

### Knowledge Organization

Logistic  
Process

Business  
Development

Sales  
Operation

Service  
Management

Strong Market Exploration

Reliable Supply Chain Solution

Principal

- Integrated Supply Chain Management

- **GDP WHO Standard 2010 ( the First Distributor in Indonesia )**

Customer

- Quality Management System, AXIS

- ISO 9001 : 2008



40  
Branches

9  
Rep Offices

64  
Stations

2  
RDC

1  
NDC

# AAM Business Portfolio

| ETHICAL | OTC and CONSUMER | MEDICAL DEVICE | SPECIALTY BUSINESS |
|---------|------------------|----------------|--------------------|
|         |                  |                |                    |





| Pharmacy   | Hospital   | PBF / PBAK  | Doctor   | Lab  | Drug Store, Traditional  | Modern Market  | Optics   |
|--|--|---|--|--|--|--|--|
| <ul style="list-style-type: none"> <li>• 17.000</li> <li>• ASKES</li> <li>• REGULAR</li> </ul> | <ul style="list-style-type: none"> <li>• 1.900 RB</li> <li>• ASKES</li> <li>• INSTITUTION</li> <li>• GOV</li> <li>• PRIVATE</li> </ul> | <ul style="list-style-type: none"> <li>• 300 RB</li> <li>• TRADER</li> <li>• PARTNER</li> </ul> | <ul style="list-style-type: none"> <li>• 5.500 RB</li> <li>• GP</li> <li>• Pediatric</li> <li>• Obgyn</li> <li>• Others</li> </ul> | <ul style="list-style-type: none"> <li>• 400 RB</li> <li>• Independent Labs</li> <li>• Chain Labs</li> </ul> | <ul style="list-style-type: none"> <li>• 5.000 RB</li> <li>• Drugstore</li> <li>• Babyshop</li> <li>• Other Retailers</li> </ul> | <ul style="list-style-type: none"> <li>• 2.500 RB</li> <li>• Hypermarket</li> <li>• Supermarket</li> <li>• Minimarket</li> </ul> | <ul style="list-style-type: none"> <li>• 500 RB</li> <li>• Independent Optics</li> <li>• Chain Optics</li> </ul> |



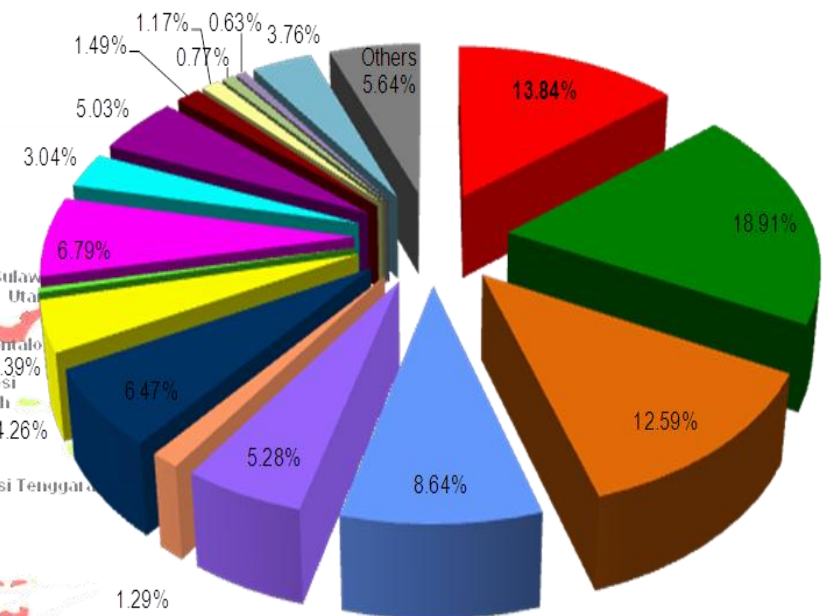
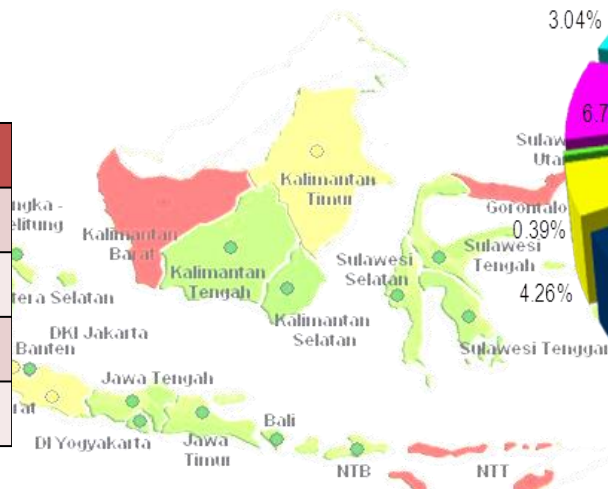
# Business Landscape: The Competition

- **There are ± 2,600 pharmaceutical distributors (wholesalers)**
  - Principals and Retailers have freedom to choose their distributors
  - Different business focus: Ethical, OTC, consumer health, medical devices, tender, etc.
- **Key players:**
  - The top 10 distributors, with a total of ± 300 branches, control 80% of market
  - Compete on Distribution Margin vs Service Quality
  - Different service standards



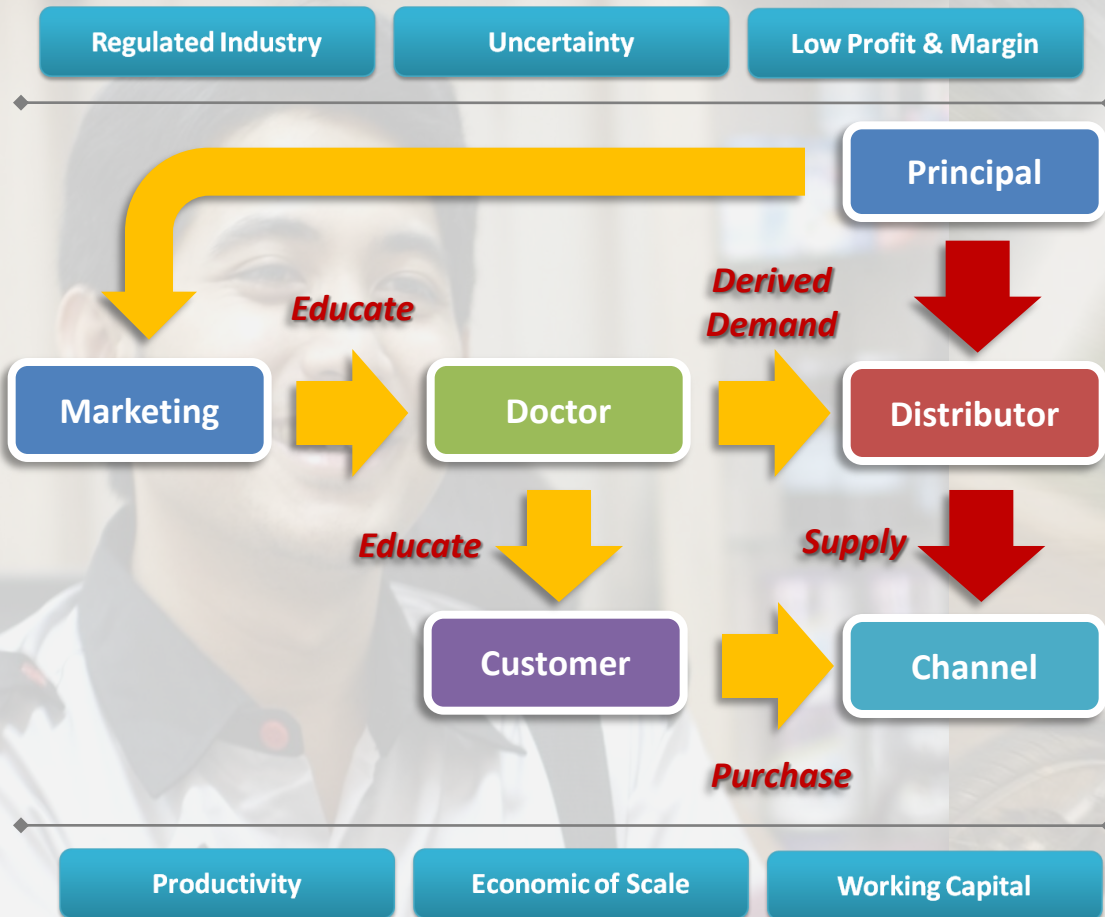
| NO | TYPE OF PRODUCT      | TOTAL  |
|----|----------------------|--------|
| 1  | Medicine             | 16.389 |
| 2  | Traditional Medicine | 7.787  |
| 3  | Supplement           | 2.504  |
| 4  | Cosmetic             | 93.964 |

Source: [www.pom.go.id](http://www.pom.go.id)



Source : IMS MAT Q3 2012 (Pharmacy and Hospital market)

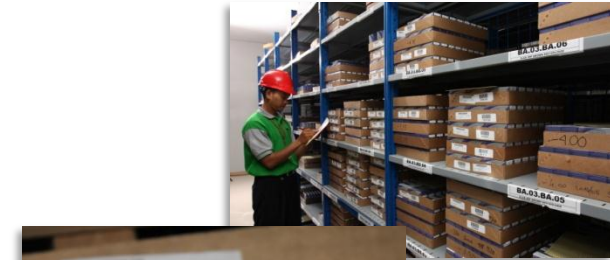
# Pharmaceutical Distribution Business Process



- Clear definition of “What business are we in?”
- Economic of Scale for each distributor
- Pressure for Principals
  - Low Margin: Capabilities vs. Cost
  - Direct Supply
- Customer behavior: demanding on daily services
- Role in distributing low-price medicines (unbranded generics and others)

# Cost of Distribution

- Distribution Cost comprises not only transportation-related costs, but also costs to:
  - **Maintain the quality of drugs** along the supply chain, especially Cold Chain Products. This includes:
    - Provision of sufficient infrastructure
    - Training of workers to become competent
    - Compliance with regulations and product handling standard
  - **Ensure product availability** at the right place, in the right amount, at the right time.
  - **Safeguard against risks of potential loss:**
    - Physical Loss (damages, lost, expired, temperature deviation for CCP, etc.)
    - Financial loss from transactions (bad debt)
  - **Working Capital**
    - Average inventory level: 1.5 month
    - Payment terms: 21 days, 60 days, and even 180 days

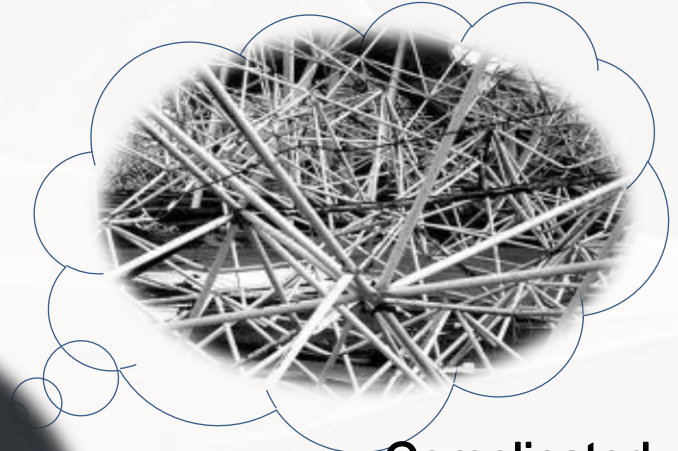




# Business Sustainability... and Why GDP?



**Costly**



**Complicated**



**GDP  
???**



**Difficult**



**Unattainable**

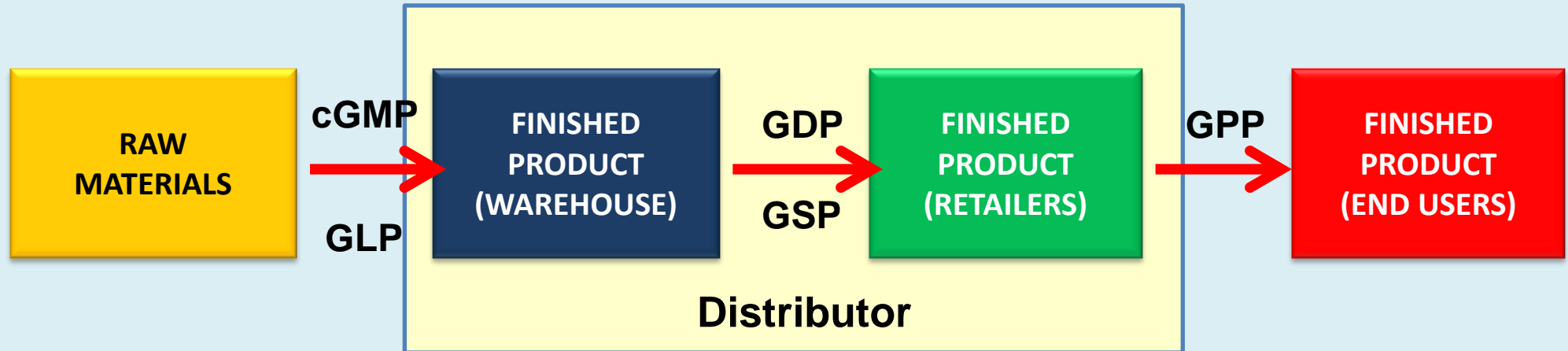
# We are Part of Healthcare System

- Distribute drugs from manufacturers to retailers
- Comply with the governing regulations:
  - Kemenkes (Ministry of Health) → Ministerial Decrees
  - **BPOM (Indonesia's FDA) → CDOB**
  - **WHO → GDP**
- Care of Pharmaceutical products that require special handling
  - Order taking
  - Storage
  - Delivery
  - Goods return
- Ensure the quality of drugs along the distribution supply chain → Quality, Safety & Efficacy





# Total Drug Quality Management



## Total Drug Quality Management

### Distributor:

- Ensure product handling in receiving, storing and distributing processes comply with the standards and guidelines from the manufacturers, government and GDP/CDOB.
- Educate retailers in ensuring their product storage handling comply with standards in GSP.

# Challenges in Product Safety & Quality Throughout the Distribution Process

## Receiving

- Procurement from Manufacturer
- Transfer between warehouses
- Good returns from Retailers

## Storage

- Storage according to product's specific requirement
- Safety during storage

## Delivery

- Selling to retailers
- Transfer between warehouse
- Good returns to manufactures

- Are goods from authorized warehouse?
- Transportation safety?
- Theft / switching to counterfeits during transport?
- Manageable good returns?

- Product damaged during storage? FEFO?
- Product safety during storage?
- Theft and product switching to counterfeits?
- Illegal replication of safety seal?

- Delivery to legitimate retailers?
- Licensed retailers to sell drugs?
- Product safety during transport?
- Reasonable frequency of delivery?

# GxP ... Consistent Philosophy

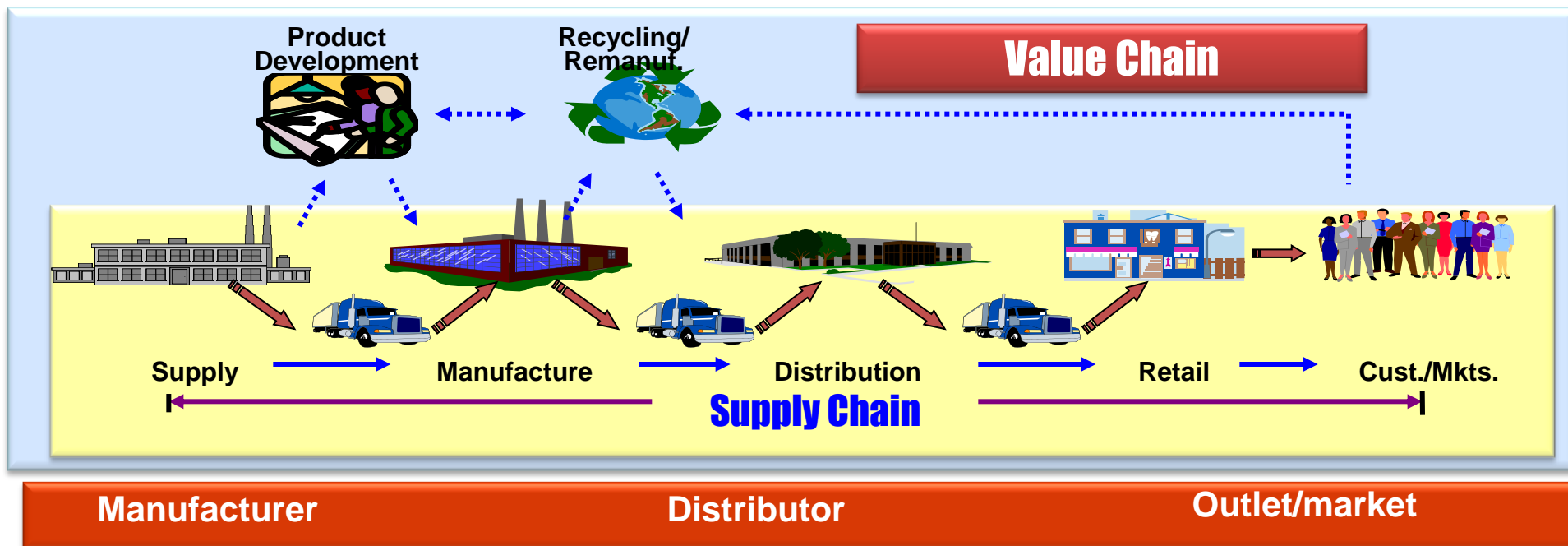


*Part of Quality Assurance which safeguards the quality of pharmaceutical products using management control:*

- **GMP (Good Manufacturing Practices):** process of manufacturing **products** from raw materials to finished goods to be consumed by patients
- **GLP (Good Laboratory Practices):** **research** activities in **laboratories**
- **GCP (Good Clinical Practices):** **Clinical Trial** activities
- **GDP (Good Distribution Practices):** activities along the **distribution processes**
- **GSP (Good Storage Practices):** **processes in storing** products
- **GTDP (Good Trade and Distribution Practices):** activities throughout the **trading and distribution processes**



# Quality Assurance Along The Supply Chain



## GMP

1. Building & Facilities
2. Process Equipment
3. Material mgt
4. Production & in process controls
5. Lab controls
6. Validation
7. Change cotrols
8. Contract manufactures
9. Agent, brokers, traders, distributorsm repackers, relabellers
10. Specific guidance fi APIs Mfg.
11. APIs for use in clinical trials

## GDP

1. Organization & mgt
2. Vehicles & equipment
3. Shipment containers & container labeling
4. Transportation & product in transit
5. Documentation
6. Repackaging & relabeling
7. Complaints
8. Counterfeit pharmaceutical product
9. Importation
10. Contract Activites
11. Self-inspection

## GSP

1. Personnel
2. Premises & fascilities
3. Storage requirement
4. Returned goods
5. Dispatch & transport
6. Product recall



# Principles of GDP

- Total monitoring and control, from order taking, transportation, products storage to sales of drugs
- Avoid from mix up, contamination and cross contamination
- Methods of storing and picking of goods in warehouse should be based on FEFO (First Expired First Out)
- Adequate and secure storage facilities and areas: space, temperature, humidity, segregation and other requirements
- Quality Management System that ensures a proper product distribution
- A system that allows for traceability
- Effective system to manage product recall
- Handling of counterfeit drugs



# CDOB = Indonesia's GDP

- CDOB = Cara Distribusi Obat yang Baik
- Areas governed by CDOB include:
  1. **Quality Management**
  2. **Organization, Management and Personnel**
  3. **Premises and equipment**
  4. **Operations**
  5. **Self Inspection**
  6. **Complaint**
  7. **Return, Suspected Counterfeit and Recall**
  8. **Transportation**
  9. **Distributor by Contract**
  10. **Documentation**
- CDOB guidelines is published by BPOM (Indonesia's FDA)
- Monitoring by BPOM is conducted by:
  - Regular Inspection (by Ditwas Distribusi, NAPZA)
  - PBF (Distributor) Mapping → CDOB standards checklist





|    | Area                                     | Description  |
|----|--|--|
| 1  | Facilities                               | Adequacy of facilities and equipment, signages, references (UU, Farmakope)   |
| 2  | Quality Management                       | Organization structure, procedures   |
| 3  | Personnel                                | Job description, qualifications, absenteeism, licensed pharmacist, staff training  |
| 4  | Building and Equipment                   | Infrastructure, cleanliness, ventilation, temperature and humidity control, pest control, storage procedures   |
| 5  | Documentation                            | IT system and manual, completeness of required documents, such as Purchase Order (SP), import documents, delivery documents (invoice)  |
| 6  | Commodity                                | Storage (procedures, FEFO, segregation , stock card), Delivery (customer list, invoice), Recall (procedure, counterfeit drugs), Returned Goods (procedure, quarantine area), returning goods to manufacturers, disposal of expired or unwanted drugs |
| 7  | Self inspection                          | Inspection team, documentation, follow ups   |
| 8  | Handling of Vaccine (CCP)                | Personnel, documents, storage facilities (cold storage room, chillers, etc), temperature monitoring, thermometer calibration, backup (generator, personnel), shipment (container, temperature monitoring during transport)                           |
| 9  | Pharmaceutical raw materials distributor | Documentation, written procedures (Protap), personnel, building and equipment  |
| 10 | Miscellaneous                            | Contingency (Disaster Recovery) plan, safeguarding against theft   |

# GDP Implementation

## CHALLENGES

- Mindset and Belief
- Lack of Knowledge
- Investment cost vs Business Scale: Size and Margin
- Manufacturer takes lead to enforce and inspect
- Reward and Punishment from Principals and Regulatory bodies

## BENEFITS

- Ethics and Compliance
- Good Control System
- Business Sustainability
- Competitive advantages and Growth potential
- People Competency
- Company Reputation



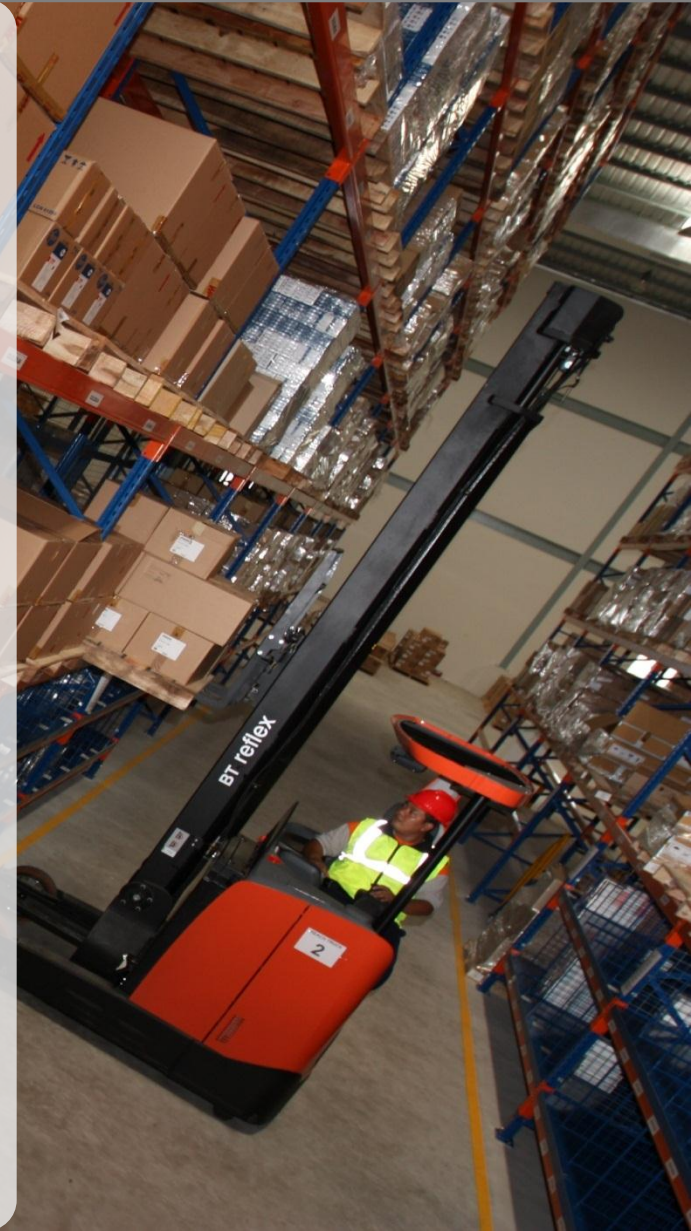
# Will GDP create Competitive Advantages?

- GDP is a belief, system and tools
- For Pharmaceutical business, GDP is mandatory – Part of Drugs Quality Management
- Business Sustainability depends on People Competency, Vision, Strategy and Execution Capability
- GDP can be a part of competitive advantages, if it is implemented as a part of Business Strategy

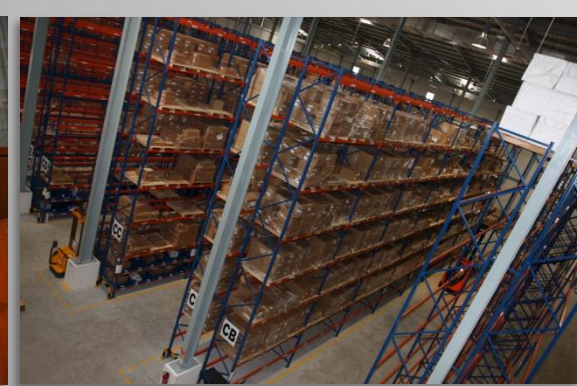


# GMP must be implemented because it addresses ...

- What business are we in?
- Organization and Business Ethics
- Control mechanism and Quality Management Systems as a part of GMP
- Infrastructure Readiness
- Leadership Value and People Competency
- Company Image and Reputation
- Customer Satisfaction







# Are You Ready for **GDP**?

Terima kasih – Thank You

