
# *How companies leverage quality and quality certifications to achieve competitive advantage*

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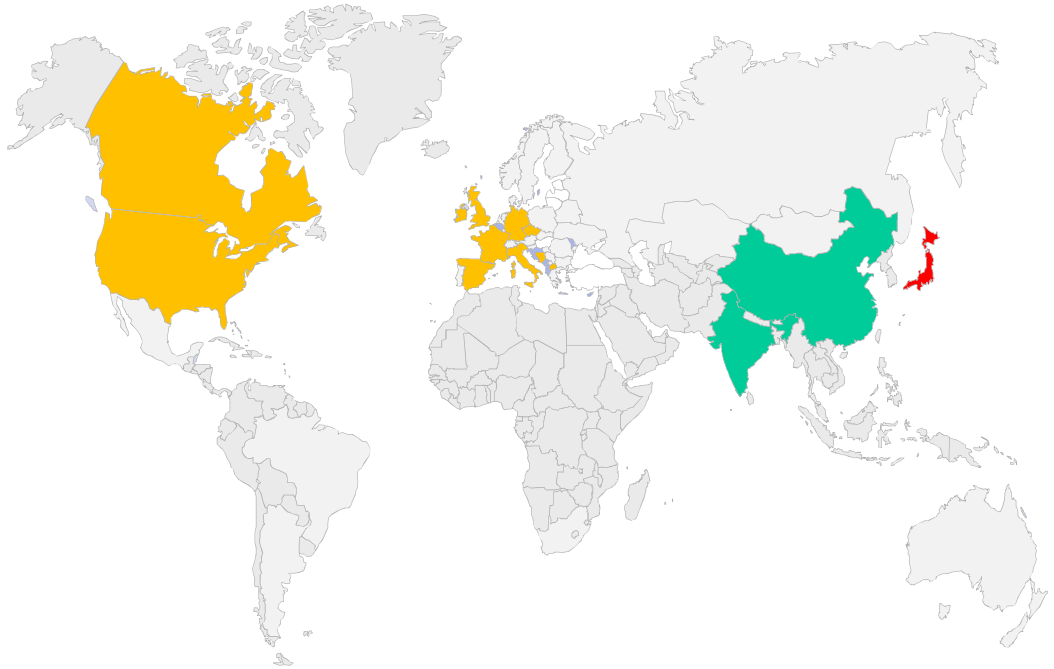
# Supply Chain for Pharmaceutical Manufacturing & Logistics

# Pharmaceutical geographies

# World Pharmaceutical market growth – focus on Asia (2009 growth)

| Asia | North America | Europe | Japan |
|---|---|---|---|
| • +15.9 % | • +5.5 % | • +4.8 % | • -1 % |



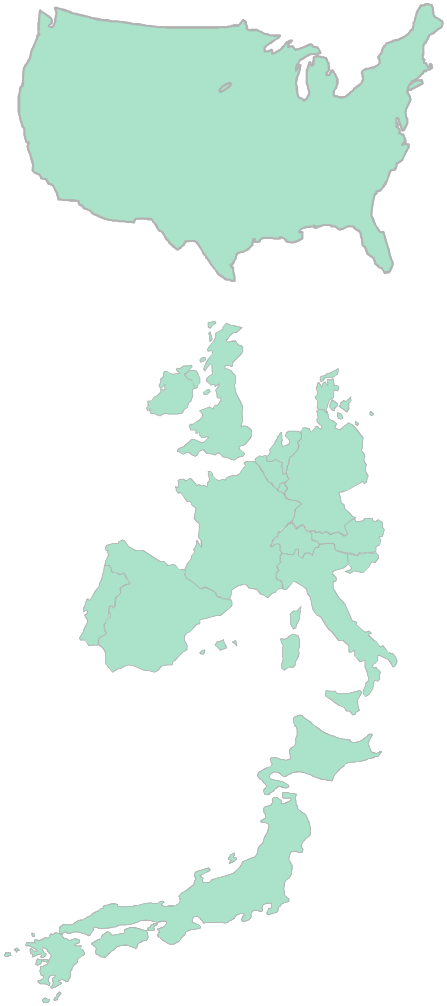
Source: IMSHealth

# The price pressure push in national healthcare

**USA**
- Generic competition
- Reduced Medicaid prices

**Europe**
- Generic competition and promotion
- Price cuts

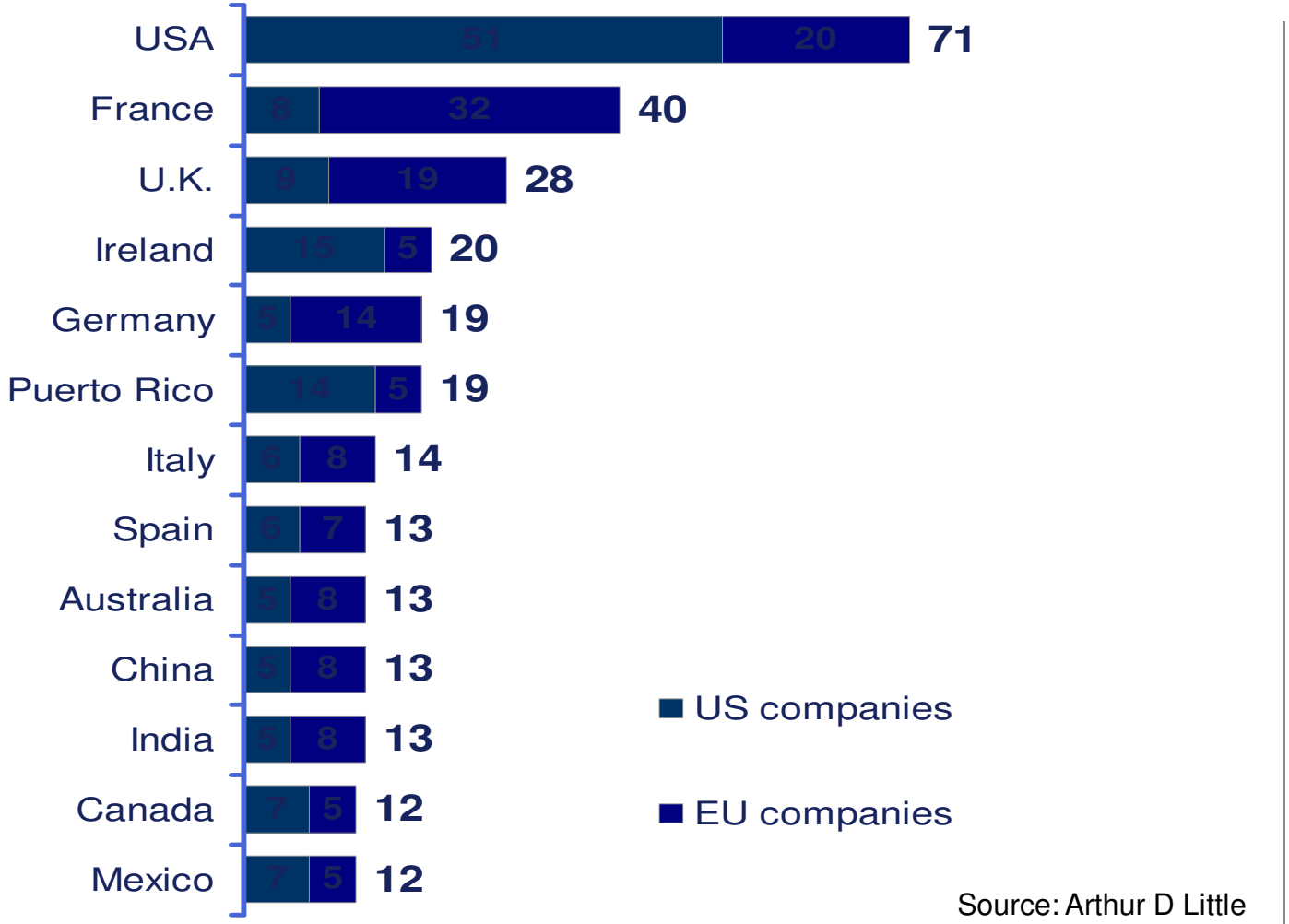
**Japan**
- Generic competition
- Incentives on prescribing generics



# Three major factors are driving the focus on Asia in the pharmaceutical industry

- Local markets in Asia becoming important for Medicines
- Price pressure in traditional markets
- Low cost manufacturing in Asian countries

# Secondary manufacturing based in home markets



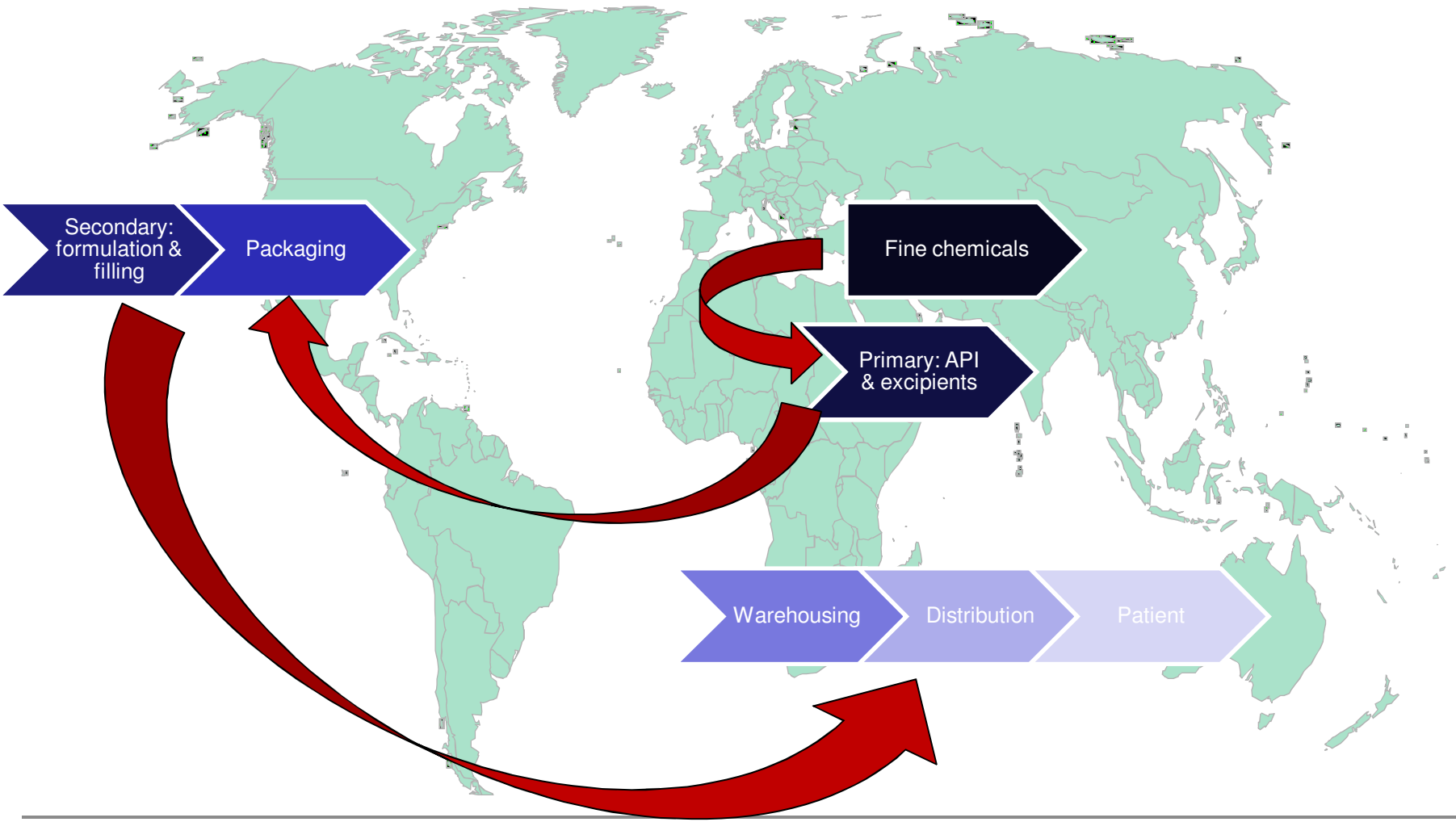

Source: Arthur D Little

# Supply Chain for Pharmaceutical Manufacturing & Logistics

Not …….


….but …..

# The actual Supply Chain for Pharmaceutical Manufacturing & Logistics is globally diverse …



# Pharmaceutical Quality issues

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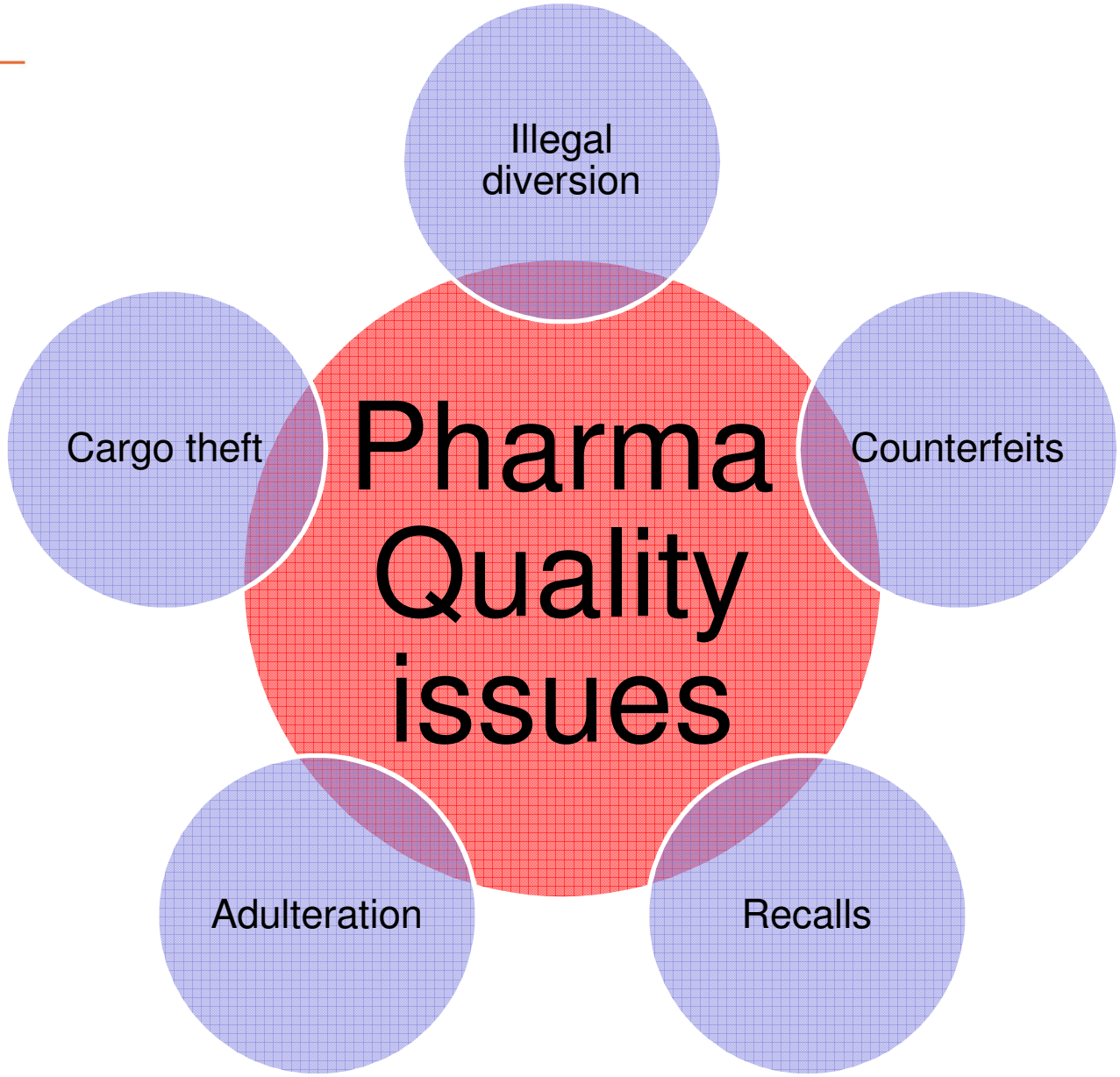
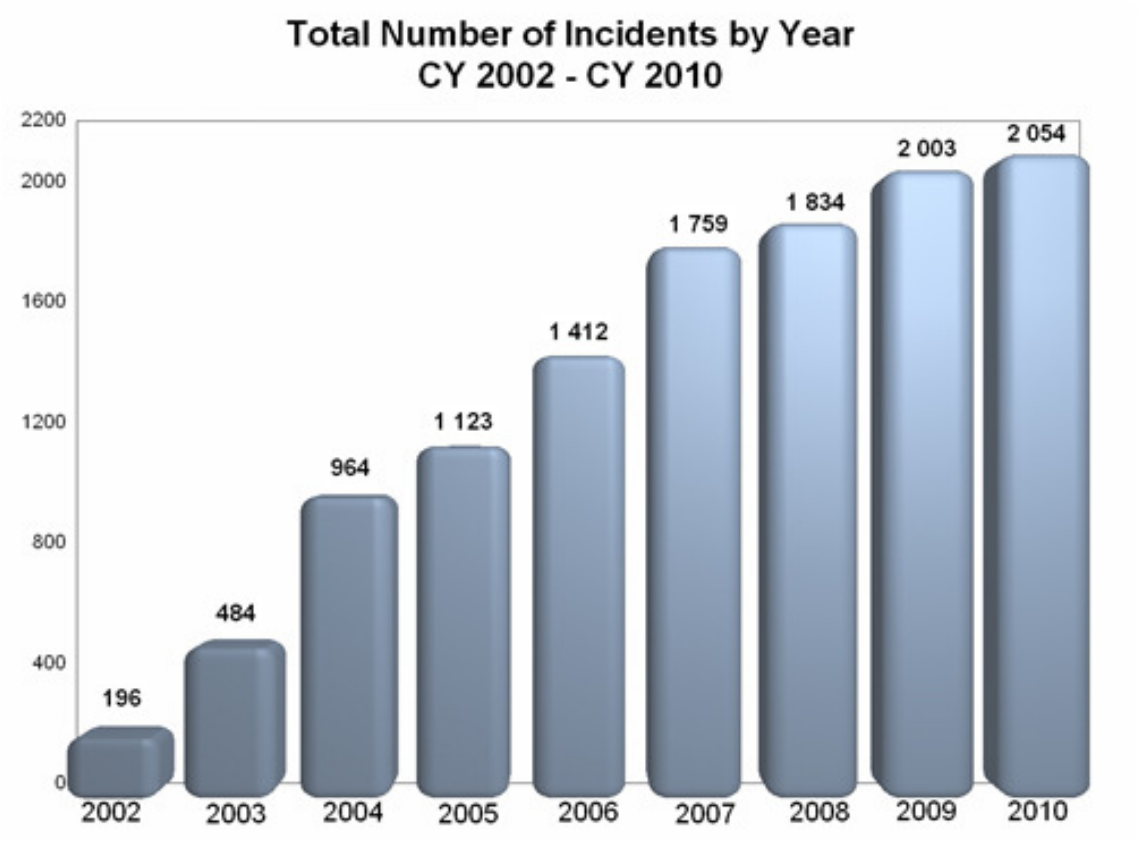
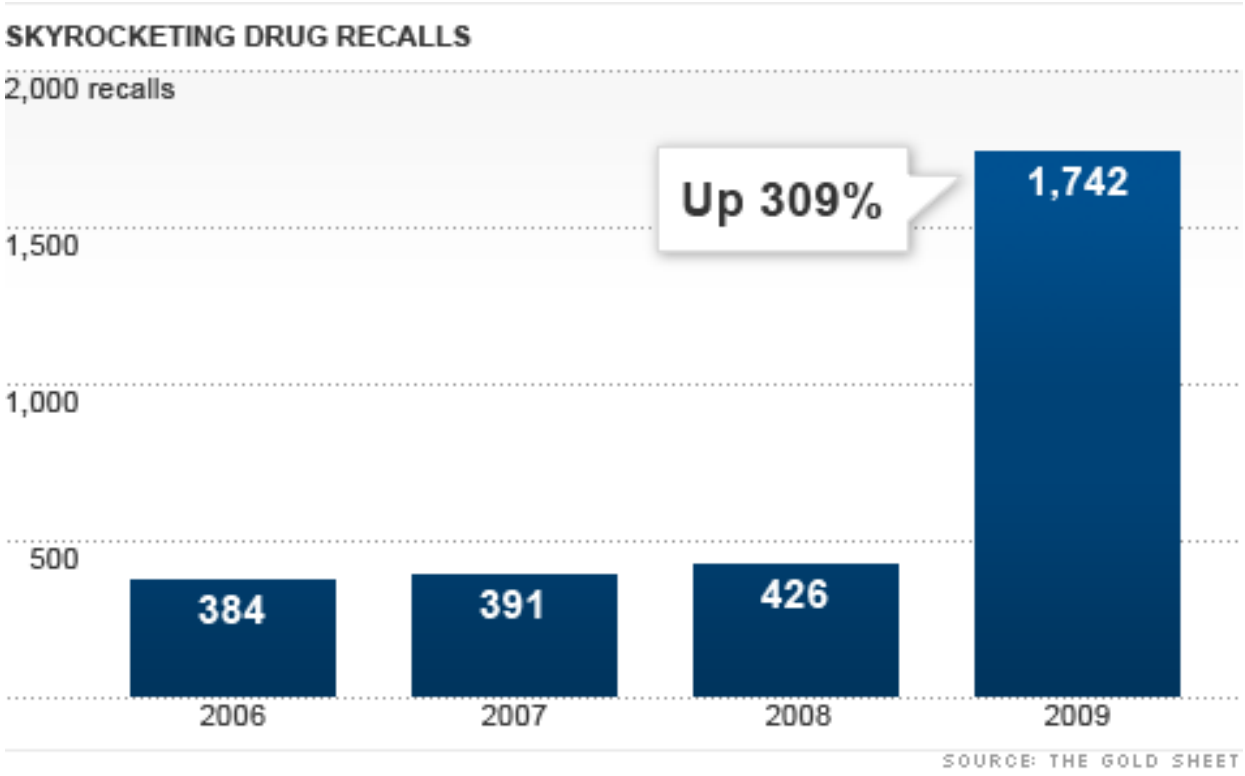

Illegal diversion
Cargo theft
Pharma Quality issues
Counterfeits
Adulteration
Recalls

# The state of the Pharmaceutical industry

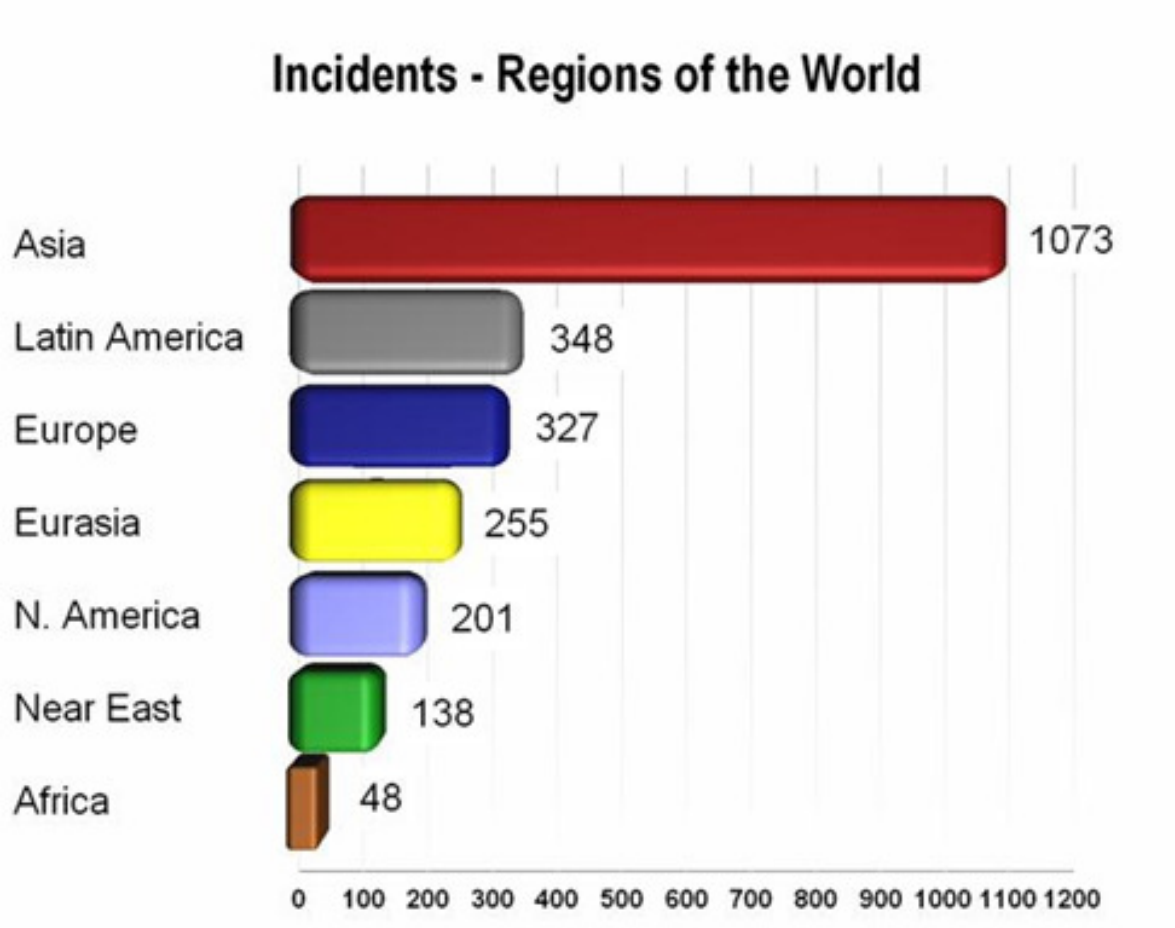



Source: Pharmaceutical Security Institute - 2011

# The state of the Pharmaceutical industry

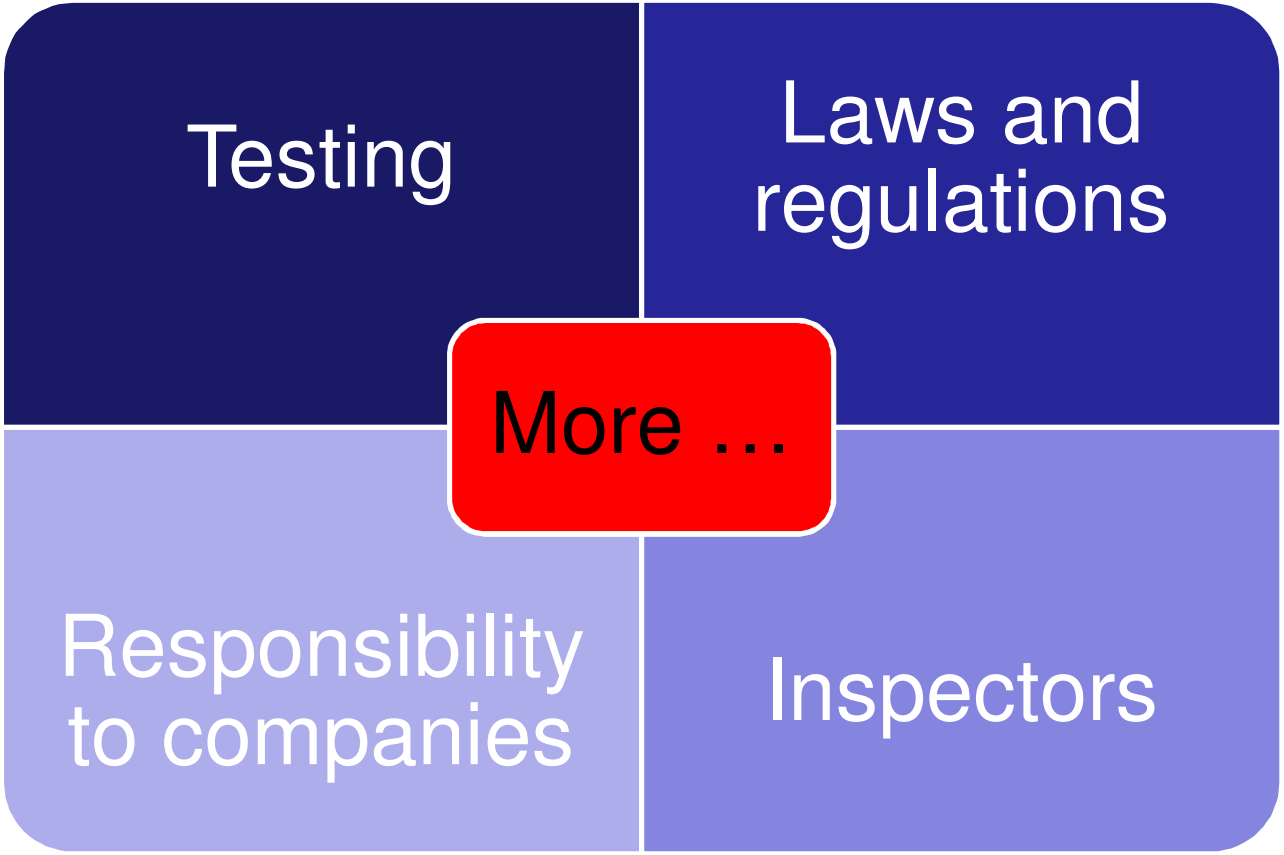


# The state of the Pharmaceutical industry




Source: Pharmaceutical Security Institute - 2011

# Regulators are responding by invoking more control



# Governmental actions:

- Amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (anti Counterfeiting).
- Revision of the EU guideline on Good Distribution Practice (GDP). The proposed guideline will replace the Guideline on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)
  - Draft to be published soon
- US FDA and EU EMA are establishing alliance
  - Joined inspections aiming to harmonize procedures
  - Drug manufacturers are being approached

# Governmental actions:

- "*Beyond our Borders Initiative*"
  - US FDA presence abroad: 13 in China and train Chinese inspectors.
  - Increasingly analyse inspection reports from foreign authorities
- "*Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century: A Risk-Based Approach*"
  - More responsibility on Drug Companies to control their suppliers and other third parties
- … and in addition: 700 extra inspectors hired for overseas inspections

# The bar is being raised … but …


Source: FDANews, june 2010

# Commitment from the industry …

## GMP for non-active ingredients – excipients

# Commitment from the industry …

## GMP for non-active ingredients – excipients


…. launch: 2011

# A Pharmaceutical GMP certification process

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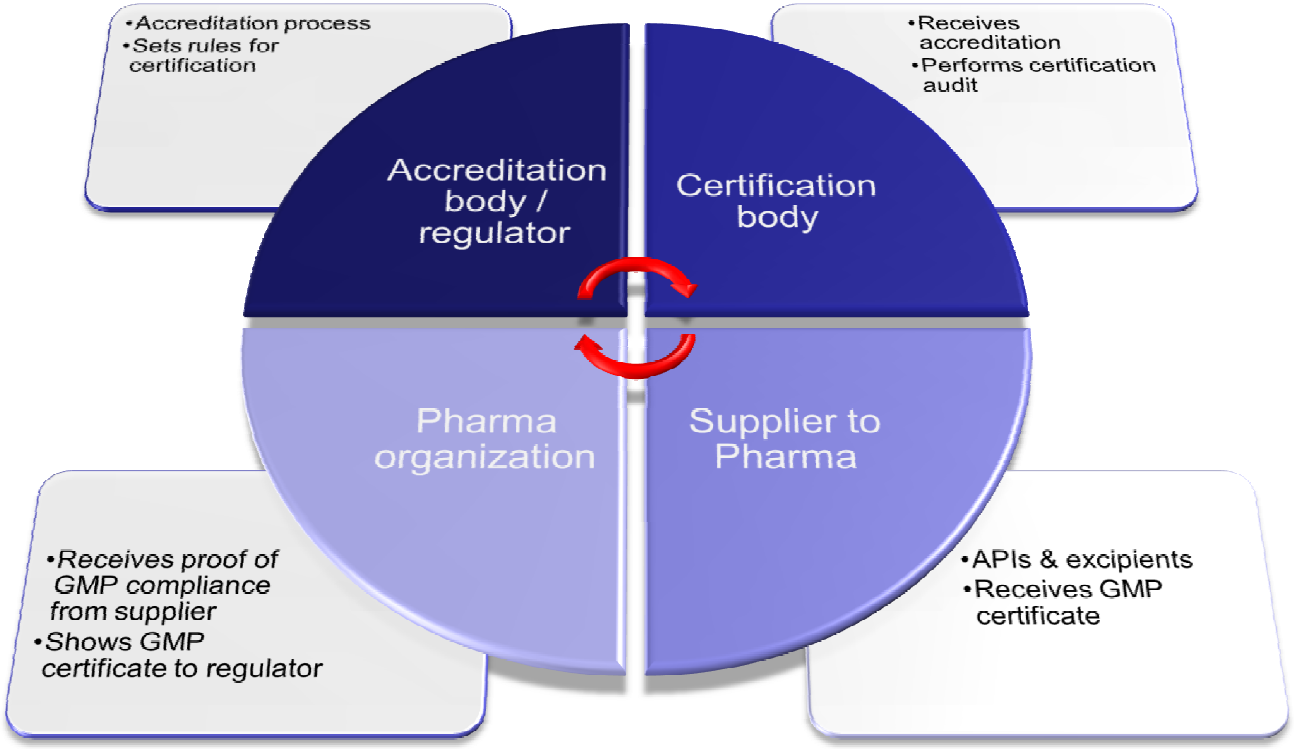
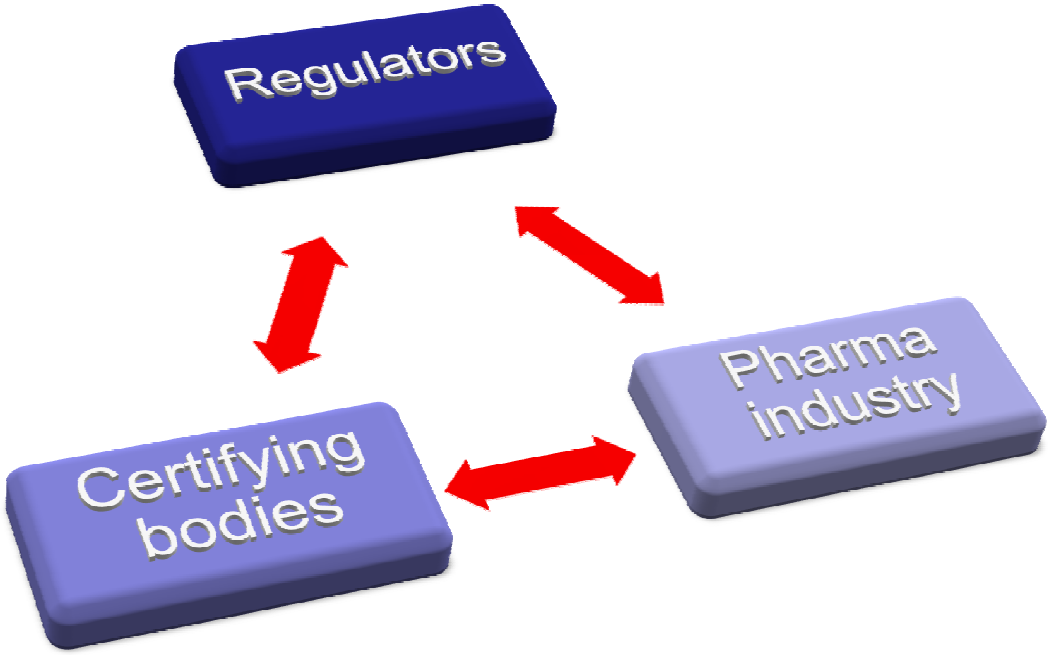
# Governmental actions:

- Amending Directive 2001/83/EC as regards GMP compliance. Holders of marketing authorizations shall verify compliance of third party manufacturers and distributors with good manufacturing practices by themselves or through a body accredited for this purpose.

# Requirements for accreditation – the certification process



# Requirements for accreditation – stakeholders that ‘own’ the scheme



# Requirements for accreditation

The Requirements for accreditation are defined in various standards

- ISO17021 and ISO Guide 65
  - For Quality Management System (QMS) and Product & Process Certification
- Scheme requirements for specific schemes
  - IPEC/PQG/FECC GMP and GDP guides for Pharmaceutical excipients (incl. auditor training)
  - APIC GMP guide for Pharmaceutical Active Ingredients.
- Requirements as set out by the European Medicines Agency (EMA)

# Key requirements for GMP certification

- Independence of the audit process from undue influence and potential conflict of interest:
  - Avoidance of risks of conflict,
  - Advisory board / impartiality committee (i.e. accreditation body, regulator, and / or Industry association as 'scheme holders').
- Deployment of competent teams
  - Auditor training and qualification is key
- Robust process to assure:
  - Business capability to fulfil requirements (resources, etc.),
  - Technical capability (auditors, decision makers),
  - Capability to assess if within scope of accreditation,
  - Mechanisms to identify non-conformities.

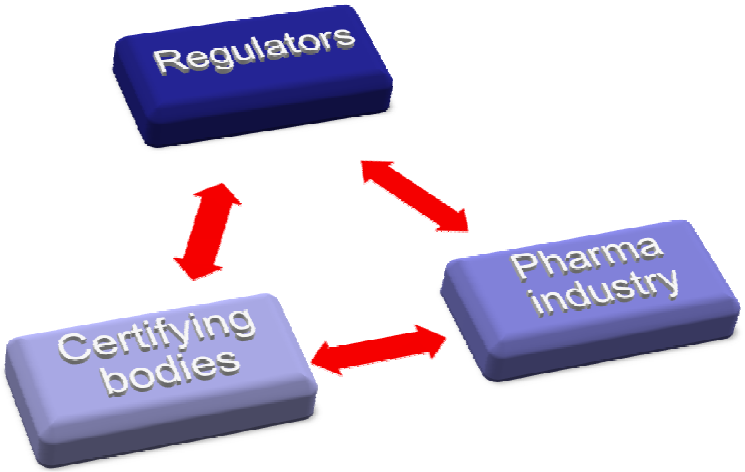
# Practical elements for GMP certification – 1 / 2

- Global system of Product Managers and Field Specialists / (lead-)auditors;
  - Define how to operate to meet accreditation requirements
  - Define how to operate to deliver consistently to Pharmaceutical organizations globally
- Global system addresses the requirements for globally or regionally harmonized certifications for Pharmaceutical GMP.
- Controlled by the global technical management team

# Practical elements for GMP certification – 2 / 2

- The global technical management team is responsible for
  - Defining and publishing the global system requirements for the certification program
  - Facilitating and supporting training and awareness
  - Monitoring alignment and compliance with the global systems and accreditation requirements as set out by the regulators and other stakeholders, through:
    - Organizing internal audits
    - Oversight of affiliate technical performance and accreditation reports
    - Ensure that auditor qualifications agreed upon are effective and performed
    - Organize external audits to the GMP certification management system

# Conclusion … three partners controlling the Pharma Supply Chain

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