# APEC-COE Pilot Training on Supply Chain Security for Medical Products

Good Distribution Practices – Current and Future

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# AGENDA

- Introduction to GDP
- Why GDP is an important topic?
- What do we know? – GDP (Malaysia)
- New trend
- Summary

# INTRODUCTION

- Distribution is an important activity in the integrated supply-chain management
- Globalisation of the pharmaceutical industry, has made individuals and organisations from locations around the world to be responsible for handling, storage and distribution of such products
- it is important to have adequate control over the entire supply chain from manufacture to delivery to the patient or end user

Source: www.npra.gov.my

# INTRODUCTION

- **Good distribution practice (GDP)** describes the **minimum standards** that a **wholesale distributor** must meet to **ensure that the quality and integrity of medicines is maintained throughout the supply chain.**
- **Good distribution practices** ensure maintaining product safety and quality during **distribution** across the supply chain and this **practice** is of **significant importance** for the pharmaceutical industry. ... Managing quality of medicines during **distribution** is a challenging operation.

# INTRODUCTION

Compliance with GDP ensures that:

- Medicines in the supply chain are authorised in accordance with (Malaysian) legislation;
- Medicines are stored in the right conditions at all times, including during transportation;
- Contamination by or of other products is avoided;
- An adequate turnover of stored medicines takes place;
- The right products reach the right addressee within a satisfactory time period.

# INTRODUCTION

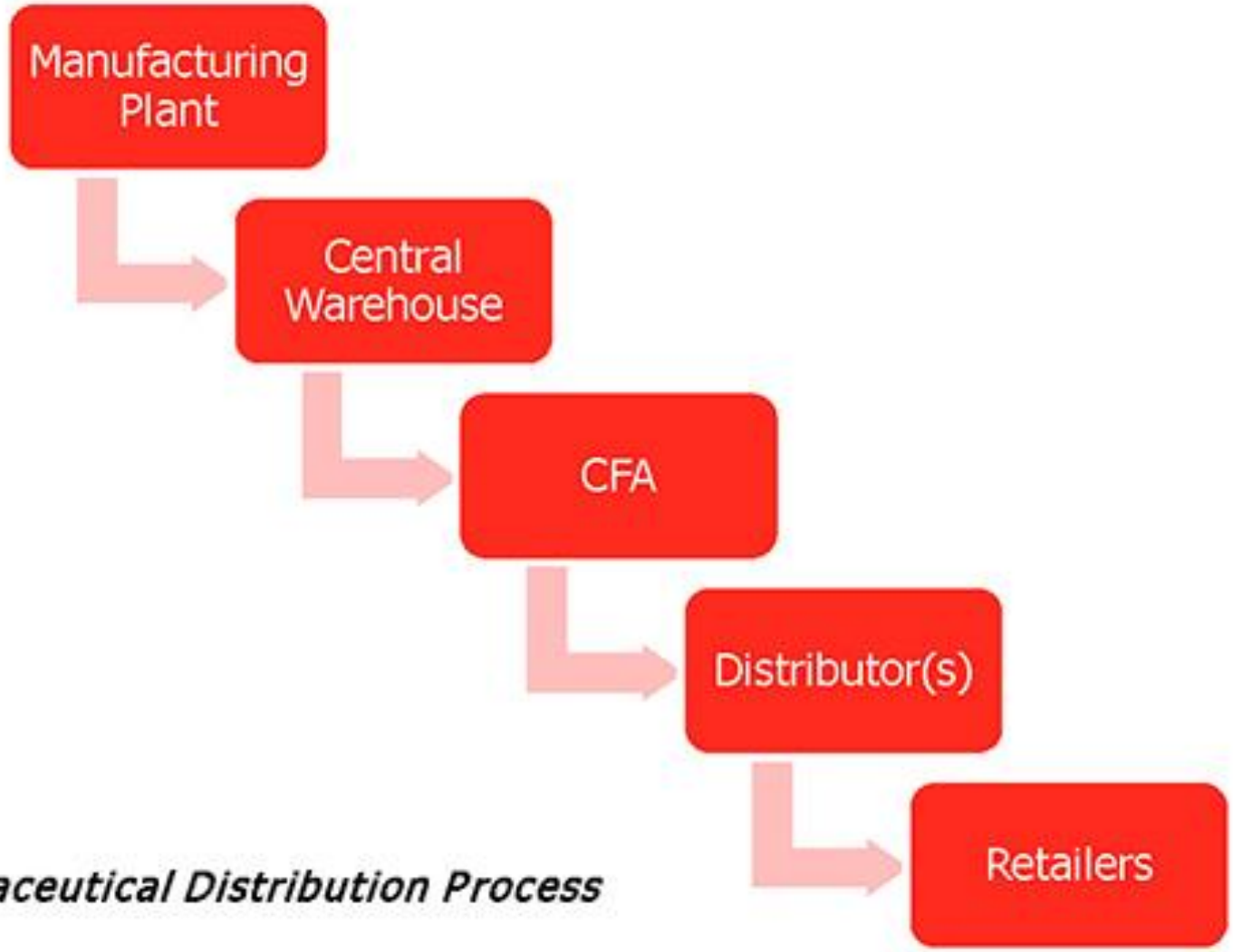
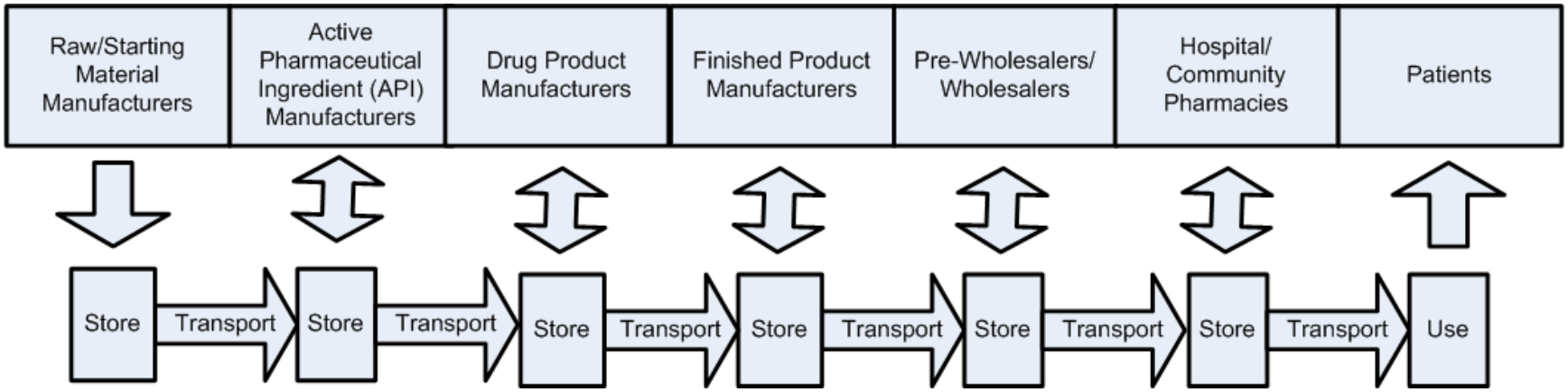



*Fig1. Pharmaceutical Distribution Process*

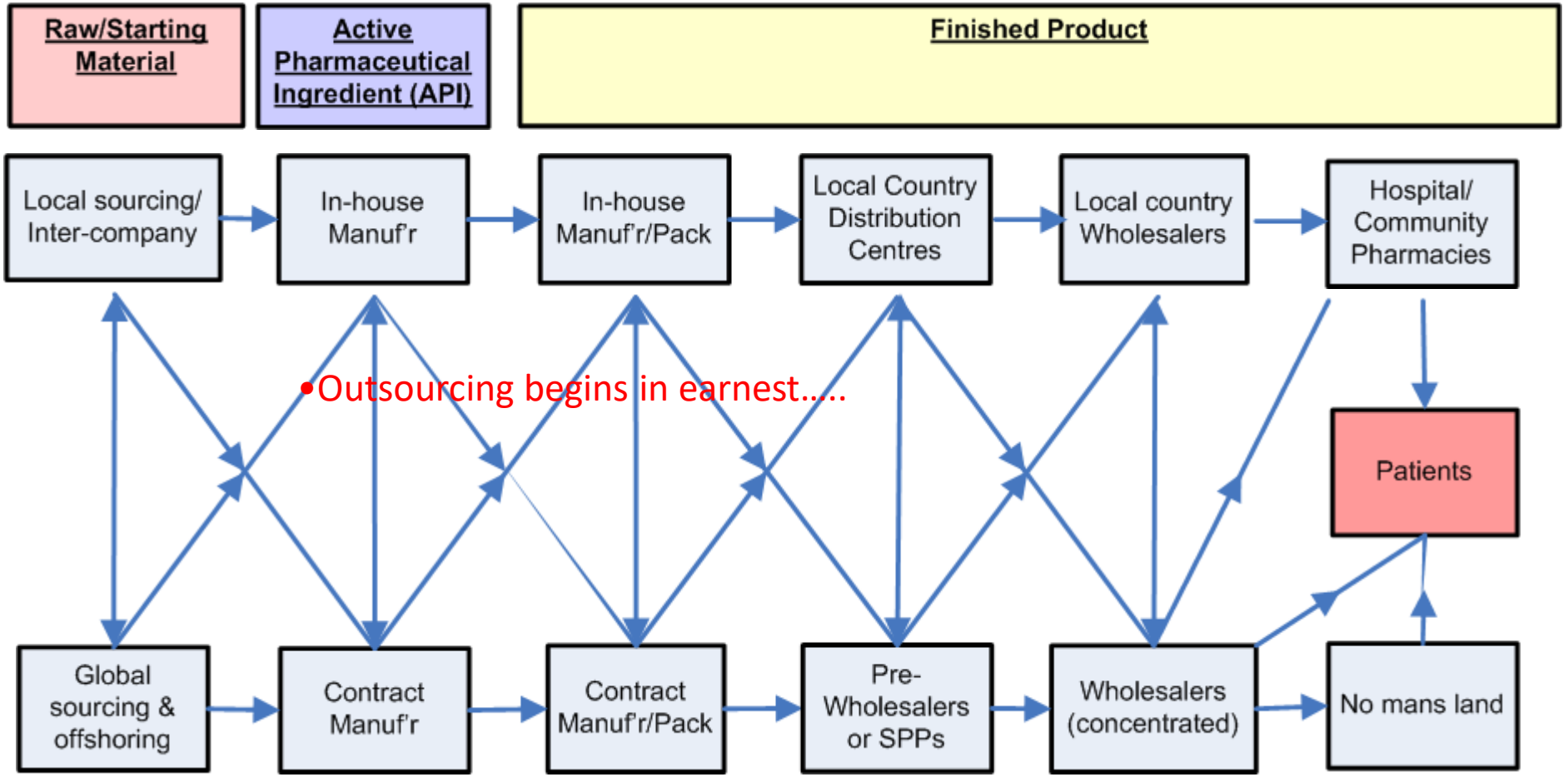
# INTRODUCTION



# Why GDP is an important topic?

- Earlier trend
  - Prevailing business model vertical integration
  - local market management presence
  - predominately small molecule manufactured by chemical synthesis
  - Outsource non-core activities
  - Manufacture, analytics, distribution, storage
- Current trend
  - New business models - innovator, virtual, biotech, generic/bio-similars and speciality Pharma
  - Biologics form important portfolio position, with temperature and time sensitivities
  - Markets have globalised into new territories
  - Number and location of third party contractors and service providers proliferate
  - Technology plays an important role – traceability, quality, communication, security….

# Why GDP is an important topic?
# Dis-integration of the supply chain



# Why GDP is an important topic? Issues related to integrity

- Economically motivated adulteration – *"Heparin, supplied by Baxter, found to be adulterated, with reports of 574 adverse events and nine patient deaths estimated*
- J&J/McNeil placed under a 'Consent Decree' after recalls associated with supply chain issues.
- Novartis shells out hundreds of millions $ in manufacturing issues
- Johnson & Johnson will have to pay the Oklahoma state $572 million for its role in fueling the opioid crisis
- One in 10 drugs sold in developing countries is fake or substandard leading to tens of thousands of death (WHO)

# Why GDP is an important topic? Issues related to Security

- *"Abbott hit by $4m diagnostics (diabetes testing equipment) theft in USA"*
- *"Eli Lilly warehouse thieves make off with $76m haul"*
- *"FDA is still concerned that the drug supply is increasingly vulnerable to diversion of legitimate drugs (ie stolen or sold illegally)"*
- Major problems for both consumers and pharma companies is the rising problem of counterfeiting and diversion of drugs
- The supply chain has been the source of several recent cyber breaches, including the well publicized incidents at Target and other retailers (Oldfield, 2014)

# Why GDP is an important topic?
# Impact

- Crippling impacts in the areas of patient safety, brand image and reputation, costs of remediation, customer service and investor confidence
- Cry for change – from regulators, governments, patient advocacy groups, and other competent authorities

# What do we know? – GDP (Malaysia)

- Quality system
  - Top management commitment, responsibilities, processes and risk management principles in relation to the activities of importation, procurement, storage, transportation and distribution of products/cosmetics
- Personnel
  - Responsible person, organization chart and training in GDP
- Premises and equipment
  - suitability and adequacy as to ensure proper loading, unloading and storage, protection from contamination and distribution of products/cosmetics

# What do we know? – GDP (Malaysia)

- Stock handling and stock control
  - receiving, stock rotation and control, returned and rejected, distribution and disposal
- Distribution
  - protect products against breakage, adulteration, theft and to ensure that temperature conditions are maintained within acceptable limits during transport

# What do we know? – GDP (Malaysia)

- Products/cosmetics complaints
  - recording and handling of complaints and returned products
- Products/cosmetics recalls
  - product recall procedure as indicated in The Control of Drugs and Cosmetics Regulations 1984
- Counterfeit products/cosmetics
  - handling of counterfeit products/cosmetics

# What do we know? – GDP (Malaysia)

- Outsourced activities
  - handling outsourced activities – contract giver and contract acceptor
- Self inspection
  - quality system must include self-inspections
  - should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures.

# What do we know? – GDP (Malaysia)

- Management of records and documentation –
  - All records are kept in accordance with legislative requirements.
  - All records must be maintained in accordance with the general requirements of GDP and other relevant guideline by the national regulatory authority.
  - Must prevent errors from verbal communication and track relevant operations during the receipt, storage and distribution of products/cosmetics.
- Source: www.npra.gov.my

# New trend

- **Big Data and Cloud Computing**
  - must be able to integrate large amounts of data from a variety of sources in real time to be able to take advantage of what these technologies have to offer.
  - Only with an integrated system can they begin to run analytics and optimize supply chains
  - Bayer AG, for example, is using predictive analysis based on analyzed sets of data regarding weather and pollen counts to help activate its supply chain when it comes to allergy season

# New trend

- **Blockchain-Enabled Control Tower for the Pharmaceutical Supply Chain**
  - Network to provide an end-to-end fulfilment backbone spanning their entire distribution process for essential medical supplies
  - Pfizer, United Heathcare, NMC Healthcare, Roche

# New trend

- **Internet of Things**
  - Making waves in nearly every industry, the interconnectivity of devices running on wi-fi and communicating with each other will be more present in the life science and pharmaceutical worlds.
  - Because of IoT devices manufacturers and medical facilities have a better understanding of pharmaceutical inventory levels.
  - Pharmaceutical companies have adopted Internet of Things technologies in manufacturing plants to improve process efficiency and optimize supply and demand.
  - IoT devices also provide real-time visibility of operations throughout the manufacturing process – from production to distribution – and they gain transparency as well as a more trackable flow of goods.

# New trend

- **Precision Medicine**
  - A promising new perspective on medicine based on genomic data aims to deliver much more personalized medical care taking as individuals genes, environment and lifestyle into account.
  - In order to make this type of medicine a reality, the data extracted from 100 million-2 billion human genomes must be handled with care
  - Life Sciences and pharmaceuticals will need a secure and reliable way to move all of these massive data sets.
  - Accelerated File Transfer protocols will be one way to handle the big data taken from genome research and use it to improve medical care

# New trend

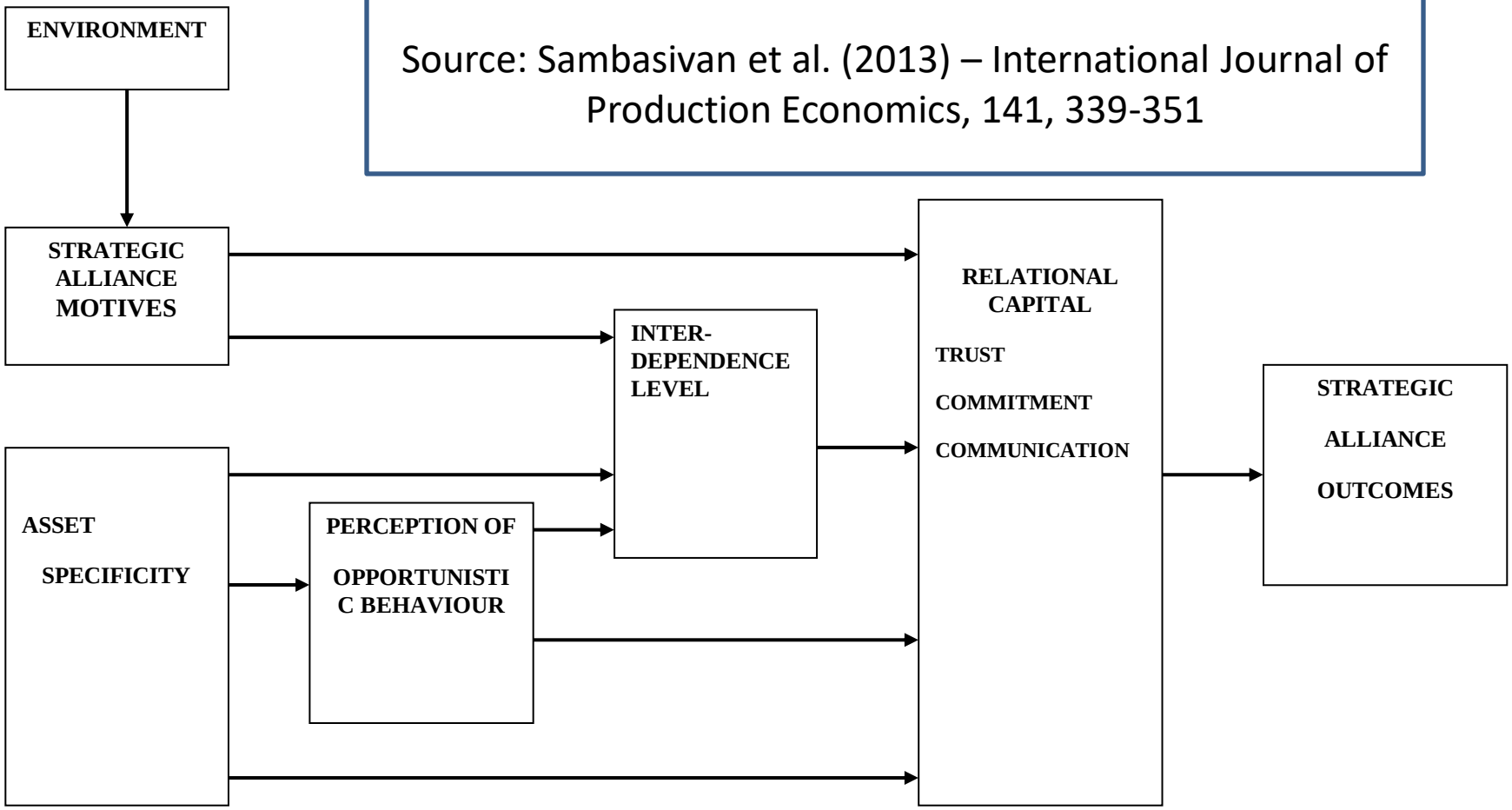
- **On-Demand Delivery**
  - Home-based healthcare has trended upward the past few years, as patients look to find more accessible, convenient ways to receive treatment.
  - Online-pharmacies, point-of-care diagnostics, and remote monitoring have already had a huge effect on healthcare delivery and are expected to increase in popularity.

# New trend

- With integrated B2B platforms, communication, security, data transfers and the supply chain can work better and stay resilient in an ever-changing digital environment.
- Taking advantage of these technological entities ensures that pharma and life sciences are able to continue to deliver the products and services that patients and customers are expecting

# New trend – Strategic alliances between supply chain partners

Source: Sambasivan et al. (2013) – International Journal of Production Economics, 141, 339-351



# New trend

- Handling counterfeit products
  - Companies including Merck KGaA and Clariant are incorporating new technologies into end-to-end anti-counterfeiting solutions with differentiating capabilities such as monitoring of high-value product flows, creation of custom-tailored data sets, and automatic reporting of counterfeiting attempts.
  - Merck KGaA’s ecosystem comprises three primary elements

# New trend

- Handling counterfeit products
  - The first element is a unique chemical marker, or taggant, that uses special nontoxic pigments to inscribe product identifiers on outer containers, primary packaging, and, in the future, pills themselves
  - The second component is hardware, in the form of handheld scanners that link information embedded in taggants to a database maintained in the cloud
  - Finally, Merck KGaA is working with an independent data administrator to create a cloud-based repository of supply chain data that allows users to track products from manufacturers through every distribution point.

# Summary – New trend

- Blockchain-enabled control tower
- Big data and cloud computing
- Precision medicine
- Internet of Things
- On-demand delivery
- Integrated B2B platforms
  - Strategic alliances between supply chain partners
- Handling counterfeit products

# Points to ponder

- Pharma industry and Universities must work closely
- More research needs to be carried out – universities must play a very active role – industry must sponsor
  - Inter-disciplinary approach is needed – Life sciences, Pharma science, IT, Business……
  - Research problems based on industry needs and challenges faced by the industry

# Thank you

Q & A