

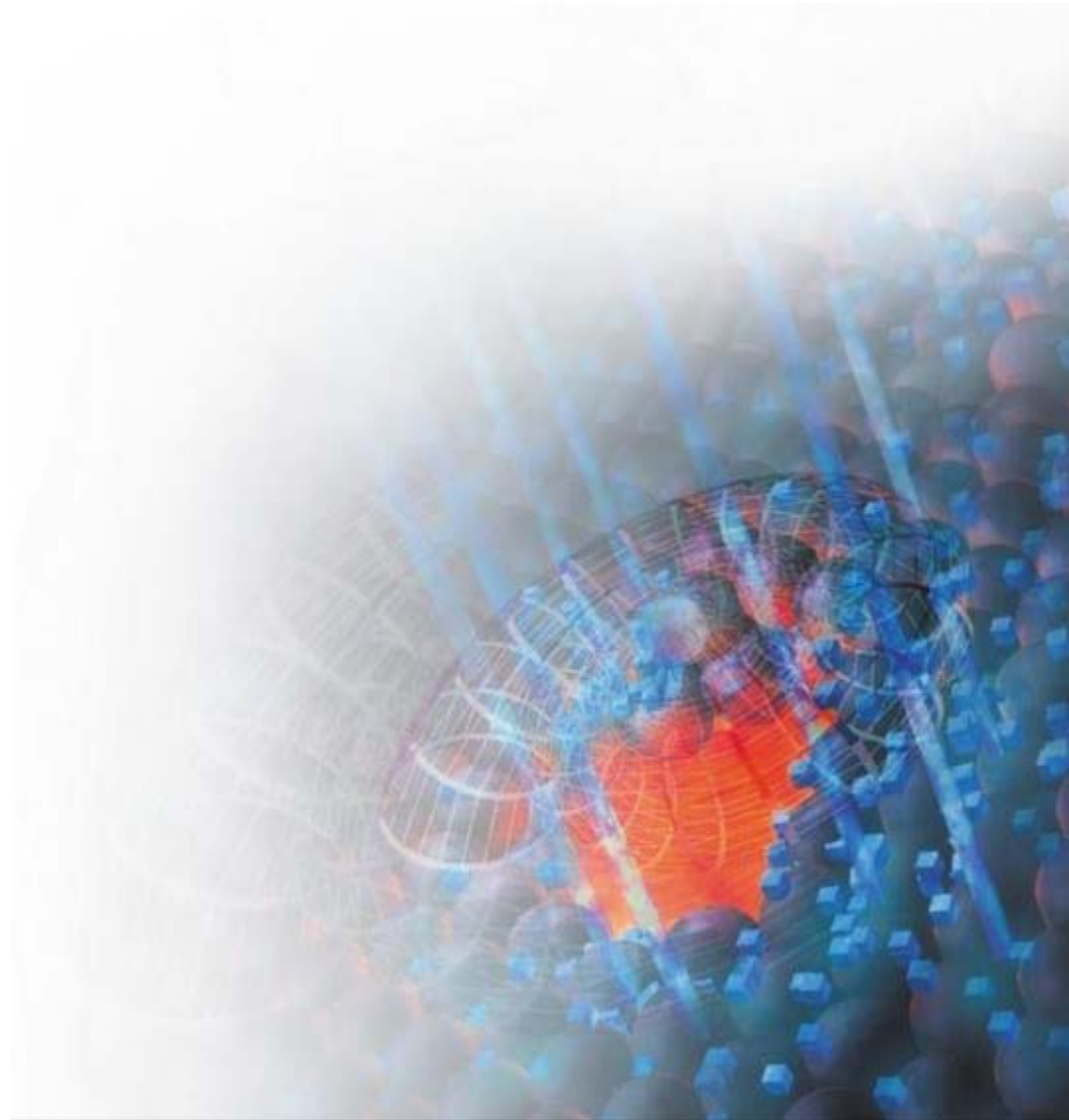
# Track & trace and anti-counterfeiting for safety-critical and high-value goods



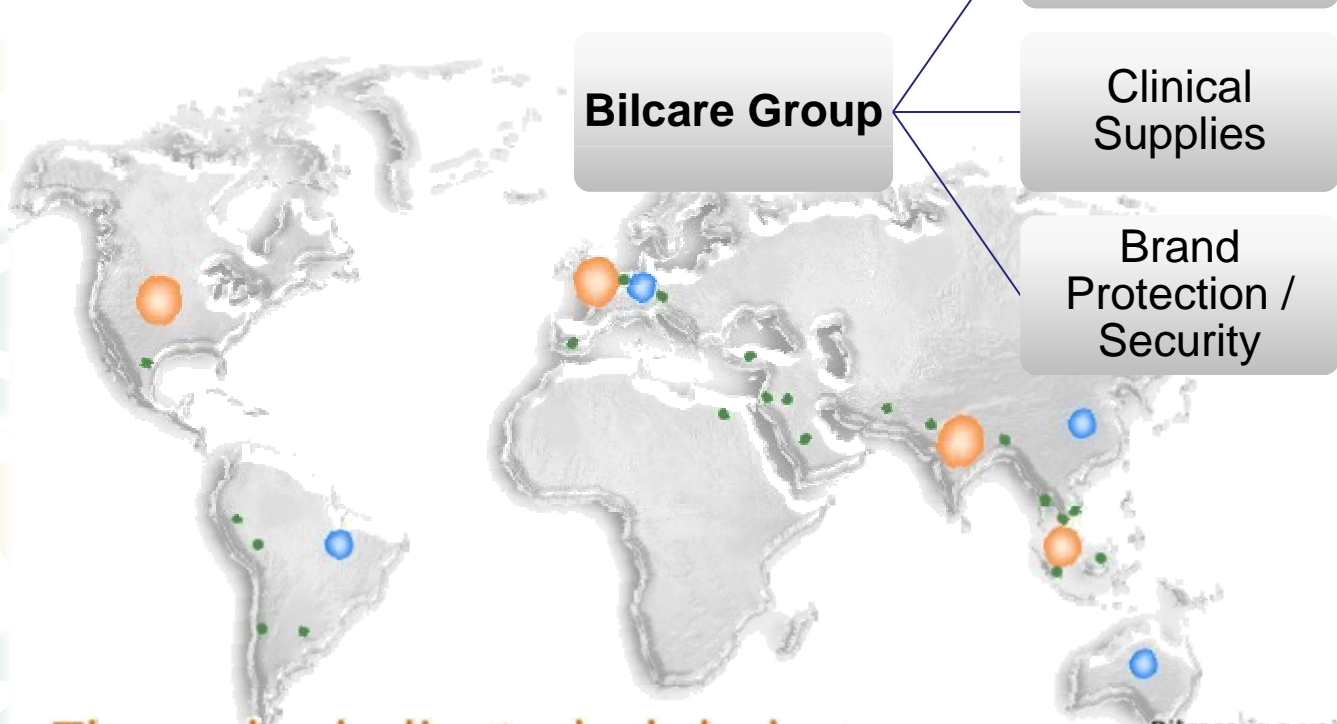
**Securing the supply chain for increased profitability**

## Overview

- Introducing Bilcare
- Securing the Supply Chain
  - Enhance traceability
  - Reduce counterfeiting
- Pharma Supply Chains
  - US
  - Europe
- Deploying Technology
- Bilcare's nonClonable™



# Bilcare



The only dedicated global company in the world focused on pharma packaging solutions facilitating life-science industry from drug discovery to market

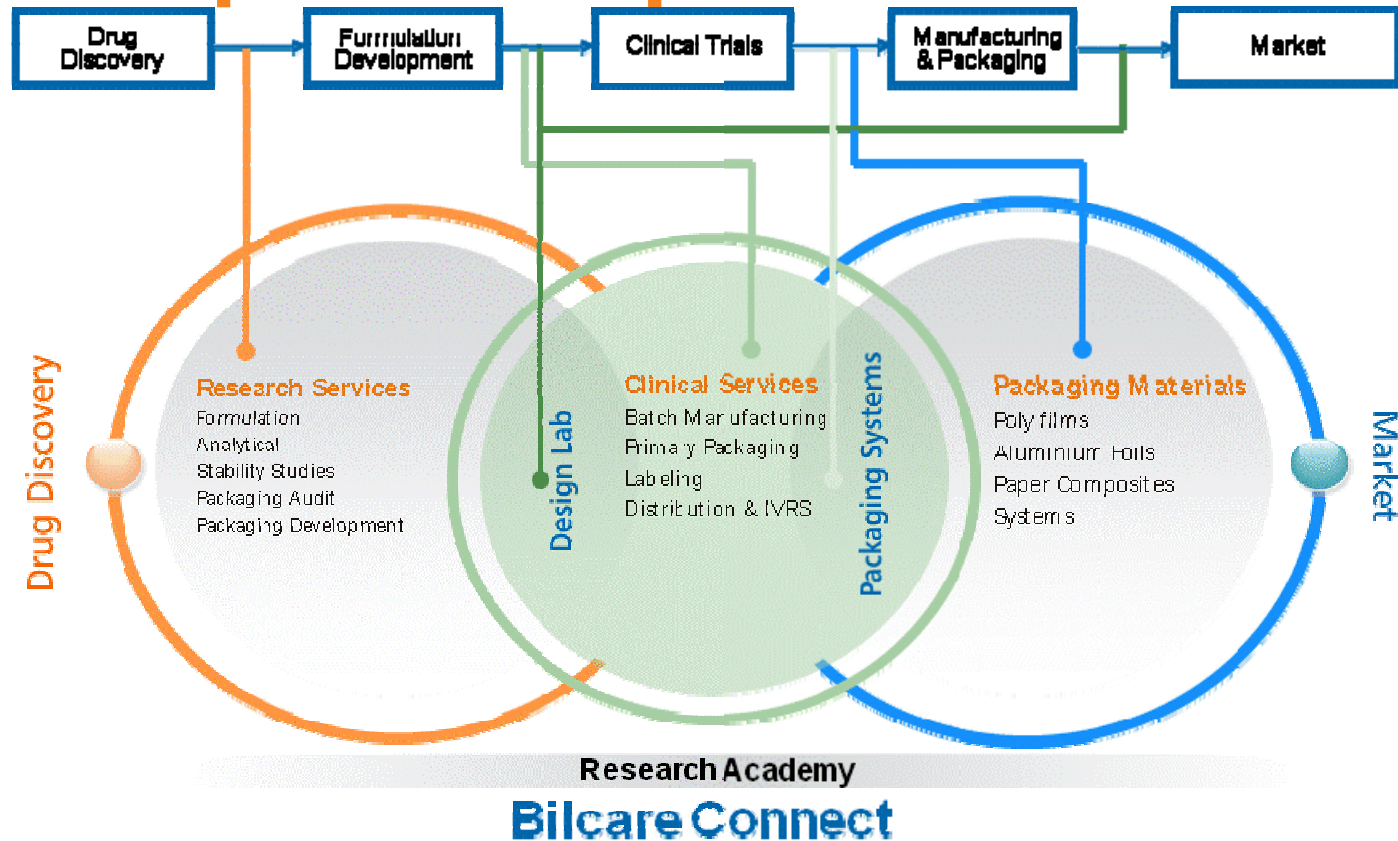
Bilcare is a unique organization with a strong research foundation and an unending quest for global leadership.

An organization integrated with global pharmaceuticals.

An organization with best in class manufacturing and research facilities spread worldwide with a focus on innovative solutions.

An organization made up of motivated people who go that extra mile to spread excellence and joy.

# Bilcare spans the pharma value chain



New medicines are expensive to develop. Once commercialized brand owners need:

- Functional packaging for the environment, security, and the brand message
- Secure supply chain to the patient

## Facts

**Counterfeiting costs the global automotive parts industry \$12 billion a year.**

- Federal Trade Commission (FTC)

**It is estimated that more than 10% of the global medicines market is accounted for by counterfeit drugs.**

- World Health Organization (WHO)

**Revenue loss to U.S. trademark holders is \$200 billion per year.**

- International Anti-counterfeiting Coalition (IACC)

**7% of the world trade is in counterfeit goods and the counterfeit market is worth \$350 billion.**

- International Chamber of Commerce (ICC)



This implies that existing supply chains are inherently unsecure

# Recent Headlines

**More counterfeit drugs seen around the globe**  
Reuters – 19<sup>th</sup> May 2010

“Fake or substandard versions of medicines are often hidden in cargos taking circuitous routes to mask their country of origin as part of criminal activity worth billions...”

**Christie’s Sold Counterfeit Wine, Collector Koch Says in Suit**  
Bloomberg – 31<sup>st</sup> March 2010

“Because Christie’s has inspected so many wine cellars and has examined so many bottles of wine, it knows how to identify counterfeit wine...”

**NASA Blames Counterfeit Parts For Some Cost Overruns**  
NASA – 9<sup>th</sup> March 2009

“Foreign manufacturers and counterfeiters make bogus equipment that has ended up in NASA's supply chain... The phony parts usually carry authentic-looking logos and manufacturer markings, and are sold at premium prices.”

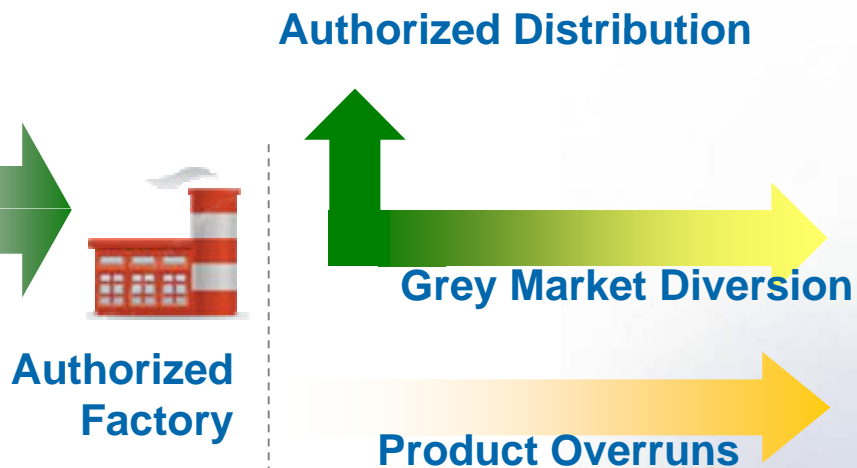


Read more at [www.notofakes.com](http://www.notofakes.com)

# Counterfeits in an Unsecure Supply Chain

**Brand Owner**

- R&D
- Quality
- Testing



## Impact on Brand Owner

- Lower margins
- Unforeseen liabilities
- Distribution license issues

- Lost revenues
- Over supply
- Increased warranty claims

- Lost revenues
- Over supply
- Increased warranty claims



## Brand Security Strategy

- Need a holistic multilayer approach
  - Identification – track & trace system
  - Overt – customer discernable solution
  - Covert – product authentication solution
  - Forensic – fail-safe lab-based authentication
- Real-time data visibility
- Secure complete supply-chain...





# Technology Options

## Product Identification

### Supply Chain Traceability

001 234 567 688  
645 455 467 323  
112 342 478 886  
113 342 887 674

**Serial Numbers**



**RFID & Chip**



**Barcodes**



**DataMatrix**


## Product Security

### Supply Chain Security


**Holograms**



**Patina/Protect/Venus**



**Covert Ink**



**"Fingerprint"**



# Limitations of Current Technology

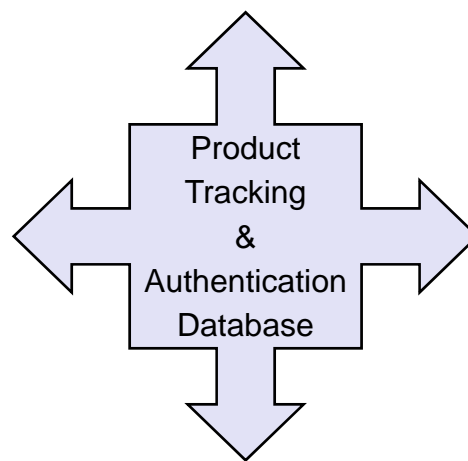
	Technology	Format	Limitations
SUPPLY CHAIN	Bar Codes	Tags & reader	Track and Trace solution Can be copied
	Serial Identification	Inscription/ motif & reader	Optical markings can be copied Central database often used
	RFID	Chip & reader	Privacy concerns High item-level cost
SECURITY	Holograms / opticals	Label	Relies on consumer knowledge Can be easily copied
	Inks and synthetic markers	Ink & reader	Covert tracking Cartons may not be retained

**Current technology does not provide an absolute solution**

# Supply Chain Management

- Chain of custody

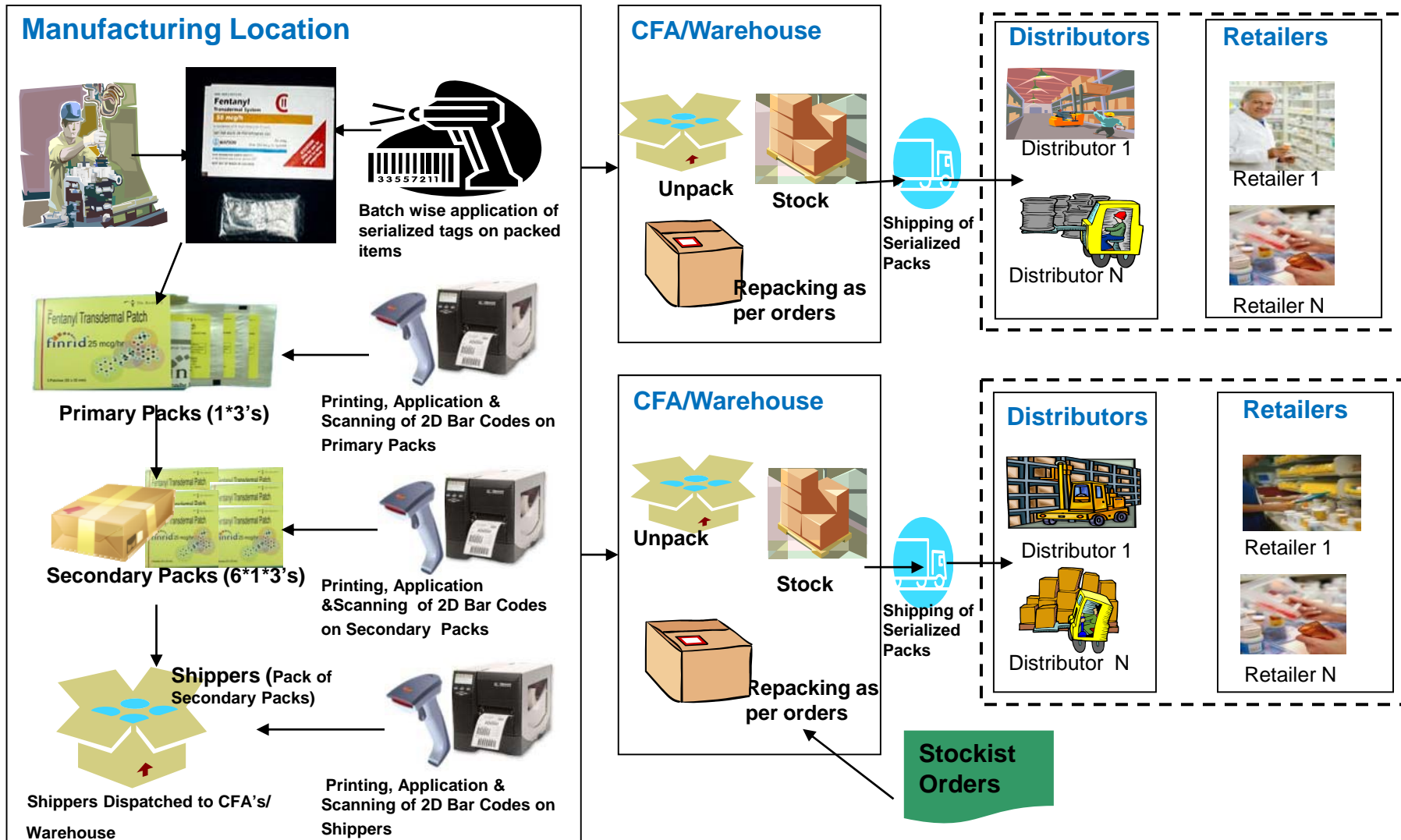
- unique number or identification code to each packaging unit.



- Verifies the product's credentials – source, route and ownership

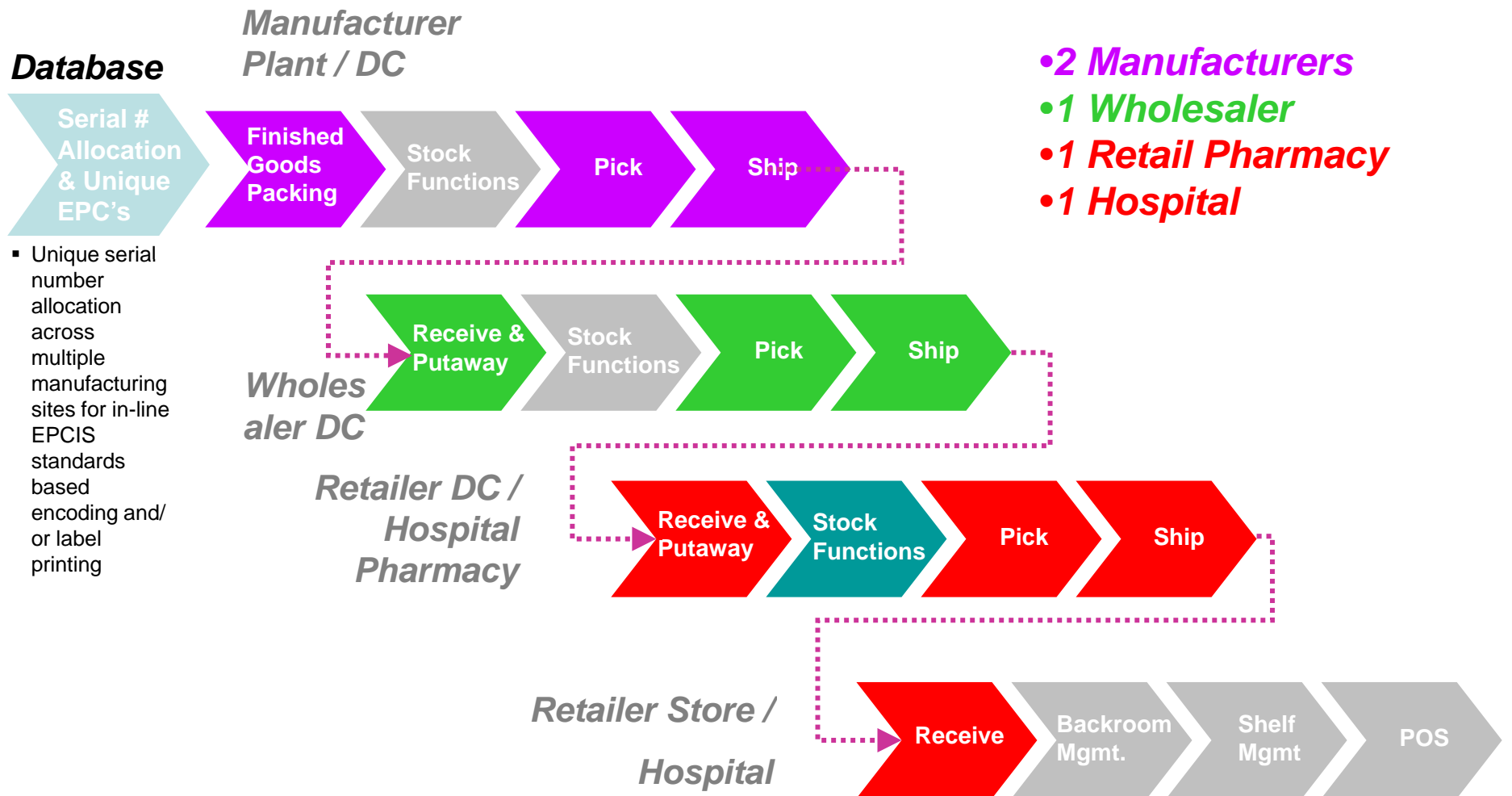
- Security to prevent tampering and replacement

# Items and batches



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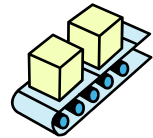
# Supply Chain Events



# Database Capability

**What**

**Manufacturing Data**  
e.g.: Lot/Batch, Expiration Date

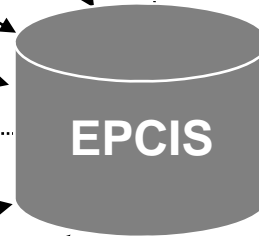


**Location Master Data**



**Where**

**Transactional Data**  
e.g.: PO, Invoice, Point of Sale

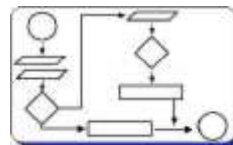


Electronic Product Code  
Information Services

**Product State**  
e.g.: Saleable, Inactive



**Business Process Step**  
e.g.: Receipt, Ship



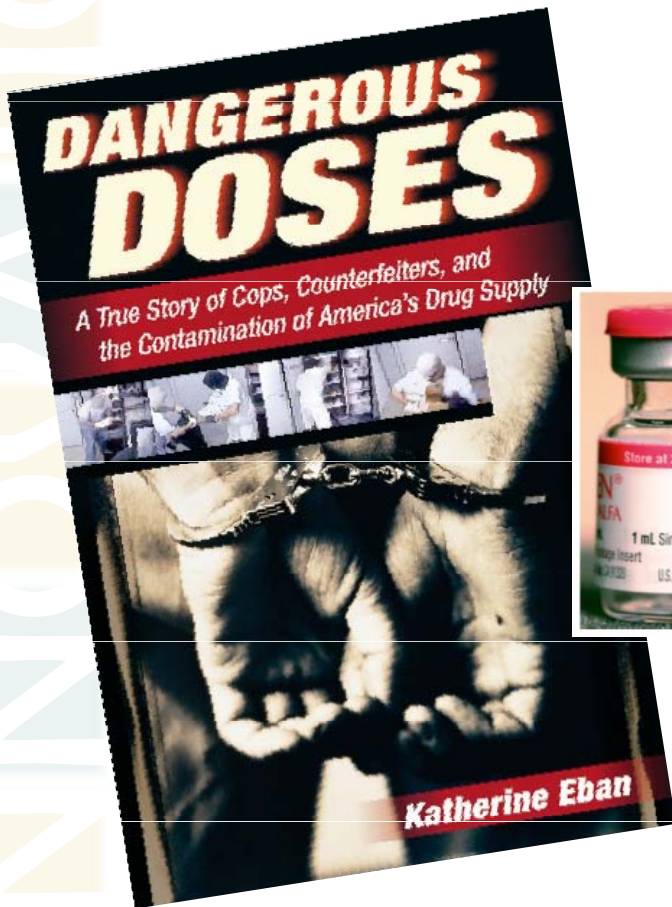
**Timestamp**



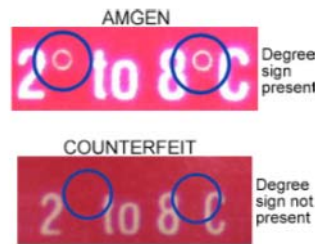
**Why**

**When**

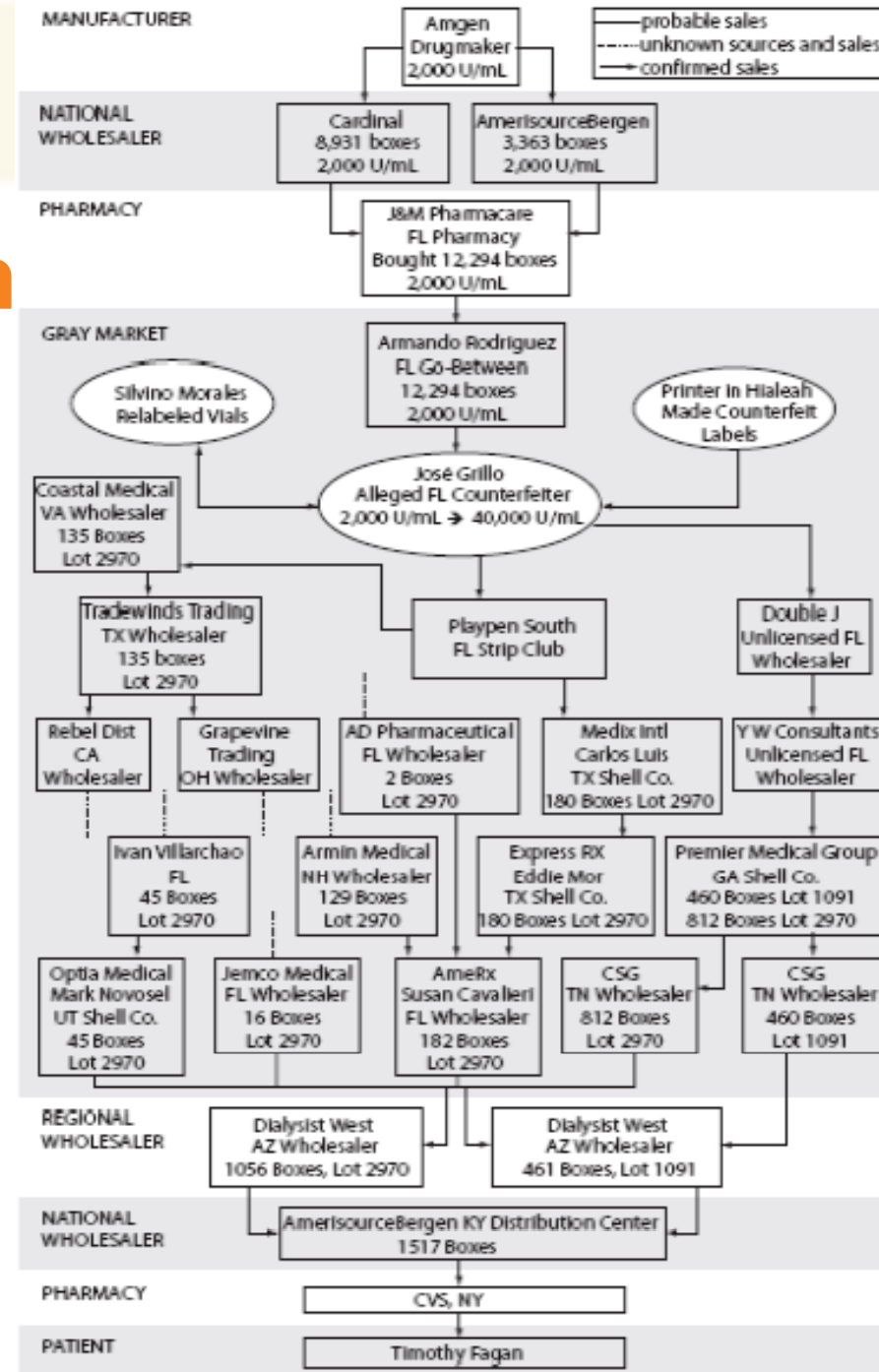
# US Pharma Supply Chain



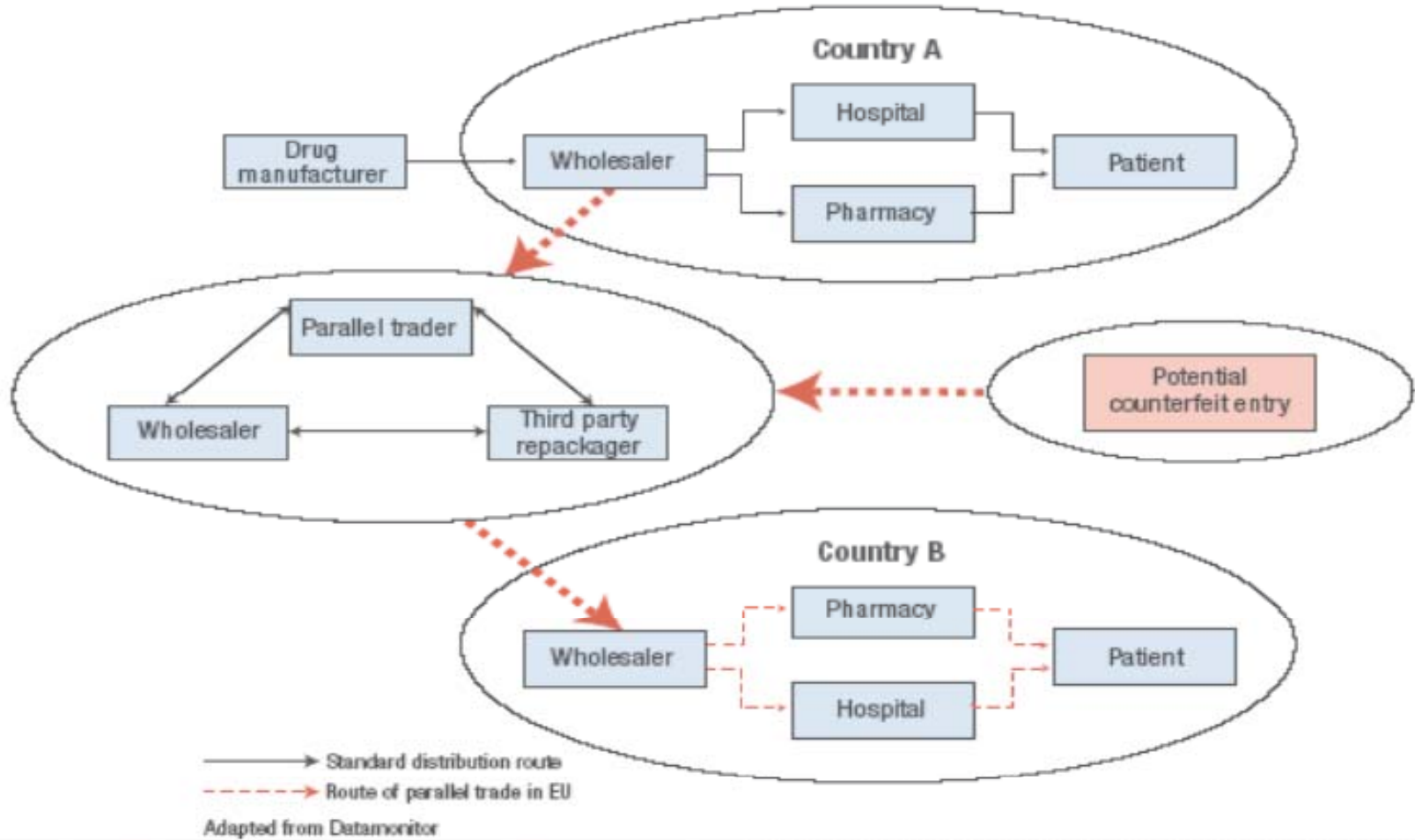
Location of storage temperature



Timothy Fagan  
Counterfeit Epogen



# European Pharma Supply Chain



From presentation by J. Harper



# Pharma in the EU: DataMatrix vs. RFID

Source: EFPIA, February 2008

	DATA MATRIX ECC200	RFID
Ability to read at distance / No direct line of sight required?	✗	✓
Difficulty to modify / alter / copy?	✗	✓
Readability robustness? Efficiency of reading rates?	✓	✗
Business processes changes? High speed and volumes?	✓	✗
Compatibility with Biologics (vaccines, biotech products)	✓	✗
Volume of data to manage? Network complexity (EPC Global) - Harmonized Standards (EU / US / Asia)?	✓	✗
Privacy issues / objections / public concerns?	✓	✗
RFID Tag cost ~ 20 to 40 cents € Data Matrix cost ~ 0.1 to 0.3 cents €	✓	✗

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# Pharma in the EU: EFPIA's Recommendations


Data Matrix – Coding proposal derived from GS1 standards  
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN/EAN14 or pseudo-GTIN]  
Unique Serial Number (randomized)  
Expiry Date  
Batch Number

14 digits  
up to 20 alpha-numeric characters  
6 digits (YYMMDD)  
up to 20 alpha-numeric characters

**+ minimum requirements on quality of randomisation !**

Example:

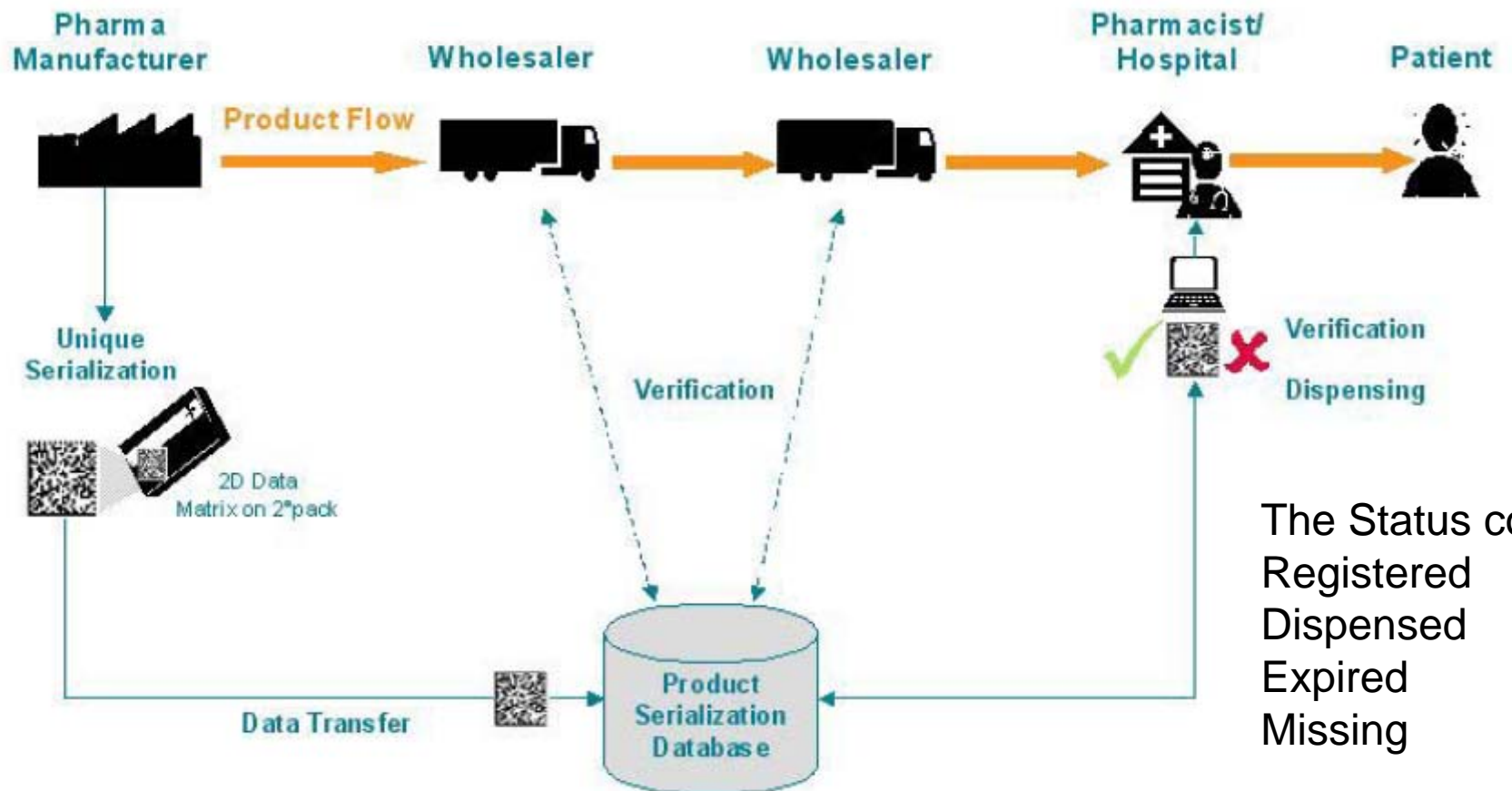
<b>GTIN:</b>	(01) 09876543210982	
<b>Batch:</b>	(10)A1C2E3G4I5	
<b>Expiry:</b>	(17)110531	
<b>S/N:</b>	(21)12345AZRQF1234567890	

<i>Evolution of french national code (pseudo-GTIN)</i>	
CIP 7:	3597441
CIP 13:	3400935974419
<b>PseudoGTIN pack:</b>	<b>03400935974419</b>



# Pharma in the EU: Approach

- Not e-Pedigree, but start and end-point verification



Extract from an EFPIA presentation / publication

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# Bilcare's nonClonable™ Solution

## Track & Trace *and* Authentication



+

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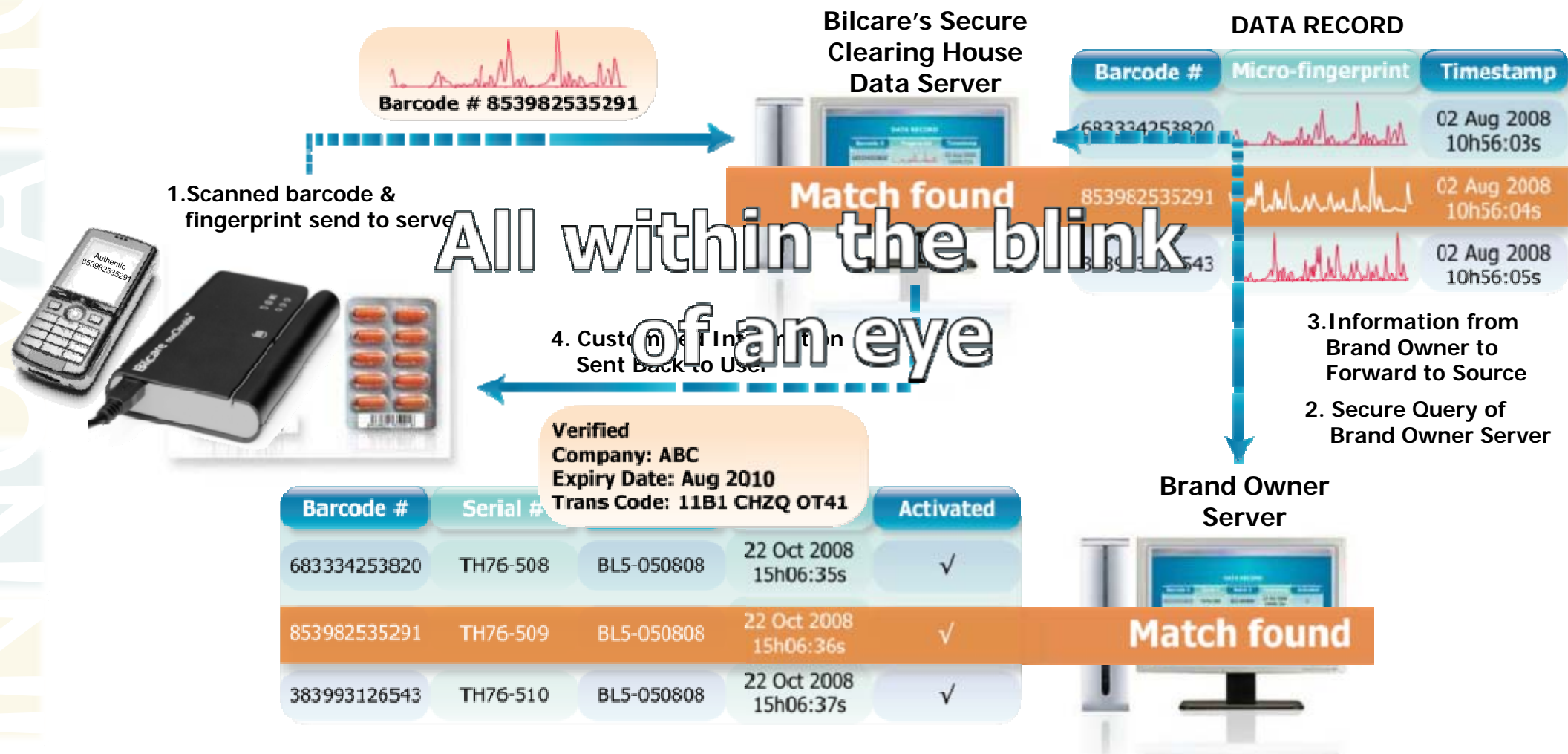
Unique and secure



# Leveraging a Remote Database

- Authentication against original signal stored in the database
- The reading can be done virtually anywhere in the world by communicating back to remote database using mobile phone / PC
- Different scanners can have different data access privileges
- Event tracking and tracing
- Unlike conventional systems, the data base allows scanners and labels to be deactivated if they are stolen or lost

# Bilcare nonClonable™ in Operation



## Key Advantages

- Secure supply-chain management
  - provides vital primary sales data
  - tracks movement of stock at each level
  - alerts date expiration / warranty issues
  - identifies parallel importation
  - provides customer relationship management
- Secure, non-reproducible, tamper-resistant **anti-counterfeiting solution**
- Applicable to many product formats and can be tailored for specific applications



# Item-level Supply Chain Management

- Need to cope with a wide variety of product formats



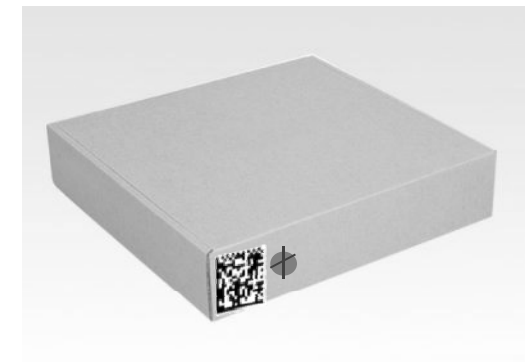
Blister-pack  
label



Carton / packaging  
label



Closure  
label



Direct print  
compatibility



Hangtag



Loyalty /  
warranty  
card



Garment label for  
apparel and  
handbags



Compact tag for  
watches and  
jewelry



Future – secure  
RFID for logistics



# Verification and Authentication

- Serial number can be read and processed by standard barcode scanner
  - ideal for verification in supply chain and in low risk outlets
- nonClonable authentication with Bilcare's scanners
  - added security for inspectors in the field, at customs, or at the point of sale
  - Bilcare's Touch scanner can also be used as a 2D barcode scanner for sales process



Industry standard barcode scanner  
for verifying tags and labels



nonClonable™ Swipe reader  
for authenticating blister packs



nonClonable™ Touch reader  
for verifying and authenticating  
barcodes and nonClonable™ labels

# Rolling-out a Secure Supply Chain

Production



Warehouse management



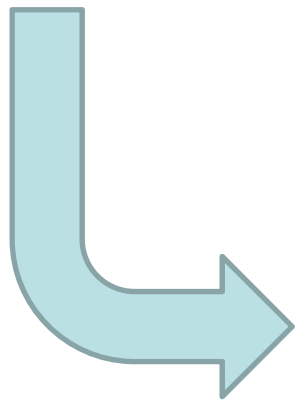
Distribution management



Customs & excise



Pharmacy / Clinic



Product data upload



Supply chain management



Patient

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# Summary

## Integration

- Overarching brand security
- Sales, returns & warranty management
- Business and consumer compliance
- Secure inventory and supply chain management

## Connectivity

- Brand owners, suppliers, distributors and end users
- Real-time exchange of appropriate information

## Unique Technology

- State-of-the-art and highly secure
- Tailored for specific applications
- Turn-key products & services

