Connecting People, Science and Regulation

Leveraging Serialization into Supply Chain Security and Visibility

Lessons Learned & Outlook

PDA Berlin, October 14, 2014

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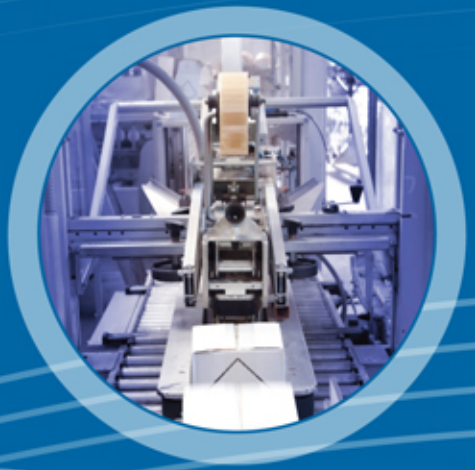


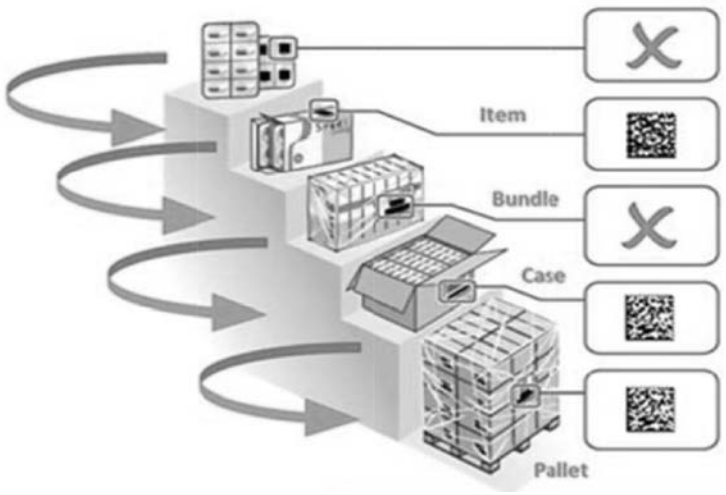
Introduction: context for this presentation

What is Serialization ?

- Serialization refers to assigning a unique nominal number to a unit of production (unit of sale, secondary packaging level, carton box).

- Multiple serialization types exist. The two most important are:
  - **Point of Dispense** = the application of a unique serial number with 2D or linear bar code as data carrier on secondary packaging. Verification at point of dispense (pharmacy).
  - **Track & Trace** = the application of a unique serial number with 2D or linear bar code as data carrier on secondary packaging, bundle level (optional), shipping case and pallet in order to track and trace the product through the supply chain. Tracking supply chain movements.

- Implicates implementation of new international coding standards (GS1) for each SKU product.



Product attributes

Serialization number

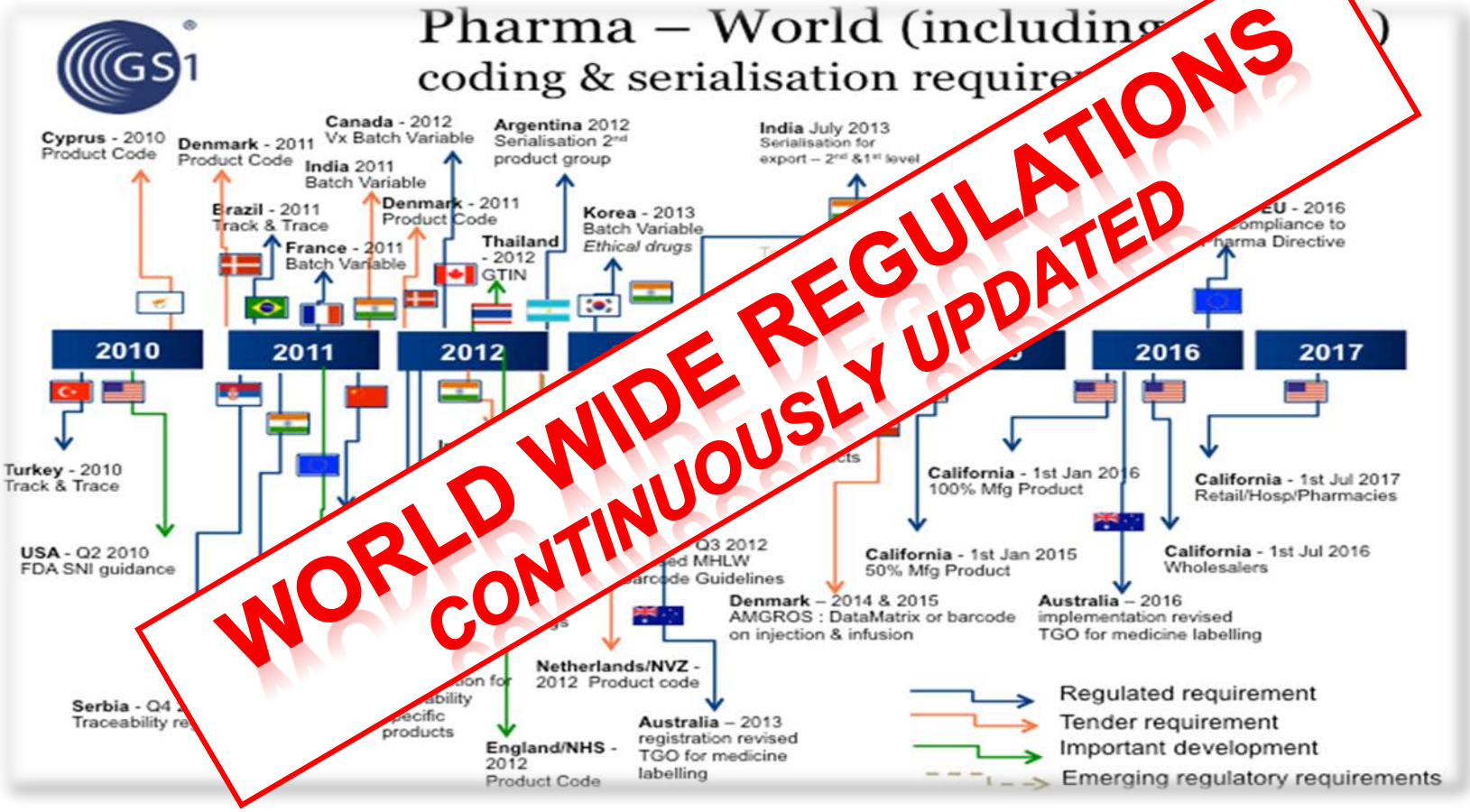
Unique serial number refers to random non-predictive code

Example:

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811

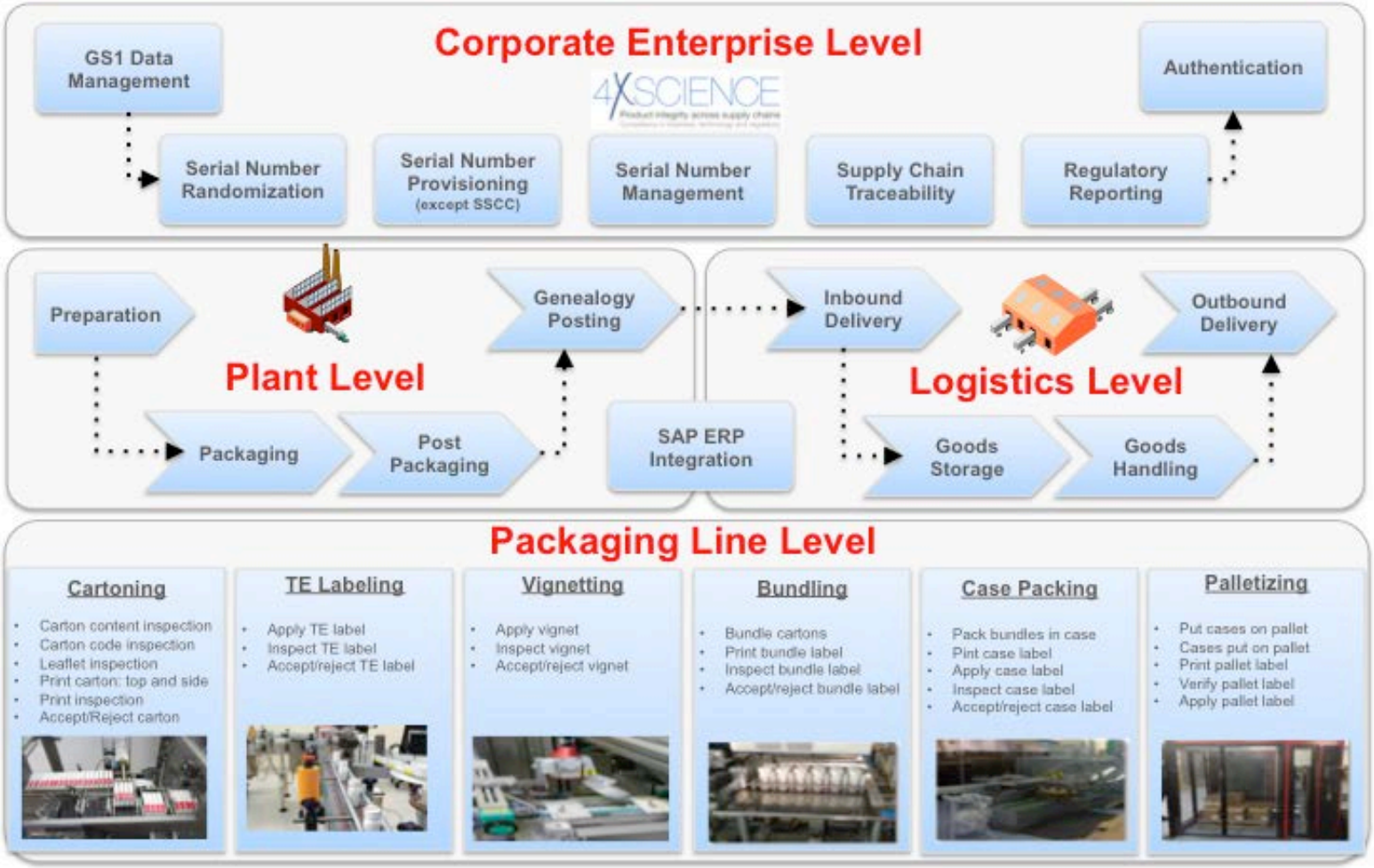
Introduction: context for this presentation

Why Serialization?



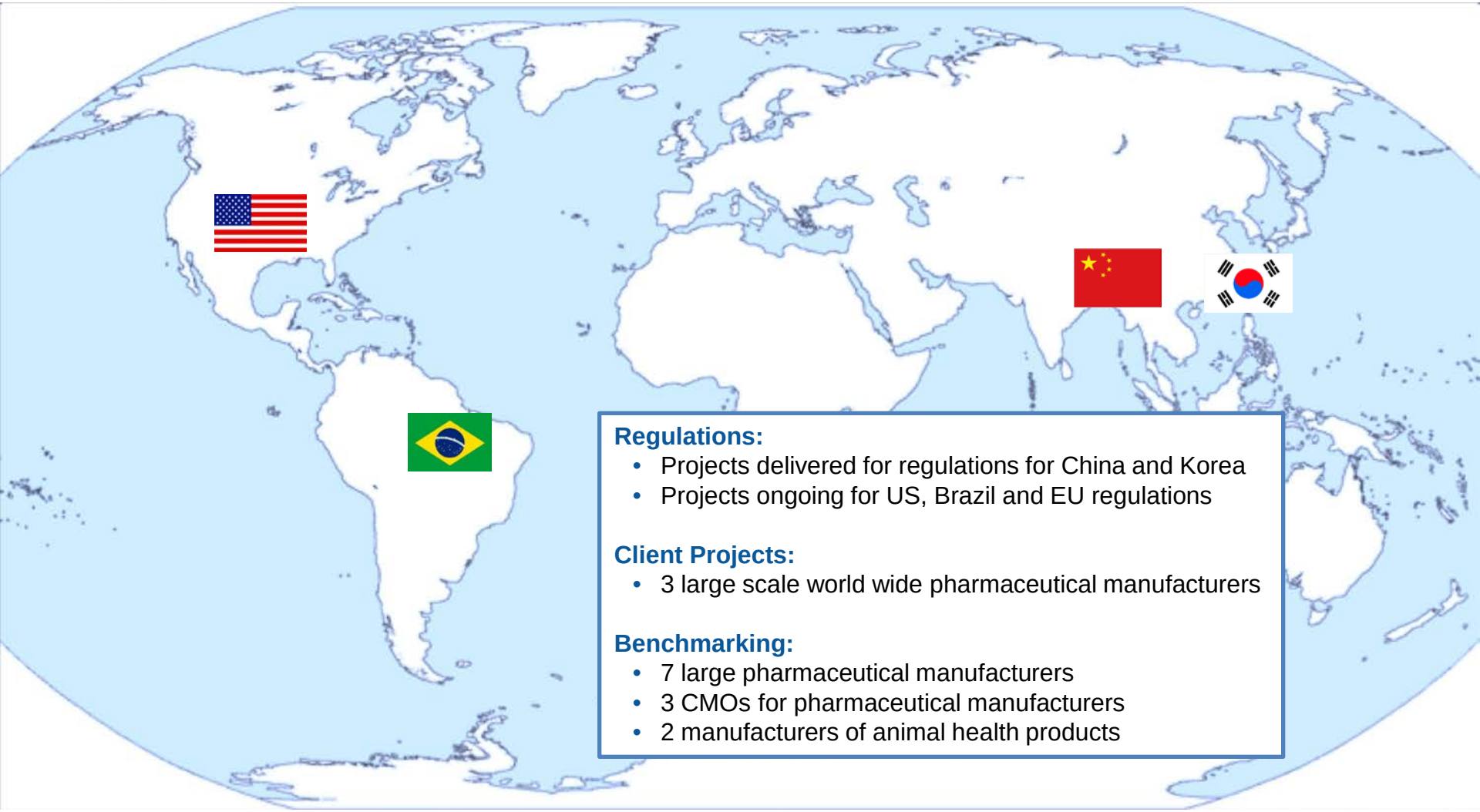
Introduction: context for this presentation

What does serialization involve?



Introduction: context for this presentation

Scope of “lessons learned”



Regulations:

- Projects delivered for regulations for China and Korea
- Projects ongoing for US, Brazil and EU regulations

Client Projects:

- 3 large scale world wide pharmaceutical manufacturers

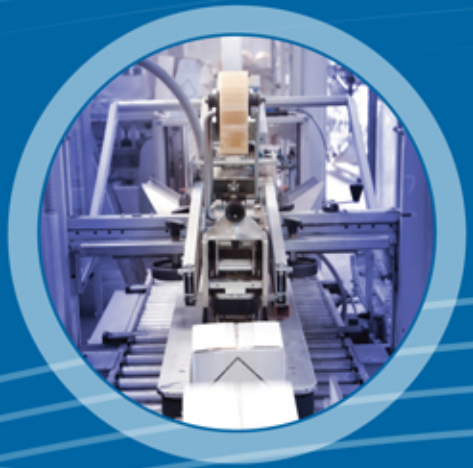
Benchmarking:

- 7 large pharmaceutical manufacturers
- 3 CMOs for pharmaceutical manufacturers
- 2 manufacturers of animal health products

Connecting People, Science and Regulation

Part 1: Lessons from Ongoing Serialization Implementations

Current state of the industry



Observation: Projects are not running well

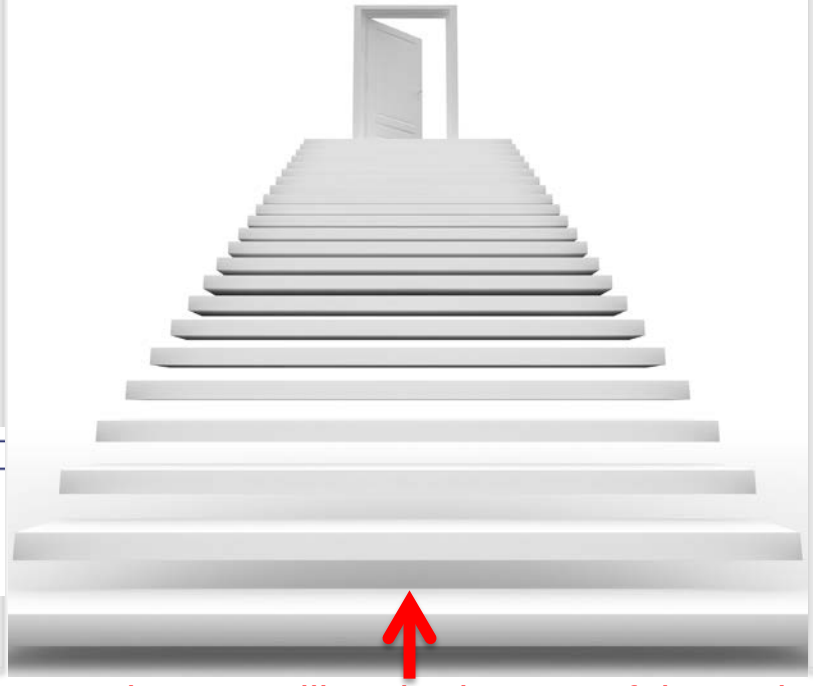
What we see from our client interactions …

The Outside

"We have success !"
"We are ready !"

- GS1 Stories
- Conferences
- Press release
- Publications

"There is no elevator to success
You have to take the stairs"



The Inside

"Real success is limited in scope"

Project Status:

- Timing[1]
- Budget[2]
- Benefits[3]
- Resources[4]
- Quality

Not ok

Companies are still at the bottom of the stairs:

1: an industry lobbying for delay as not ready e.g. Korea
2: continuous request for new budget: wrong estimates
3: packaging and supply chain inefficiencies
4: struggling to build strong teams with experiences

Question: Why are projects not running well?

7 common pitfalls in serialization projects

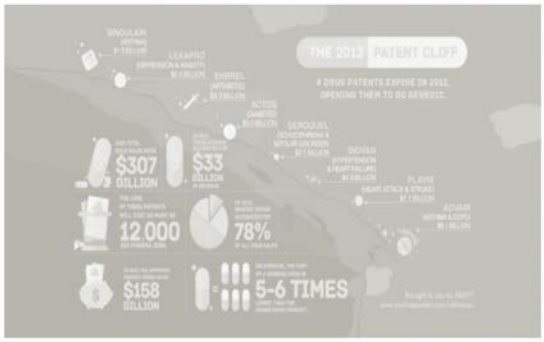
 # 1 Strategy: Disconnect between project strategy and company business drivers

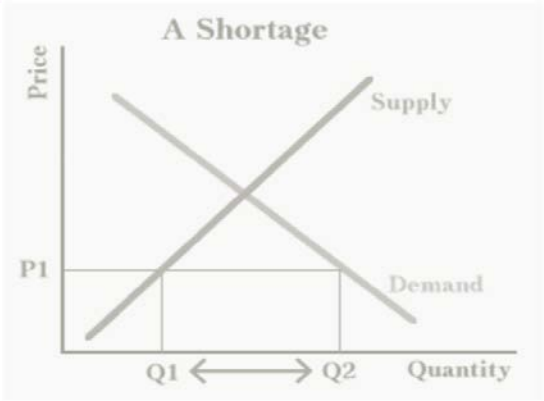
Observations

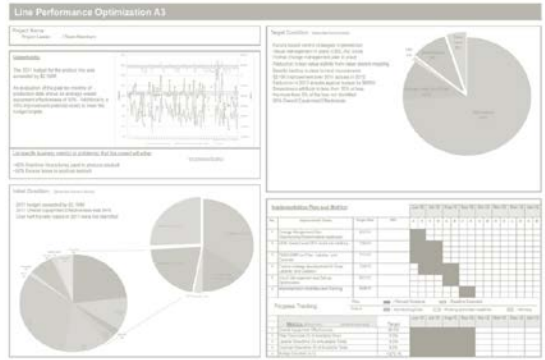
- Unstable regulatory landscape
  - Official changes plus many rumors and un-clarities
  - Role of GS1? Role of consultants? Role of vendors?
- Different business strategies between companies
  - Supply chain interruption – shortage - patent cliff - counterfeits
    - Minimum compliance versus more functions
    - Mandatory products versus optional products
  - Lack of trust from upper management
    - History of serialization (e.g. US boom in 2008, 2012, now 2017)
    - Stop when regulations change
- Continuous correction and approval of budgets needed

Recommendations

- Close link needed between business and project strategy
- Differentiate reality versus rumors: continuous alignment
- Fast reactions to build trust relationship with management
- Open team to answer questions from management







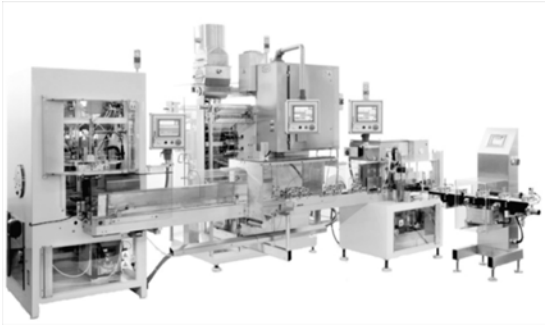
2 Scope: Disconnect between packaging lines and the rest of the supply chain

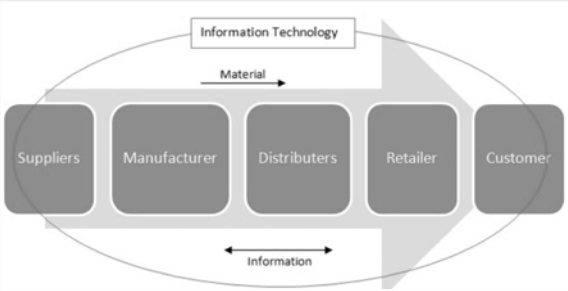
Observations

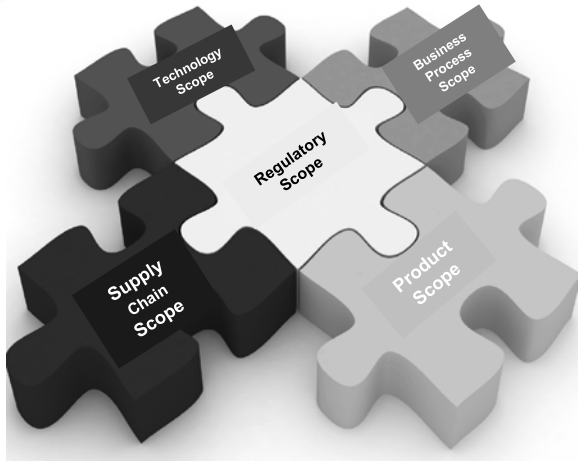
- Original focus: technology deployment on the packaging line
- Focus on rolling out advanced technology to lines: all T&T functions deployed on lines to maintain flexibility
- Unclear or not well defined scope leads to inefficiencies and/or over investments in supply chain processes (e.g. US, China, Korea)

Recommendations

- Be customer oriented (who sits at the end of your supply chain)
- Conduct detailed scoping on 5 dimensions:
  - Regulations / Products / Technology / Processes / Supply Chain nodes
  - Understand relation from each SKU per line to the market
  - Understand efficiency impact from line decisions on supply chain
- Fully understand technology needs for supply chain processes from Plant to Warehouse, DCs and End-Market
- Act in alignment with business strategy and limit investments
  - e.g. explore moving SKUs to T&T lines



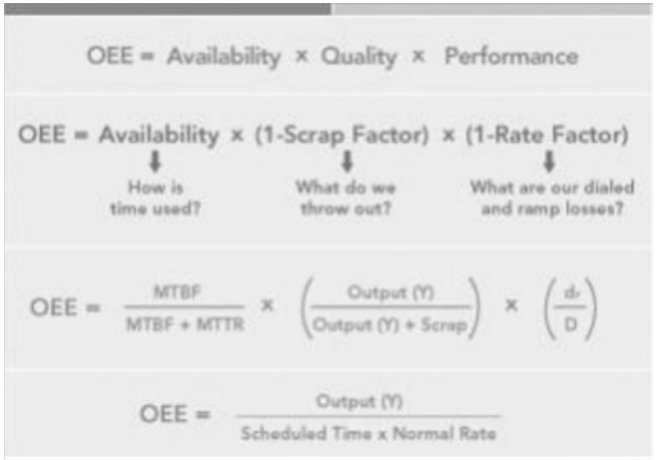


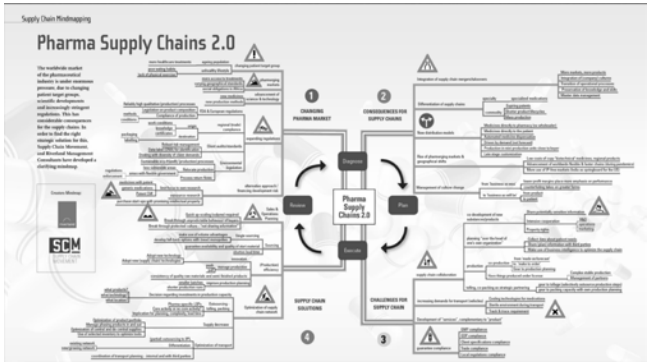


3 Process: Process efficiency impacts and optimizations across the supply chain

Observations

- Impact OEE on packaging lines
  - Additional start / stop activities?
  - Commissioning versus decommissioning efforts?
  - AQLs efforts? Other wins?
- Efficiency impact supply chain logistics
  - When to decommission, what to decommission?
  - When to create receive and to ship events?
  - What to aggregate, when to aggregate?
- More scanning and other non value activities





Recommendations

- Automation to reduce manual efforts
  - Less manual scanning
  - Integrated solutions
- Aggregation only when needed (T&T limited e.g. Brazil)
  - Determining the legal point using law interpretations
  - Costs-benefit for optimal & additional aggregations
- Pilots first to learn and understand efficiency impact

4 **People:** Selecting leaders, do-ers and challengers. All people in the right seats.

Observations

- Diversity of people across multiple departments
- Who is leading?
- Managing the dependencies & responsibilities
- Confirmation of consultants and their information
- GS1 confirmations
- Saving on daily rates versus fixed fees

Recommendations

- Select the right leader, from the right department
- Focus on disciplined people that deliver
- Go for change of current methods if needed
- Go for different people if needed
- Learn (and accept to learn)

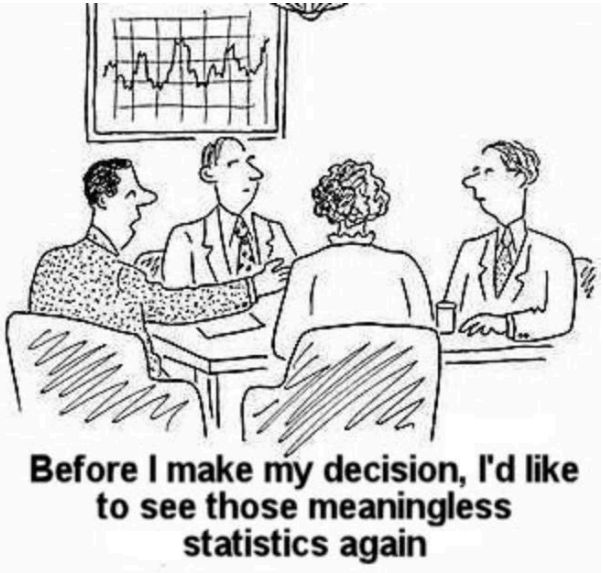
5 Benefits: Leveraging beyond compliance, more than words only?

Observations

- Many discussions, but real reason for project is compliance only
- Track & trace versus item serialization
- Vendors are finding other reasons
- Packaging line versus logistics processes

Recommendations

- Go for minimum compliance first
- Stay aligned with your business strategy
- Additional benefits? be realistic and evaluate your specific case versus current state
  - Examples: brand / patient centric / security / visibility for diversion
  - Do they deliver real value? Case by case analysis, benefits are limited when deployed globally for all SKUs. Benefits multiple stakeholders.
- Be aware of the consultant / vendor talk
  - Regulations?
  - Beyond compliance?



6 Management: Lack of focus and efficiency in project management and execution

Observations

- Many departments and stakeholders involved (complex multi departments, multi sites)
- Not always the best leader
- Traveling around the world to meet with regulators, stakeholders, conferences … failing to deliver …
- Continuously act in alignment with strategy

Recommendations

- Business leaders from supply chain (to secure uninterrupted supply chain) and commercial (leverage beyond compliance after first delivery)
- Ensure team focus and execution efficiency
- Refocus ongoing projects: 2D, serialization, line optimization projects, line maintenance, logistics
- Awareness upper management sometimes lacking

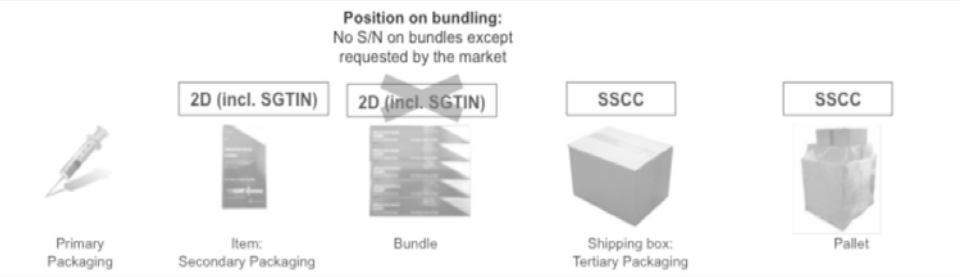
7 **Competences:** Understanding the deep experience required

Observations

- SSCC or GTIN
- Bundling: yes or no?
- Manual case packing or not
- Nested HU or aggregation
- When to aggregate
- Decommission or not
- What to track and were to start?
- Plant server versus SAP AII

Recommendations

- Network and benchmark within your industry
- Check on real cases, not stories or plans
- Understand the real practical problems
- Be aware: failures will not easily be shared
- Take your decisions and “go for it”



Towards a successful approach

Back to Basics: 3 steps

1. Keep things as simple as possible

- Compliance / sales market protection first
- Clear and optimal ownership & leadership
- Don’t over invest or over promise
- Set up learning environment

2. Allow for flexibility in unstable landscape

- Regulations continue to change
- Business requirements continue to evolve
- Phased budget planning within an overall portfolio

3. Build your corporate vision beyond serialization

- Create path towards this vision
- Product and risk based: serialization is a business project
- Leverage unique 2D customer interaction point (per product, per volume)
- Measure benefits before further investments (security, visibility, cost reduction)

Towards a successful approach

Back to Basics: From Strategy to Implementation

Cycle 1 - Module 1:

Strategic Planning & Alignment with Senior Management

Cycle 1 – Module 2:

Grouping into Phased Business Programs

Effective project team with the right people

Cycle 1 – Module 3:

Project Execution

- Customer Oriented
- Disciplined
- Focused
- Milestone Driven

Cycle 1 – Module 4:

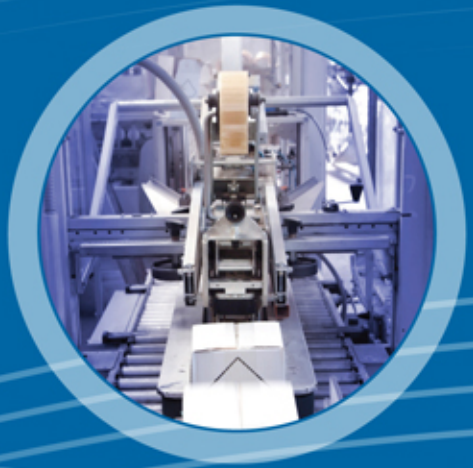
Benefit Realization & Evaluation

Step by Step

Connecting People, Science and Regulation

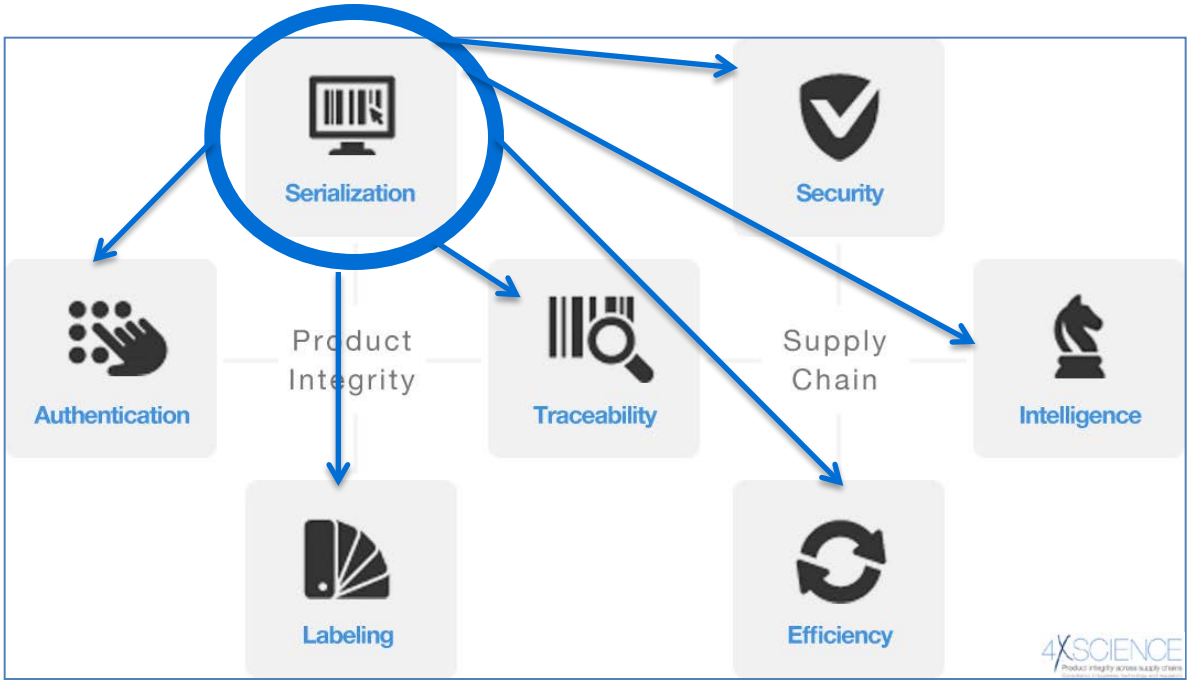
Part 2: Leveraging Serialization Beyond Compliance

Additional benefits or not?



Leveraging Beyond Compliance

Serialization: 1 out 7 capabilities

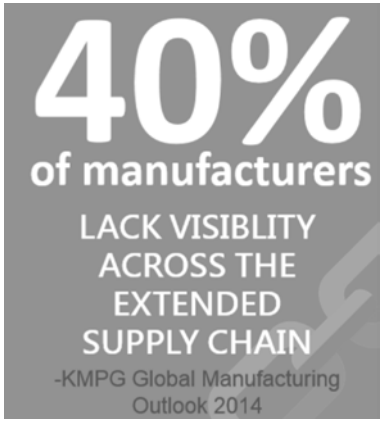


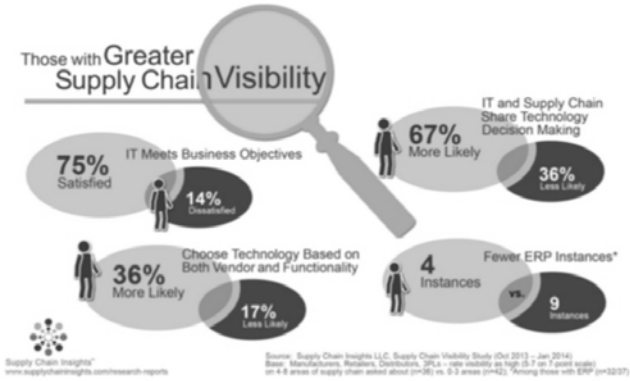
Following slides explore:

- Supply Chain Visibility
- Supply Chain Security
- Authentication & Brand Management

Serialization and Supply Chain Visibility

Benefits are perceived being “low”





- To be solved via item serialization and T&T?
  - Already available at batch level (via your ERP solutions)
  - Detailed monitoring using cold chain functions
  - T&T: will not help for your external supply chain
- Business intelligence not yet fully used at batch level
  - First improve visibility at batch / lot level
- But product authentication will help for external Supply Chain
- An estimated 10 years to mature using i-Apps

Serialization and Supply Chain Security

Internal Supply Chain Processes are “under control”

Supply Chain Security is well managed at lot level for all internal supply chain processes in case products are shipped per batch (for most pharmaceuticals - smaller batches trends)

Opportunities exist for the external supply chains and transport logistics (e.g. cargo theft) when partial batches are shipped and/or various products combined

SAFETY IMPROVEMENT (External Supply Chain)

Counterfeits

- Protecting your online business

Quality: Safety & Recall Management

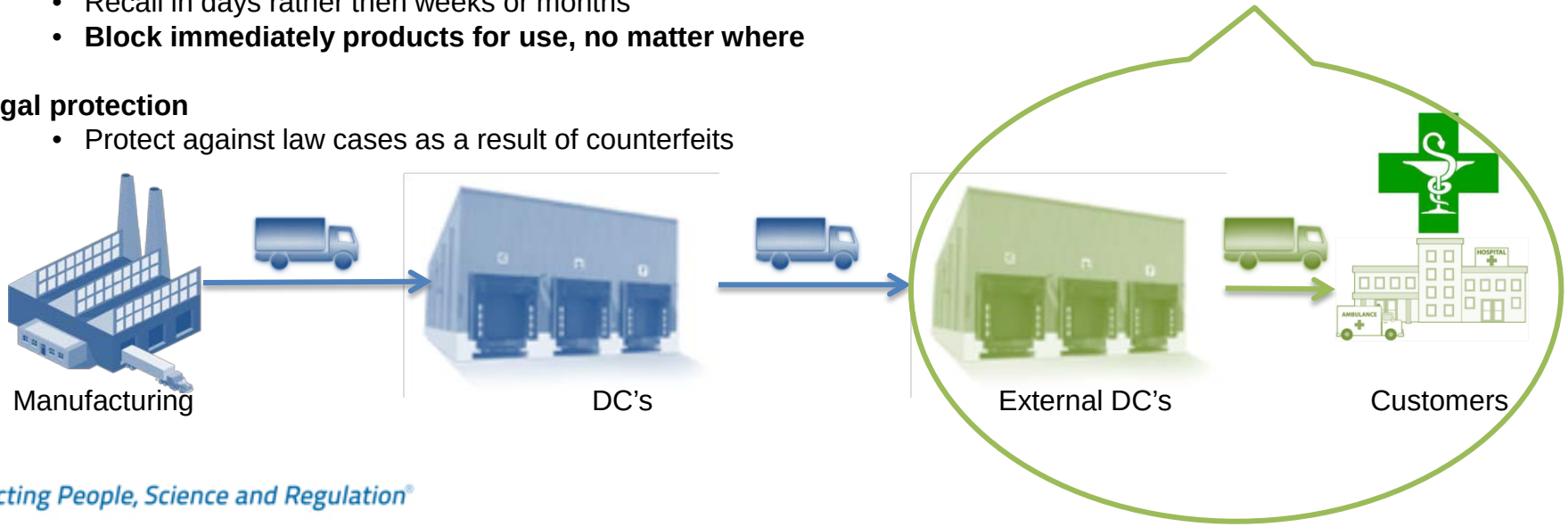
- Recall in days rather then weeks or months
- **Block immediately products for use, no matter where**

Legal protection

- Protect against law cases as a result of counterfeits

Main risk in External Supply Chain:

- **Partial batches**
- **Various distributors**



Serialization and Supply Chain Security

External Supply Chain Processes: Example of Cargo Theft

Opportunities exist for the external supply chains and transport logistics (e.g. cargo theft) when partial batches are shipped and/or various products combined

Novartis/Alcon Notification of Product Theft

FDA posts press releases and other notices from firms as a service to consumers, the media, and other notified parties.

Date Posted: August 12, 2011

Novartis and its Alcon Division are working with the U.S. Food and Drug Administration (FDA), industry cargo thefts organizations, and law enforcement officials to recover Novartis, Alcon, and Falcon* products that were stolen on July 18, 2011 while being delivered to a customer's distribution center in Florida. The products stolen are listed below and represent a small portion of each product lot, which have already been distributed within the United States, Puerto Rico, and its territories. Products from the below listed lots that were delivered prior to July 18 are not affected by this event.

*Falcon is a line of generic eye care pharmaceuticals from the Sandoz Division of Novartis.

BRAND	PRODUCT	DESCRIPTION	DOSAGE	NDC#	LOT/BATCH	QUANTITY
ALCON	I-CAPS AREDS TABLETS (TIME-RELEASE)	Nutritional Supplement	120 COUNT	N/A	1CR0301	9 CASES
ALCON	I-CAPS LUTEIN & ZEAXANTHIN TABLETS	Nutritional Supplement	120 COUNT	N/A	1ER0141	20 CASES
ALCON	OPTI-FREE EXPRESS MULTI-PURPOSE DISINFECTING SOLUTION	OTC Lens Care Solution	10 OZ	N/A	183045F	34 CASES
ALCON	OPTI-FREE EXPRESS MULTI-PURPOSE DISINFECTING SOLUTION	OTC Lens Care Solution	2 OZ	N/A	192174F	25 CASES
ALCON	OPTI-FREE EXPRESS MULTI-PURPOSE DISINFECTING SOLUTION	OTC Lens Care Solution	2 x 10 OZ	N/A	179296F	1 CASE
ALCON	OPTI-FREE EXPRESS MULTI-PURPOSE	OTC Lens Care Solution	2 x 10 OZ	N/A	187037F	10 CASES

Source: FDA (August 12, 2011)

Notification of Stolen Johnson & Johnson Group of Consumer Companies Products (Clayton, Indiana)

FDA posts press releases and other notices from firms as a service to consumers, the media, and other interested parties.

Issued: September 12, 2011

The Johnson & Johnson Group of Consumer Companies is working with the U.S. Food and Drug Administration, Office of Criminal Investigations (FDA), and other law enforcement officials to recover cases of select lots of retail, non-prescription, consumer healthcare products. The trailer containing the products was stolen while en route to a Johnson & Johnson Distribution Center in Mooresville, IN on August 28, 2011. The trailer was parked at a truck stop in Clayton, IN at the time of the theft. The stolen trailer contained multiple products and partial lots of Johnson & Johnson Consumer products, including brands such as Monistat®, Reach®, Cortaid®, Aveeno®, Neutrogena®, and Johnson & Johnson First Aid to Go!®. Potentially impacted lots are listed in the table below.

The Johnson & Johnson Group of Consumer Companies, along with FDA and local authorities, has initiated efforts to locate the stolen product and identify the individuals who were involved in the theft.

The Johnson & Johnson Group of Consumer Companies and the FDA are asking for the public's help in reporting any information regarding the stolen consumer healthcare products to FDA's Office of Criminal Investigations (OCI) by calling 800-551-3989 or by visiting the OCI Web site (http://www.fda.gov/OCI).

The Johnson & Johnson Group of Consumer Companies advises consumers and retailers to always purchase product only from trusted and reliable sources. For consumer inquiries about a specific product, please call the toll-free number identified on the package.

In addition, as always, consumers and retailers should report any evidence of suspected product tampering to our toll-free number 800-962-5357.

Brand	Description/Size	Lot
Aveeno	Sun Continuous Protection Lotion SPF 100- Face 3oz	1191L0031
Monistat	Monistat 3 Cream Combo .18OZ	0701DW
Monistat	Monistat 3 Cream Combo .18OZ	0071DW

Source: FDA (September 12, 2011)

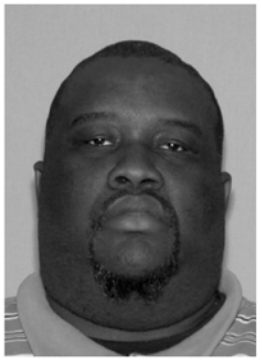
5 arrested in Englewood, 1 sought in connection with $140K in stolen Aveeno wipes

MAY 10, 2014, 2:59 PM LAST UPDATED: SATURDAY, MAY 10, 2014, 4:43 PM
BY STEPHANIE DAZIO
STAFF WRITER
THE RECORD

ENGLEWOOD –Englewood police have arrested five people and another is being sought in connection with the discovery of nearly $140,000 worth of stolen Aveeno wipes in a house in the city.

Gary Caviness, Andre Chance, Chanel Chance, Ghanore Gnegbo and Kavon Major were all arrested on second-degree charges of receiving stolen property after city police discovered about 2,900 boxes of the Johnson & Johnson makeup removers crammed into a house at 239 Epps Avenue on Sunday. City resident Michael Ratliff, 35, is also being sought for his alleged role in the crime, police said.

Englewood police Detective Capt. Timothy Torell said the boxes were apparently diverted from a facility in the Nyack/Clarkstown, N.Y., area during a cargo theft, which is still under investigation. Johnson & Johnson officials told police that all of the seized products will have to be destroyed, Torell said, and cannot be resold.



Police said their investigation continues and more people could be implicated. "The possibility exists that there will be more arrests," he said.

The discovery was made last Sunday, when police responded to a report of the assault and robbery of a 40-year-old Chinese food deliveryman on West Forest Avenue.

The victim was supposed to deliver about $50

Source:

- http://www.northjersey.com/news/5-arrested-in-englewood-1-sought-in-connection-with-140k-in-stolen-aveeno-wipes-1.1013641 (May 15, 2014)

Serialization and Supply Chain Security

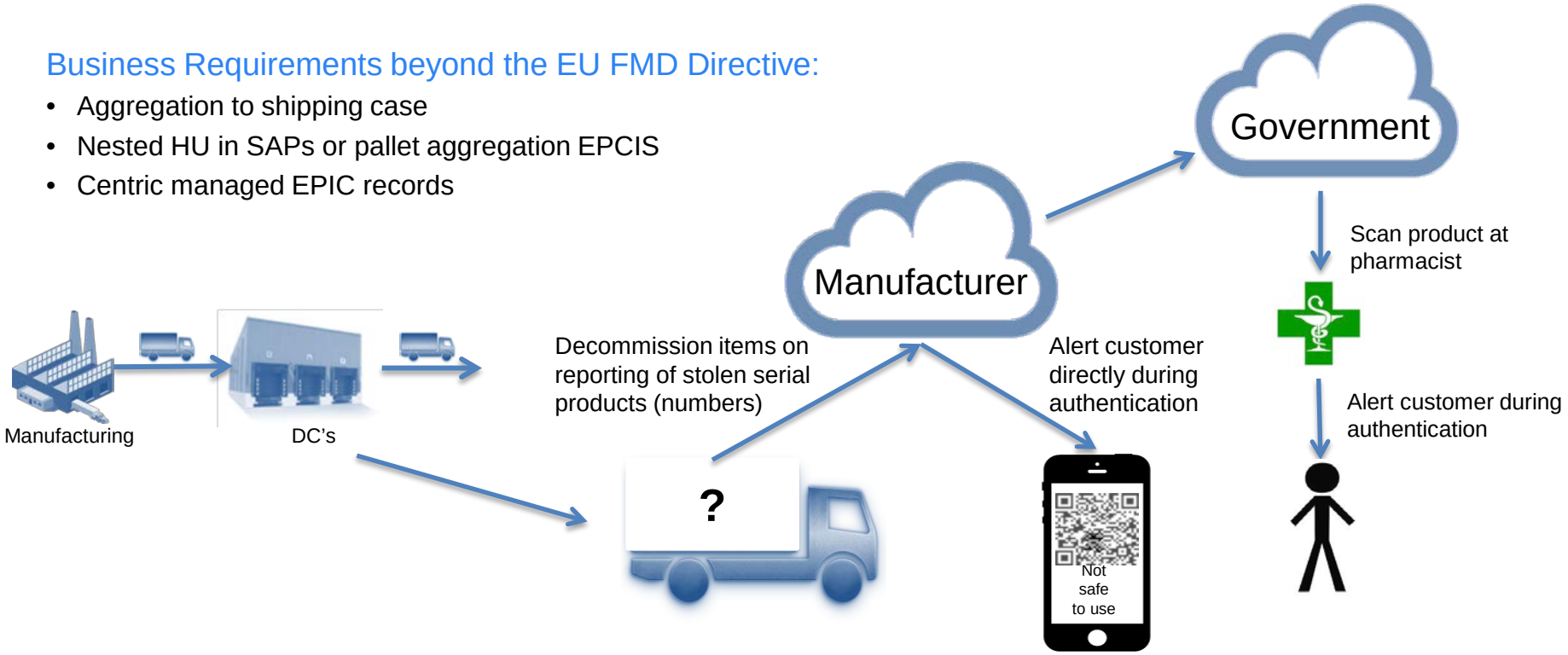
External Supply Chain Processes: Example of Cargo Theft

SAFETY IMPROVEMENT (Cargo Theft):

which item is in which truck ?

Business Requirements beyond the EU FMD Directive:

- Aggregation to shipping case
- Nested HU in SAPs or pallet aggregation EPCIS
- Centric managed EPIC records



Serialization and Authentication Brand Management

Leveraging significant investments in customer oriented Apps

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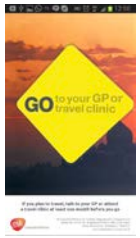

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Hi there !
You have bought an unique identified product. You can be sure this product is authentic and safe to use. Would you like to add extra product information to your user account?

Serial Number

Manufacturer

Serialization can help:

- Enhance customer-product relation
- Promote existing application services
- Improve compliance adherence
  - Keep track of exact medication use
  - Take full subscriptions
  - Eliminate human error
  - Inform stakeholders (e.g. parents)
- Offering discounts to the real customer

Serialization and Brand Management

Serialization can impact Pharmaceutical Life Cycle Management

CONTRIBUTE TO SALES INCREASE

Promote your current sales channels
- Support and facilitate web sales

Customer relationships
- Engage end customers to request a specific brand

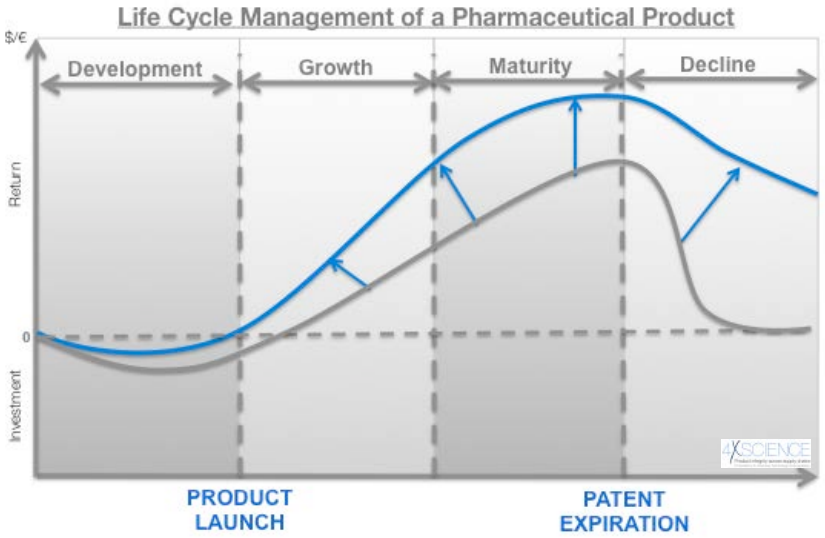
Compliance Adherence
- Ensuring products are taken as prescribed

Brand Management
- Customer relationship building
- Facilitating use of products
- Including differentiation from generics

Off Patent Extension
- Installing drivers to motivate usage (US)
- Against unofficial “black markets”

4 Conditions:

1. The product is intended for repeated use
2. A service program for the product is available or in pilot.
3. There is heavy competition of generics and/or other products.
4. The impact to the decision takers is high or existing.



Example: Remicade (JnJ)

- **What?** Treatment of Crohn’s and Rheumatoid Arthritis (RA), both chronical diseases
- **Service Program?** Care 4 Today (only in US ITunes Store)
- **Competition?**
  - Yes: Enbrel, Humira, Cimzia, etc.
  - Patent expiry date: US patent until September 2018; in majority of EU countries until February 2015.

- **Impact on decision takers?** The app in combination with serialization can benefit the customers:
  - Ensure patient safety
  - Enhance the service program (reminders, unique connection with the product and company, invite to workshops, etc.)

Serialization and Authentication Brand Management

Stakeholders require different serialization strategies (Rx, OTC)

Hospital

Patient

Manufacturer

Warehousing & Transport

Insurance

Retailer

Humanitarian Aid

Wholesaler

Doctor

Government

Pharmacy

4SCIENCE

2014 Serialization Benchmark Pharmaceutical Industry

United States
European Union
Brazil
Saudi Arabia

Start: Monday October 13, 2014
Due: Friday October 31, 2014

Thank you !

SCIENCE

Product integrity across supply chains

Consultancy in business, technology and regulatory

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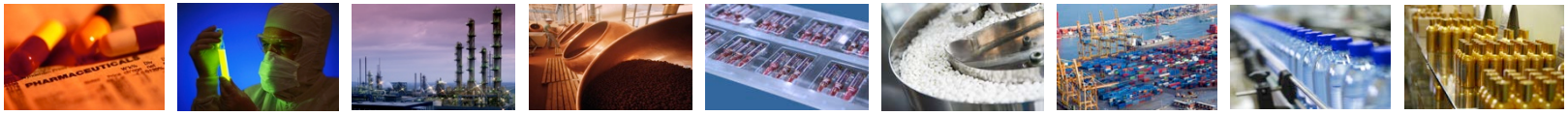
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