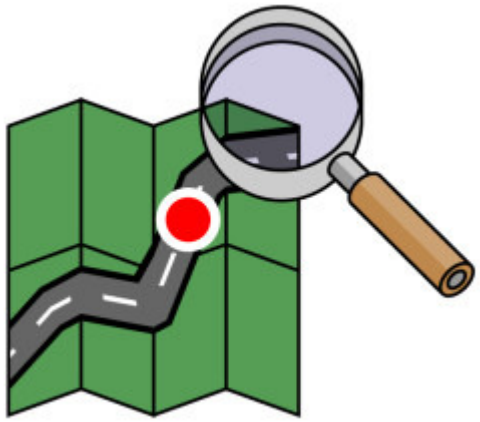
The Global Language of Business

Pharmaceutical Traceability for manufacturers and wholesalers



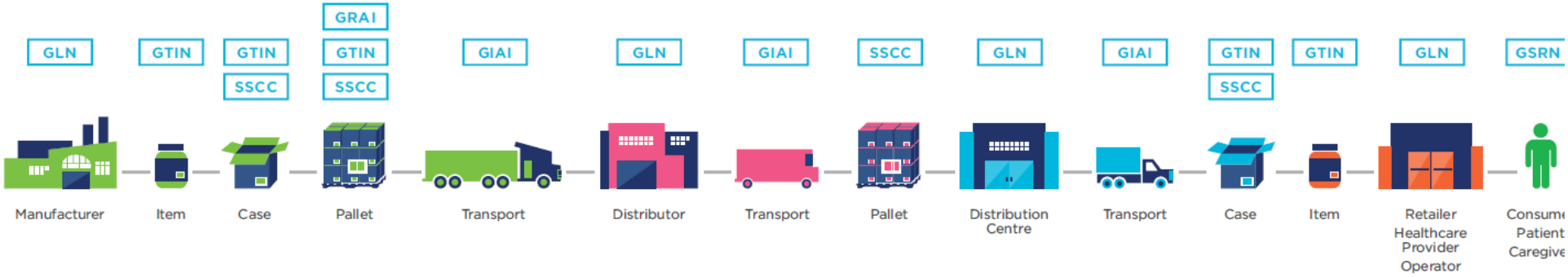
GS1 Healthcare Conference

25 October 2016 in Beijing

GS1 Identify Capture Share

Identify: GS1 Standards for Identification

GLN Global Location Number **GTIN** Global Trade Item Number **SSCC** Serial Shipping Container Code **GRAI** Global Returnable Asset Identifier **GIAI** Global Individual Asset Identifier **GSRN** Global Service Relation Number

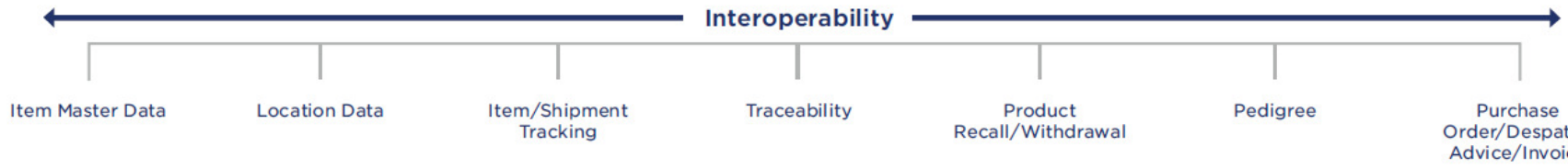


Capture: GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes **GS1 EPC/RFID**

Share: GS1 Standards for Data Exchange

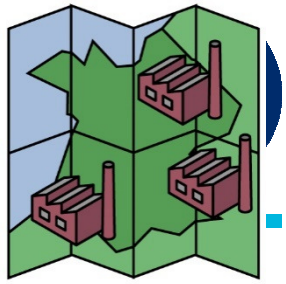
Master Data Global Data Synchronisation Network (GDSN) **Transactional Data** eCom (EDI) **Event Data** EPC Information Services (EPCIS)



Batch/Lot vs. Serialized Visibility

Feature	GTIN	GTIN + Lot	GTIN + Serial
Low Precision Identification	✓		
Medium Precision Identification		✓	
High Precision Identification			✓
Additional data needs to be physically marked		✓	✓
Serialization required			✓
Traceable item exist in multiple locations at the same time	✓	✓	
Traceable item exist only at one locations at the same time			✓
Product Recall	All units of a given GTIN	All units of a given GTIN + Lot	Only specific units with matching GTIN + Serial
Enables anti counterfeit measures			✓
Enables to monitor products with finite shelf life		✓	✓

EPCIS enables supply chain visibility



- **Tracking**

  Where are the pharmaceuticals I shipped?

- **Tracing**

  Where did this batch of pharmaceuticals come from?

- **Chain of Custody (CoC)**

  Which parties had custody of these pharmaceuticals?

- **Recall**

  Where are products produced at site XYZ on 2016-10-20 ?

For more information on EPCIS . . .

Craig Alan Repec

Senior Manager

Supply Chain Visibility, EPCIS & RFID

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Belgium

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Serialization Implementation and Traceability

Peggy Staver
Director, Product Integrity

October 2016

Overview

Pfizer Global Serialization

- Introduction
- Serialization Implementation
- Traceability
- Pfizer's Program Operating Model and Governance
- Key Challenges

About Pfizer

Pfizer Global Serialization

Our Purpose:

Innovate to bring therapies to patients that significantly improve their lives

Our Mission:

To be the premier, innovative biopharmaceutical company

Our Four Imperatives:

1	2	3	4
Fix the innovative core and generate medicines that profoundly impact health	Make the right capital allocation decisions to maximize value and enhance shareholder return	Earn greater respect from society	Create an ownership culture

Our Values

Our Combined Company*

$49
BILLION
in revenue in 2015

63
MANUFACTURING
sites worldwide

175
MARKETS
in which Pfizer sells products

7
PRODUCTS
with sales greater than $1 billion in 2015

MORE THAN
200
NEW R&D COLLABORATIONS
in 2015

MORE THAN
97,000
COLLEAGUES
around the world

*As of April 1, 2016

SERIALIZATION IMPLEMENTATION

Serialization Implementation

Pfizer Global Serialization

Packaging Sites (Pfizer sites, Contract Manufacturers, etc)

Configuration of Pfizer and Contract Manufacturers packaging lines based on unique mandate requirements.

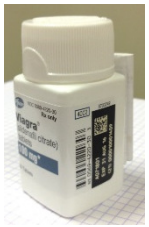
All data management occurs with the Serialization Control Tower (SCT) system

Packaging Line

Pfizer / CMO Plant Warehouse

Capture of key events from Operations for each Serial Number as it moves through the Supply Chain.

Encoding of key data elements into a GS1 2D Data Matrix barcode.



- GTIN
- Serial Number
- Expiry Date
- Lot Number

Wholesale Distributor

Hospital / Pharmacy

Communicating event data to governments and/or trading partners in support of compliance.

Patient

Site Server/Line Management Systems

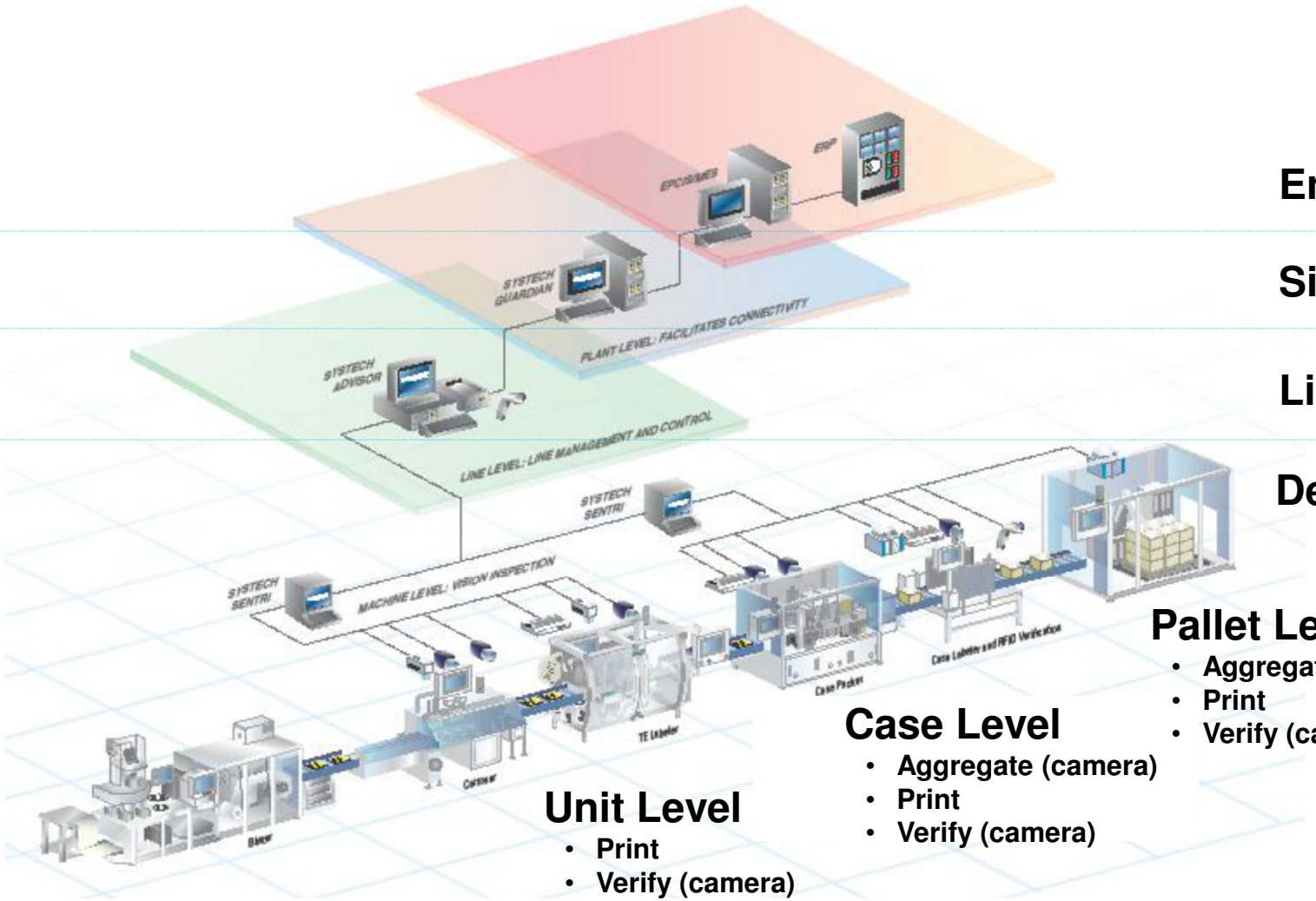
SCT

Enterprise

Site

Line

Device



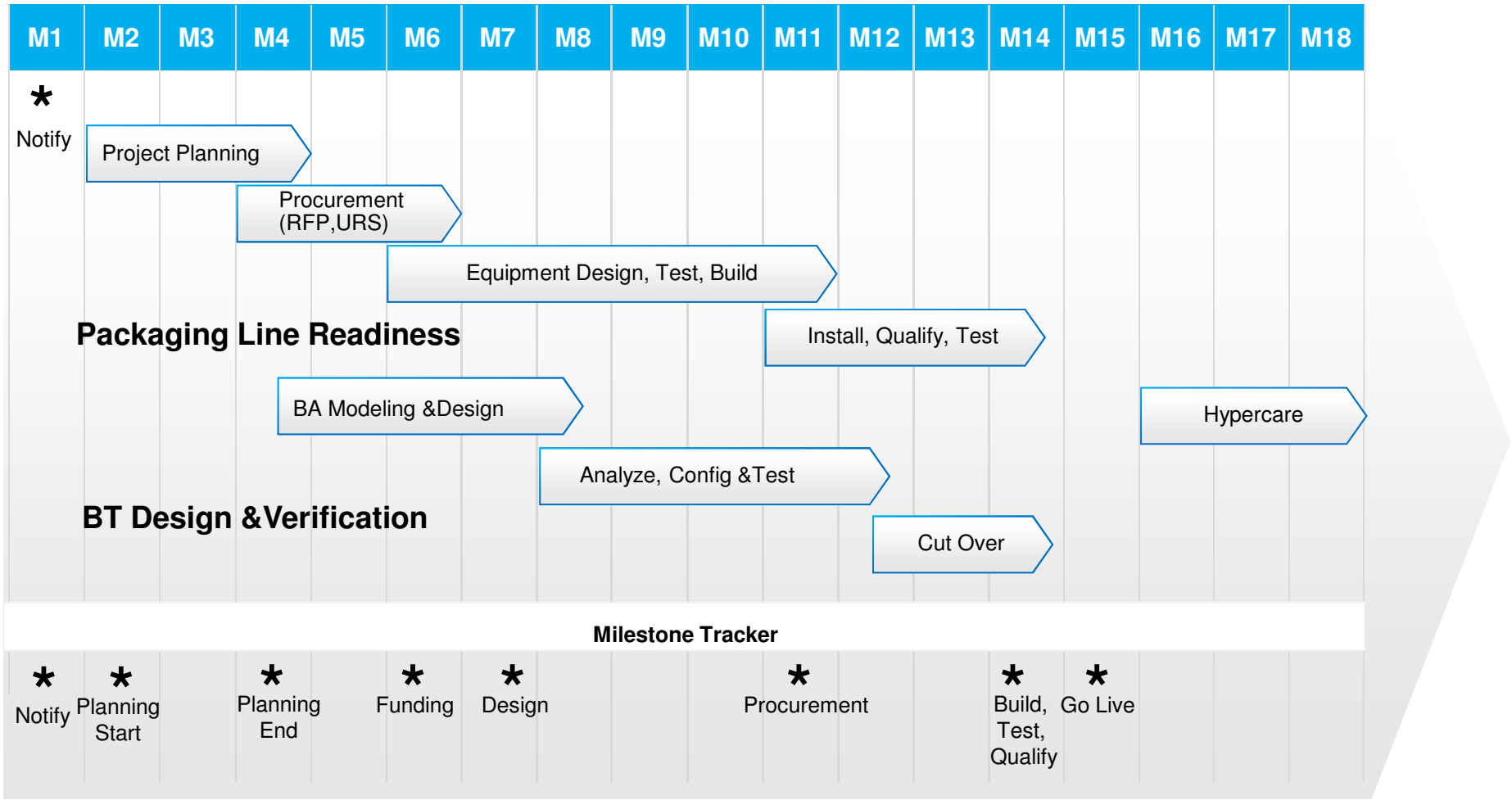
Unit Level
- Print
- Verify (camera)

Case Level
- Aggregate (camera)
- Print
- Verify (camera)

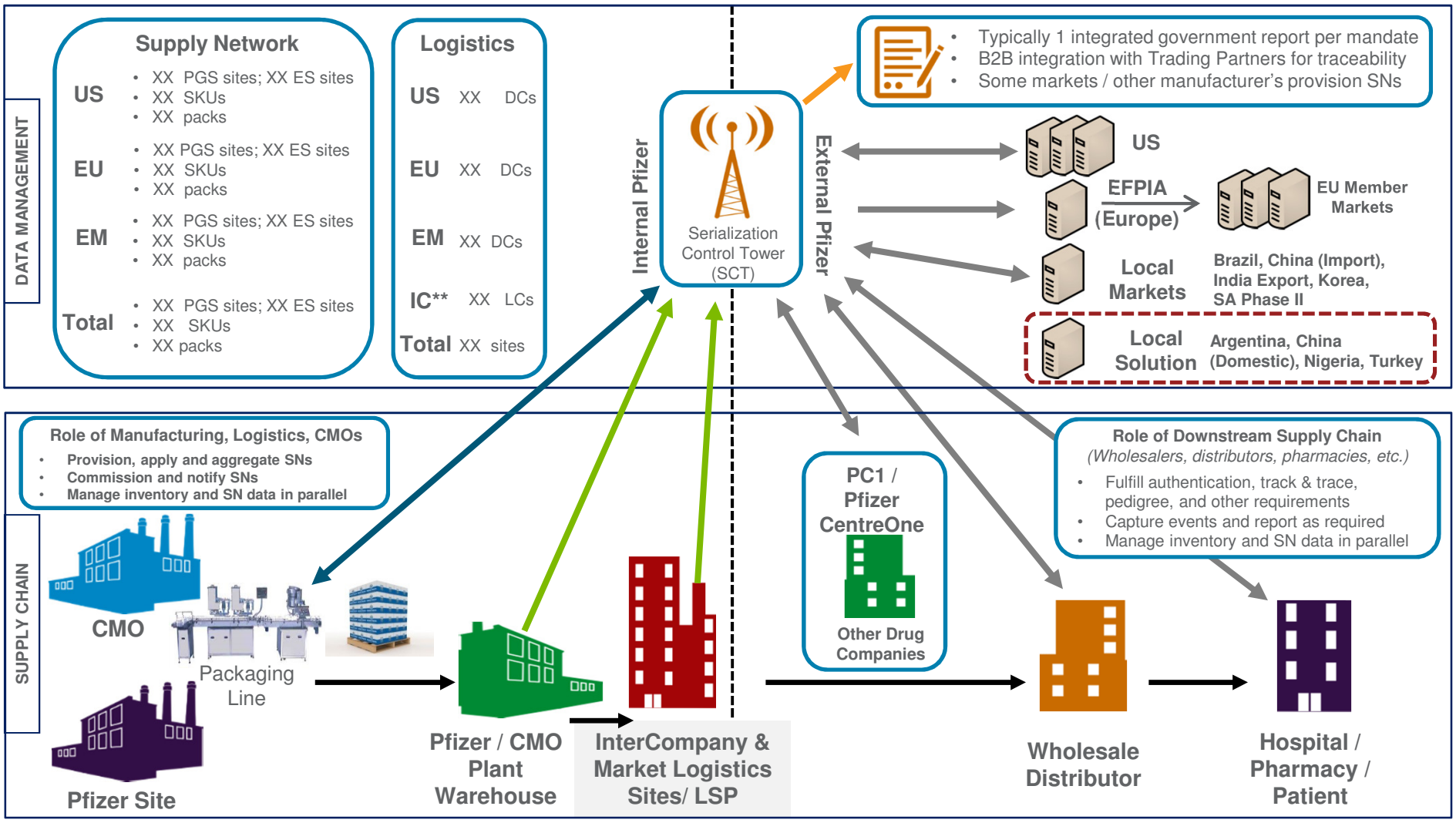
Pallet Level
- Aggregate (camera)
- Print
- Verify (camera)

Typical Enablement Project Timeline

The average timeline for enabling a packaging line for Serialization is 18 months start to finish, and requires integrating with numerous other site priorities.

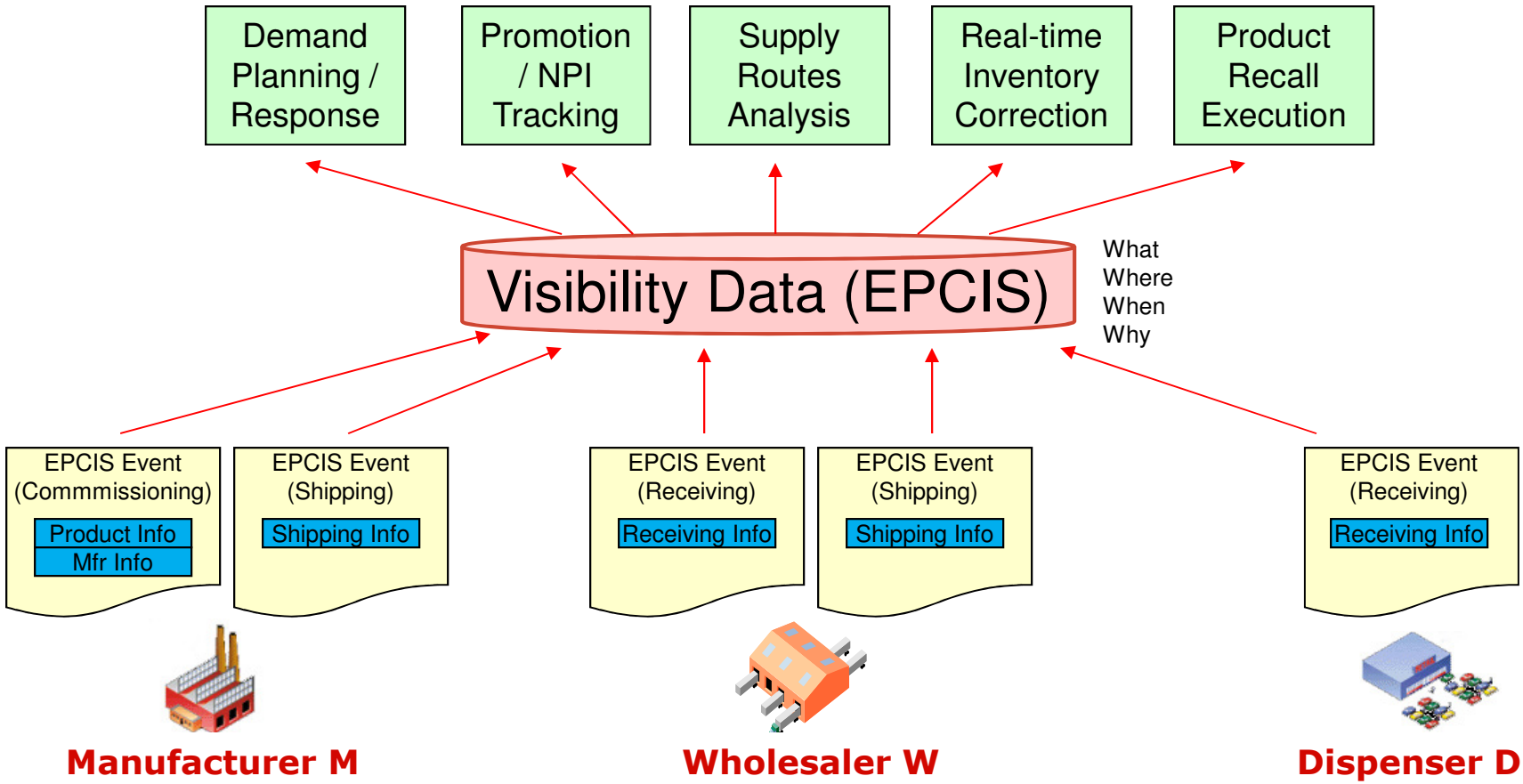


Serialization Enterprise Solution Overview



TRACEABILITY

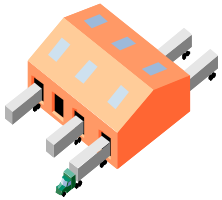
Traceability



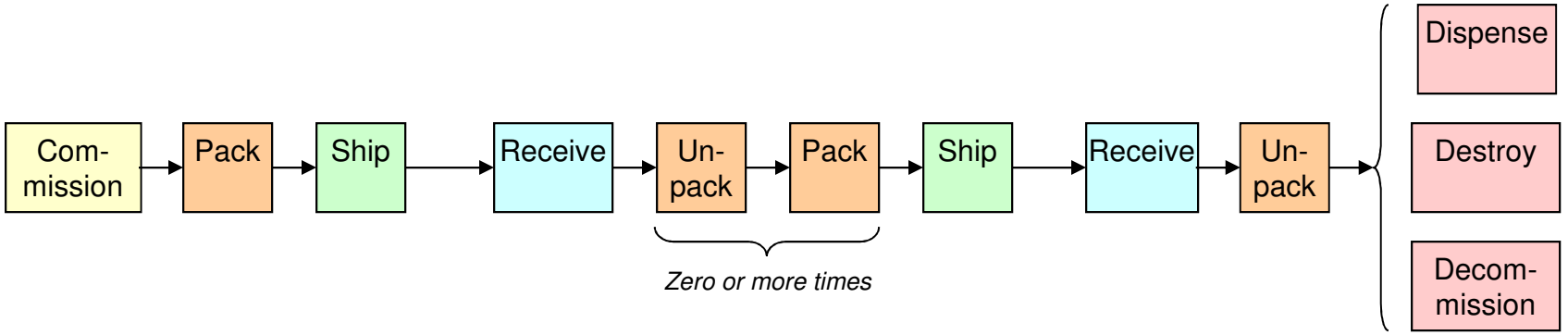
- Electronic Product Code Information Services (EPCIS)
  - Standard for supply chain "events" recording handling of products in the supply chain
  - What, when, where, why
  - Useful for many different business purposes

Used with permission from Ken Traub Consulting

Forward Path Steps in History



Manufacturer | Distributor(s) | Dispenser



Each step is recorded by an EPCIS Event

Used with Permission from Ken Traub Consulting

PFIZER'S PROGRAM OPERATING MODEL AND GOVERNANCE

High Level Operating Model

Pfizer has developed a "Program Operating Model" to guide each new mandate from initial requirements through to Business as Usual.

Program Operations

Activity:
- Coordinate alignment of all workstreams to ensure successful mandate compliance
- Management of Enterprise schedule
- Report Program and mandate status
- Manage Issue and risks
- Monitor and track progress across all in scope mandates
- Manage program communications
- Manage program scope and financials

Monitoring

Activity:
- Actively monitor mandates / regulations not in scope of program
- Monitor in program local solution requirement changes
- Monitor in program enterprise solution for requirement changes
- Determine impacts of Pfizer wide initiatives based on mandate requirements
- Monitor and bring back learnings from pilots

Evaluation

Activity:
- Determine initial scope and sourcing strategy for mandate
- Document mandate compliance milestones
- Request and approve program funding
- Initiate market engagement

Engagement

Activity:
- Form in country team and meeting cadence
- Finalize approach and design for scope
- Update Enterprise master schedule to include enablement schedules from all workstreams impacted
- Enhance Enterprise solution
- Secure site / source funding

Enablement

Activity:
- Coordination of schedule and resources
- Enable impacted Pfizer supply chain
- Enable data management across Pfizer supply chain
- Lead change management and training across Pfizer Supply Chain
- Transition to Enterprise support

Compliance Management

Activity:
- Onboard SKUs within the network
- Monitor and track SKU onboarding / compliance

Business as Usual

Activity:
- Transition supply chain and enabling functions to standard operational activity
- Ongoing monitoring

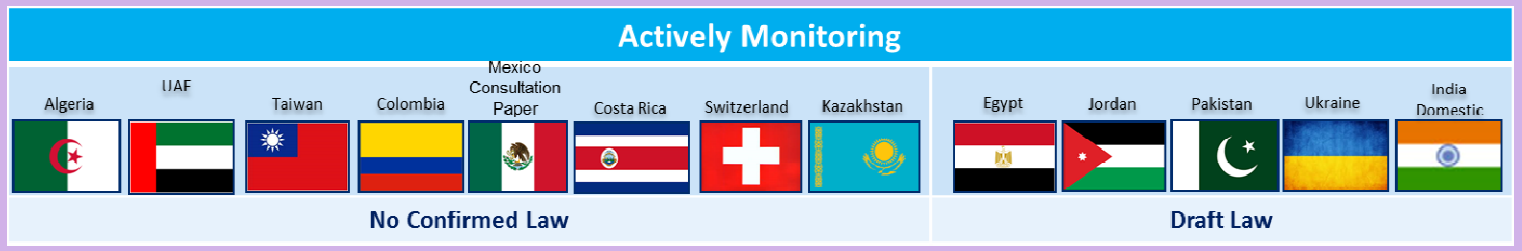
**Phases may occur in parallel or cyclical nature*

Program Operating Model

1

Monitor Regulations: *Mandates are monitored for emerging regulations, and ongoing changes to existing requirements.*

- Local Regulatory
- In-Country Teams
- GS1 and other groups



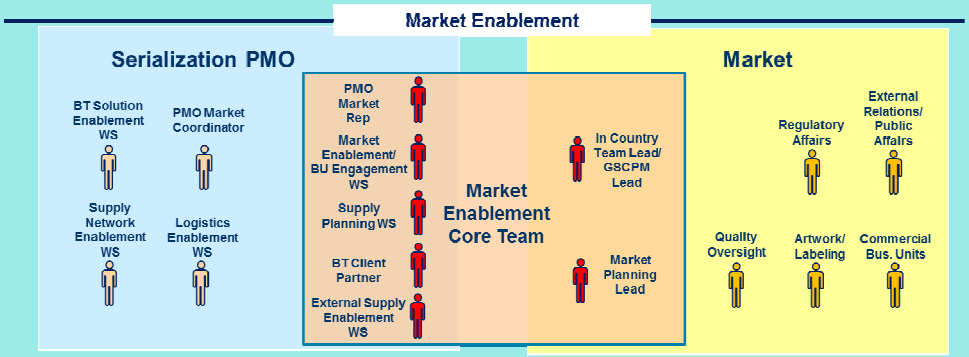
Program Operating Model

2 **Evaluate Impact to Pfizer:** *Program works with source locations to identify impacts and technical configuration requirements.*

Program Operating Model

Pfizer Global Serialization

3 Engage Cross-Functional Teams and Plan for Enablement: *Collaborate across stakeholder groups (country, center, site) to begin enabling network for serialization.*

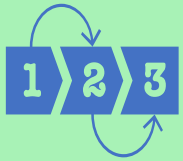


- Local project managers identified
- Center led project managers appointed to ensure standard processes are utilized

Program Operating Model

4 **Enable Supply Chain:** *Standard implementation methodology is utilized to accelerate timelines and ensure compliance with Enterprise Solution.*

Standard Core Solutions



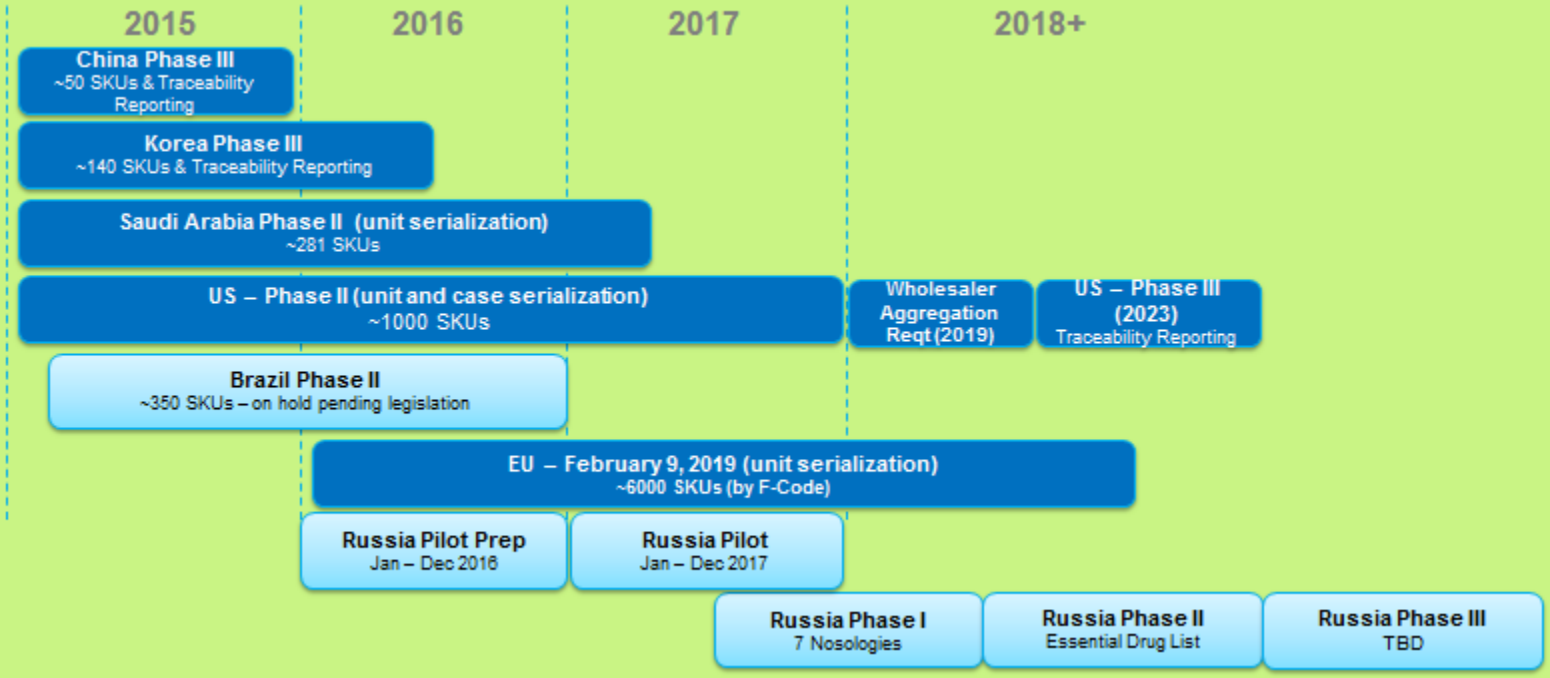
Repeatable Implementation Process

Modular

Program Operating Model

5

Monitor Compliance: *Stakeholders monitor compliance and ensure supply continuity.*

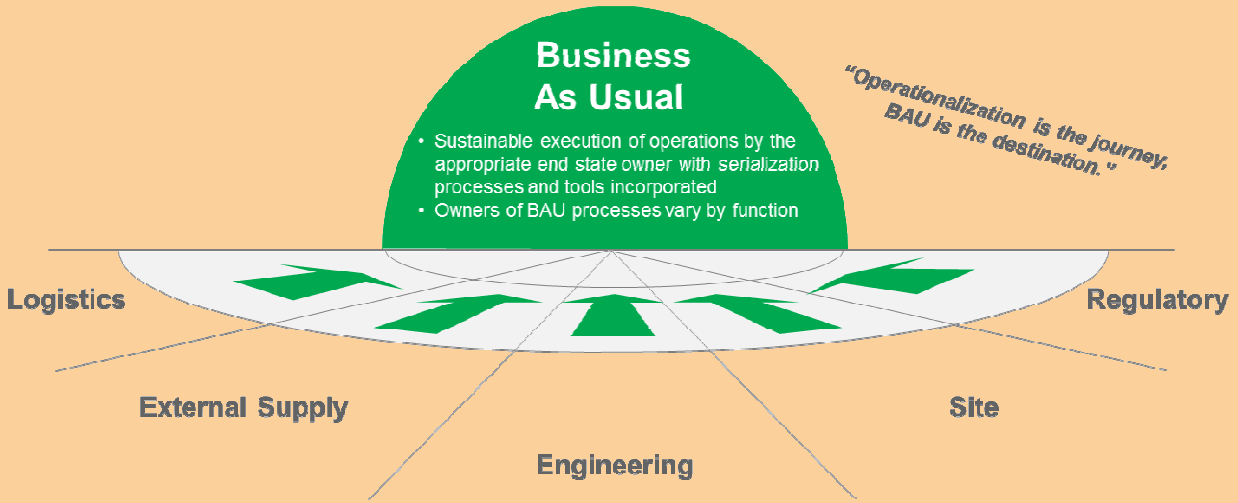


Note: Slide depicts overlapping work efforts and is not reflective of compliance deadlines.

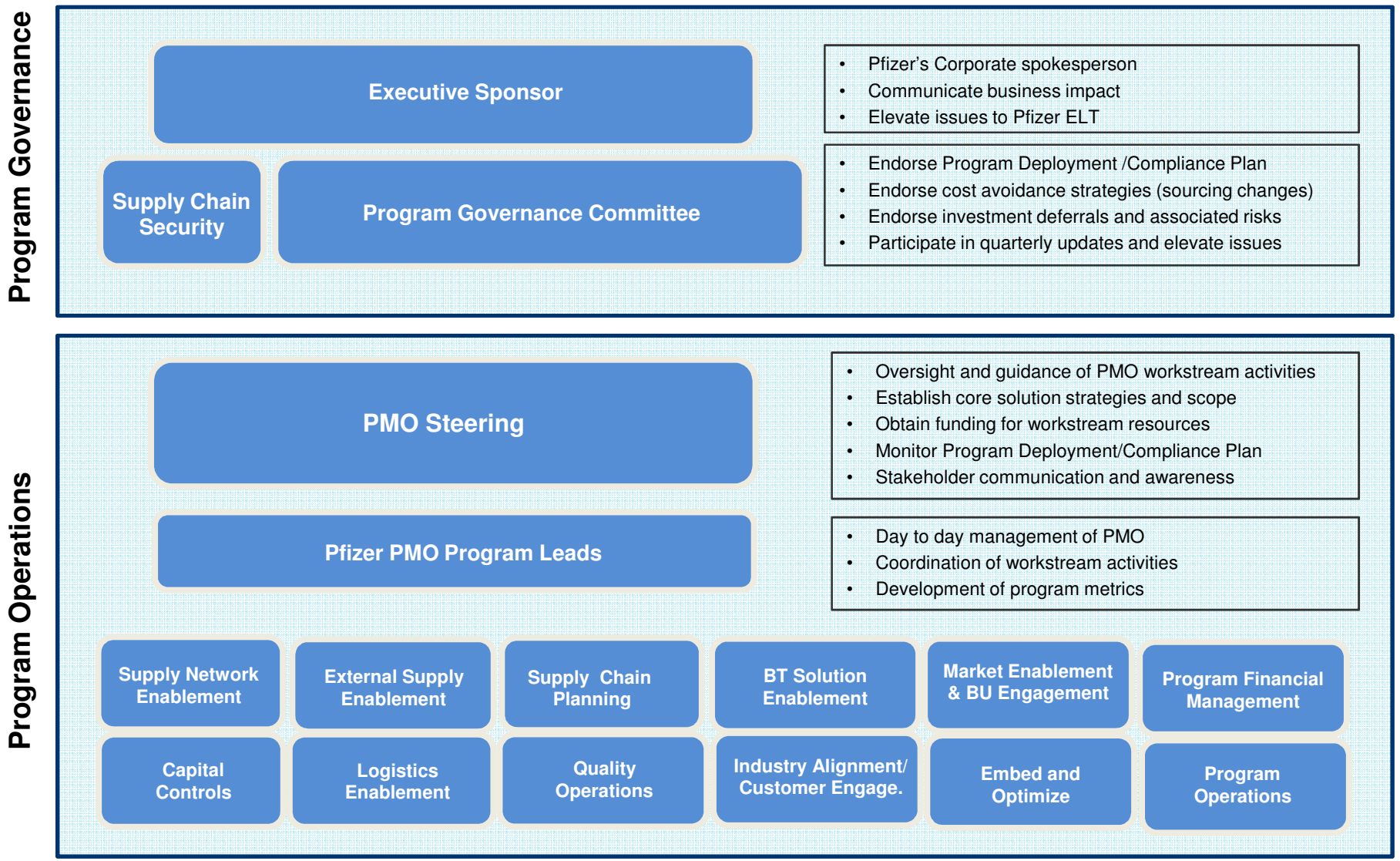
Program Operating Model

Pfizer Global Serialization

6 **Transition to BAU:** *Process standards created for long-term transition to Business as Usual strategy.*



Program Governance



KEY CHALLENGES

Key Challenges

Serialization is a broad and complex area of impact for an organization. We will spend some time explaining key challenges across the program.

Pfizer Program Stats

- 10+ Mandates (current focus)
- 18+ Mandates (monitoring)
- 100+ Sites
- 350+ packaging lines
- ~10,000 SKUs
- 30+ Plant Warehouses
- Thousands of data transmissions

Harmonization and Standardization is key to success!

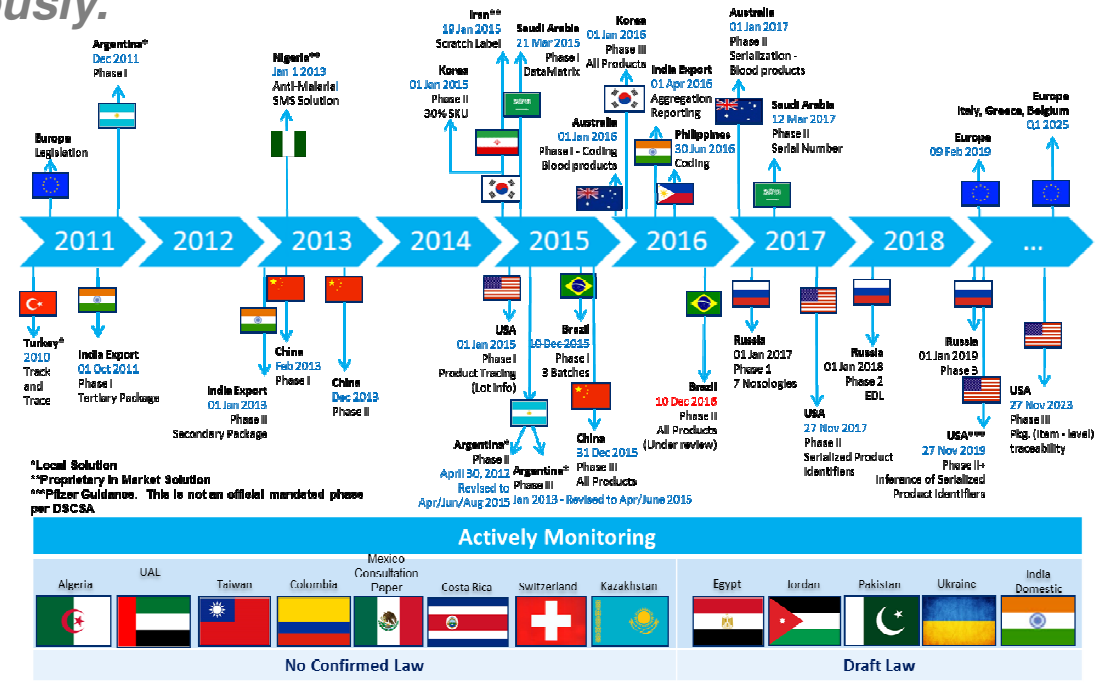
Key Challenges for Discussion:

1. Timelines
2. Project Complexity
3. Stakeholders
4. Operational Impact
5. Journey to BAU

1 Timeline Challenges

Pfizer Global Serialization

Timelines for serialization compliance are often extremely challenging, especially with changing requirements and multiple mandates occurring simultaneously.



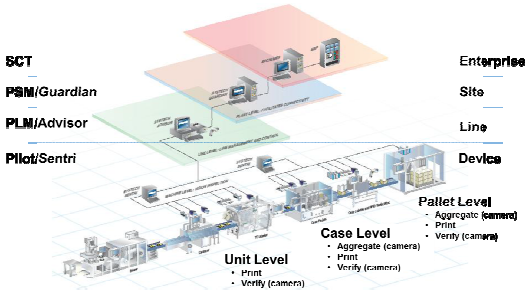
TAKEAWAYS

- Leverage industry trade associations and regulatory groups to drive for reasonable implementation timelines and clear requirements
- Phased implementations are desirable
- Reporting requirements are needed early in the process
- Encourage the adoption of GS1 standards
- Start the implementation process early!

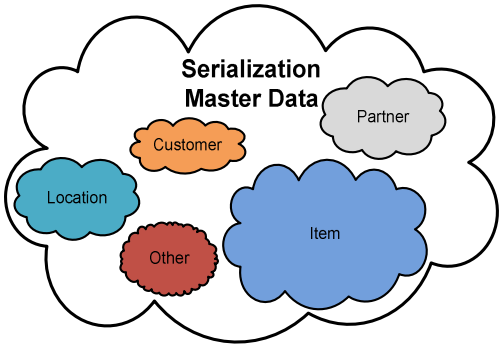
2 Project Complexity

Implementing Serialization is highly complex, and much more than adding packaging line equipment.

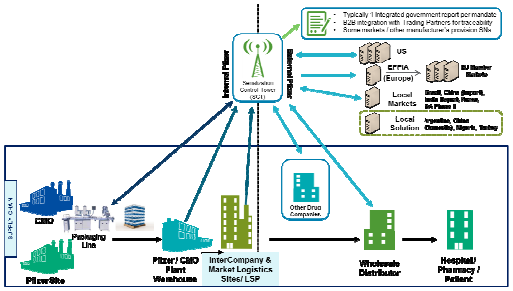
Site/Line Level Technology



Extensive Master Data



Global Technology Solution



TAKEAWAYS

- Standardization of a global technology solution for Serialization data configuration and reporting
- Create interoperability with multiple types of site/line solutions
- Rationalize master data
- Leverage centralized project management capability to ensure compliance to global standards

3 Stakeholders

Serialization impacts a large number of internal and external stakeholders throughout the supply chain.

Network Locations

Packaging Sites
(Pfizer, ES, PC1, etc)

Pfizer / CMO
Plant Warehouse

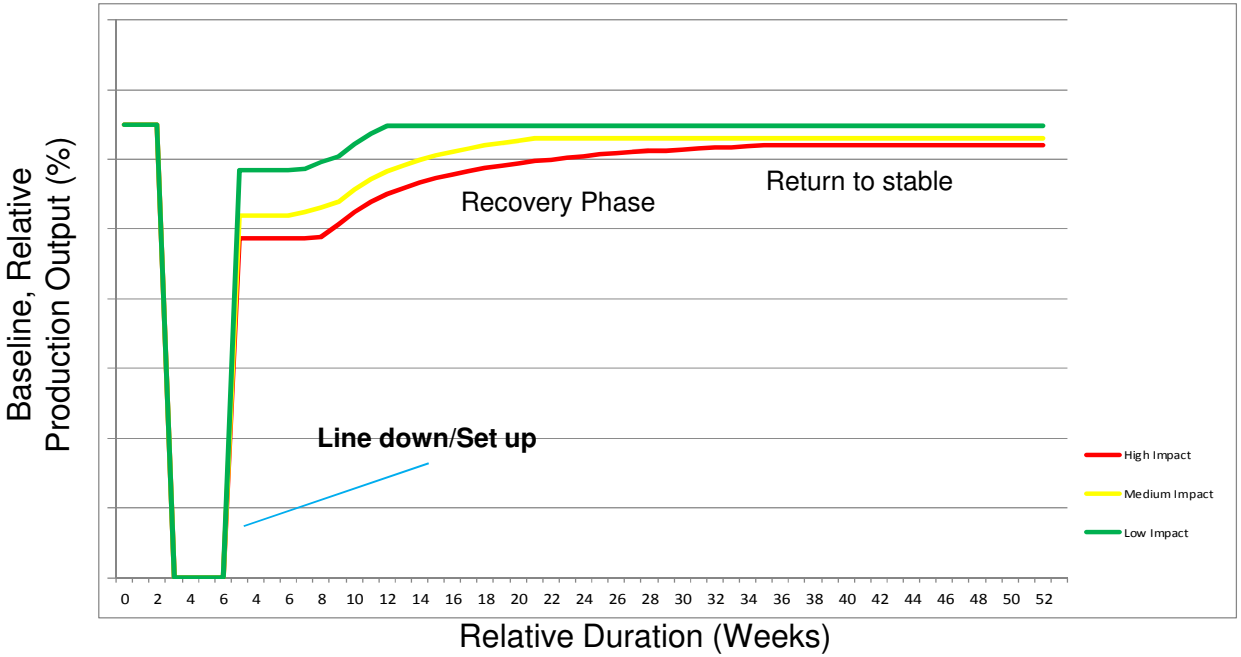
People

TAKEAWAYS

- Campaign for broad organizational awareness of impacts of Serialization
- Leverage a strong governance structure to gain support of senior leaders
- Collaboration with trading partners and regulators is key to a successful deployment

4 Operational Impact

Serialization comes at a large cost (financial and operational) to the organization that must be minimized. Deviations from global standards further increases cost and complexity and reduces efficiency.



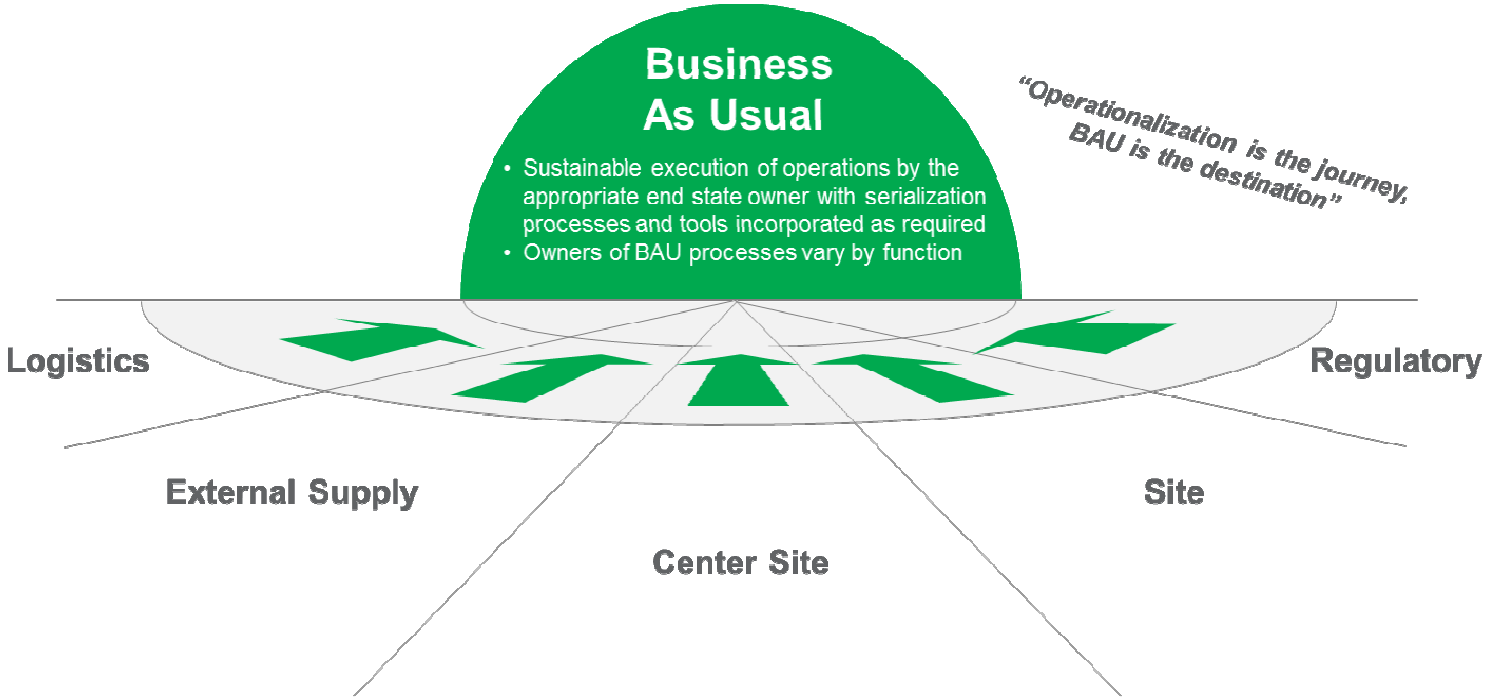
- **Operational Efficiency impacts can be significant in beginning phases, and eventually return to normal**
- **Implementation costs can be high, especially if utilizing a non-standard solution**

TAKEAWAYS

- Align with business and investment plans (network optimization, sourcing strategies, etc.)
- Create harmonized standards, modular builds and consistent timing
- Leverage global solution architecture to improve speed and flexibility
- Focus on sharing learnings and working for continuous improvement

5 Journey to Business As Usual

Achieving initial compliance is the first of many steps towards sustainably embedding serialization in BAU operations.



TAKEAWAYS

- Drive for broad awareness from the onset
- Leverage existing business processes, systems, and stakeholders wherever possible
- Develop solutions with a mindset for future operationalization in the business
- Embed and Optimize

Questions?

Thank You!

Contact Information
Peggy.A.Staver@Pfizer.com

GS1 – China Conference
AmerisourceBergen Overview

DSCSA Activity Update

October 2016

AmerisourceBergen®

Who Are Our Customers?

Pharma Manufacturers

Purchase services that increase product awareness and market share, including:

- Strategic Consulting
- Patient Support Services
- Global Logistics
- Customer Contracting

Healthcare Providers

Purchase pharmaceuticals and healthcare products and provide them to their patients:

- Retail Pharmacies
- Specialty Pharmacies
- Health Systems
- Physicians Offices
- Veterinary Practices

AmerisourceBergen®

Leading Global Healthcare Solutions Company

LEADING PROVIDER OF

- Pharmacy Services Administration Organization (PSAO) services
- Retail pharmacy business consulting
- Patient access services
- Hub programs
- Commercialization services for manufacturers of all sizes
- Sterile compounding solutions
- Unit dose packaging

LARGEST

- **DISTRIBUTOR** of blood plasma, nephrology, vaccine & biological injectable products
- **DISTRIBUTOR** of specialty oncology products to private practice settings
- (Part of largest) Global generics purchasing **ORGANIZATION**

GLOBAL PROVIDER of clinical trial logistics

AmerisourceBergen®

AmerisourceBergen: By the Numbers

$136 Billion
in annual revenue

18,000+
associates

Daily delivery to 50,000+
North American healthcare facilities

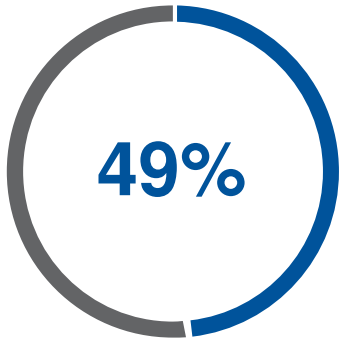
170+
offices

1.5M product lines
delivered from 30+ North American distribution centers

50+
countries

Percentage of major U.S. pharmaceutical manufacturers served

U.S. hospitals served with specialty medications

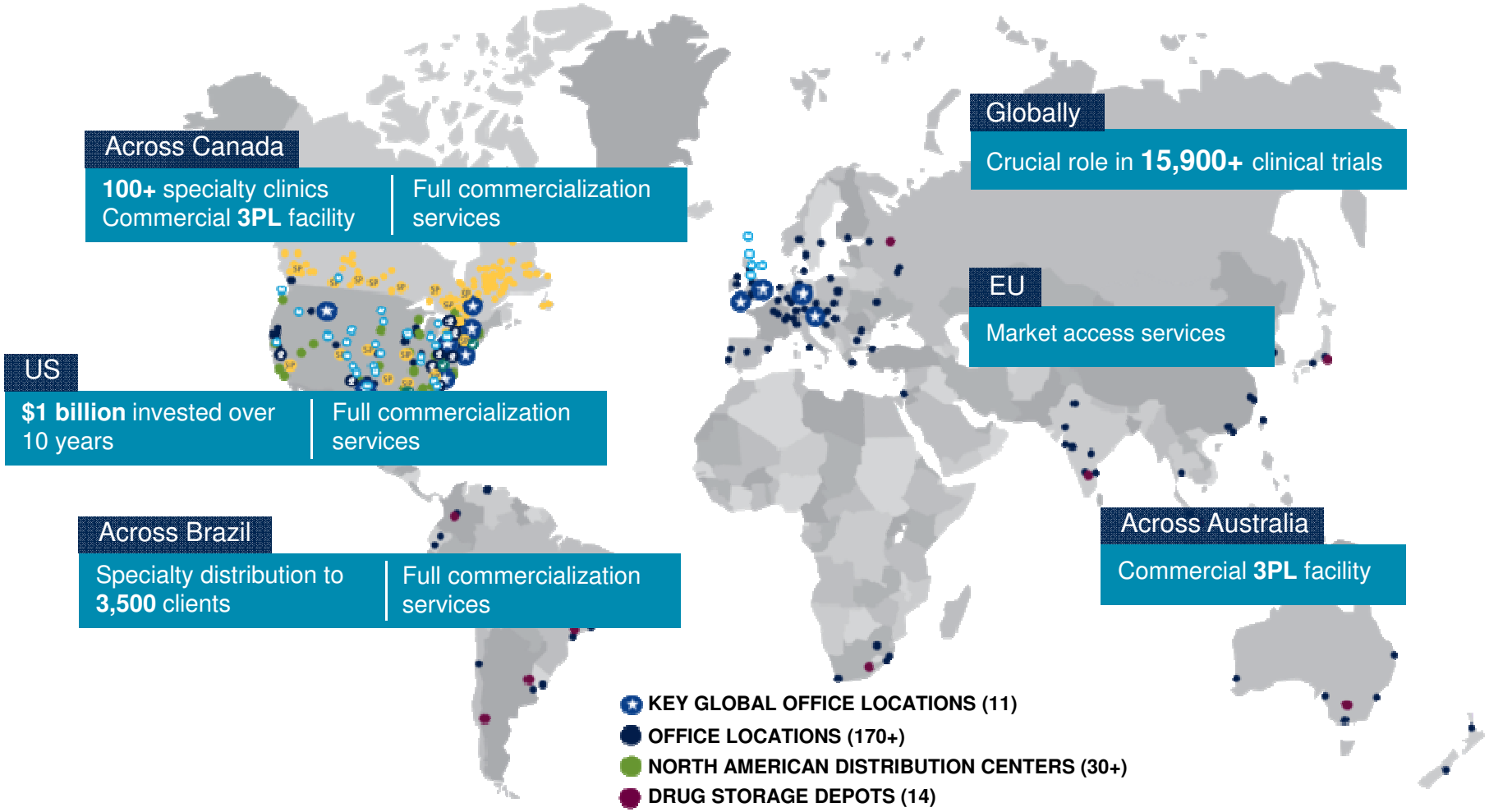


Market share of specialty distribution to U.S. physician practices

AmerisourceBergen®

Expanding global market opportunities

Bridging human and animal health



AmerisourceBergen

Sourcing and distribution

At the core of our business and your success

We drive access to products

- Single point of access for providers
- Serving 60,000+ facilities daily in human health and animal health
- Largest distributor of specialty products in the United States

AmerisourceBergen

US DSCSA Requirements

What industry is currently focused on:

November 27, 2017:

- Manufacturers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.
  - ✓ The serialized barcode contains the following data elements: a product identifier, serial number, lot number and the expiration date.

Global Trade Identification Number (GTIN)
Serial Number (SNI)
Lot (Batch) Number
Expiration Date

November 27, 2018:

- Repackagers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.

*data from June 2014 to June 2015

AmerisourceBergen

US DSCSA Requirements

What industry must plan to deliver:

November 27, 2019:

- Wholesalers may only engage in transactions that have the serialized barcode placed on the package.
- Upon the receipt of a saleable return, verify the serialized barcode is accurate before being able to resell that return, and also associate the transactional information to the returned product.

November 27, 2020:

- Dispensers may only engage in transactions that have the serialized barcode placed on the package.

November 27, 2023

- Manufacturers, wholesalers and dispensers shall exchange the required serialized transactional information in a secure, interoperable, electronic system. Serialized data exchange is required between all trading partners upon a change of ownership.

*data from June 2014 to June 2015

AmerisourceBergen

Business Units Impacted by DSCSA

And associated timeline

DQSA Expectations	Effective Date	AHP	Blue-point	ICS 3PL	ICS Title	ABSG	Onc. Supp	Drug	Thera Com Dist.	Thera Com Pharm.	US Bio	Central Fill
Transactional Information Provided by Manufacturer, Wholesaler and Re-packager	1.1.2015	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Suspect & Illegitimate products - SOP	1.1.2015	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Authorized Trading Partner	1.1.2015	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Transactional Information Accepted by Dispensers	7.1.2015		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Federal Licensure Standards Wholesale/3PL	2015	✓	✓	✓	✓	✓	✓	✓	✓			
Manufacturers Serialize	11.27.2017		✓									
Re-packagers Serialize	11.27.2018	✓										
Wholesalers Accept/Sell Serialized Product & Validate Serialize Number on Saleable Returns	11.27.2019	✓			✓	✓	✓	✓	✓			
Dispensers cannot accept product that is not serialized	11.27.2020									✓	✓	✓
Complete Traceability	11.27.2023	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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ABC DSCSA Program Objectives:

:

- One ABC Enterprise System – Add Value to the Business
  - Single point of data exchange environment
  - One source of truth to customers, suppliers and regulators
- Managed as an Enterprise Program – Leverage Existing Synergies
  - Various teams engaged representing all company sectors and IT
  - Budget managed at the Enterprise Level
- Deliverables will exceed all regulatory mandated timelines
- Leverage Existing Customer Solutions
- Leverage Existing Investments
  - Object Event Repository (OER) – Processing Rules and Data Storage
  - Process Integrator (PI) – Data Transfer and Translation
  - New – HUB / Cloud Service (Pharma Hub Network)

*data from June 2014 to June 2015

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DSCSA Time Frame

Timeline of Requirements

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2019 Saleable Returns

What is the impact to AmerisourceBergen

- Annual revenue dollar: $2.1B per year.
- 15,259,042 saleable returns per year.
  - Representing 2% of our annual business revenue and 1.7% of all units.
- Daily number of saleable returns across network: 62,000 →115,000.
- ABDC peak number of saleable returns for a Greenfield: ~10,000 units per day.
- ABSG average number of salable returns ~200 units per day.

No established industry solution to manage serialized returns

*data from June 2014 to June 2015

AmerisourceBergen

HDA Returns Pilot Objectives

- Gain key learnings on various processes to address salable return
- Illustrate to members of the supply chain the relative practicality of possible solutions
- Identify where standards can be applied for simplification in the communications and providing access to information via interoperable systems.
- Provide data to the FDA to illustrate the realities faced by manufacturers and wholesalers in processing DSCSA compliant saleable returns.
- Begin the process of building consensus on likely approaches that will work without adding significant burden to the supply chain.

AmerisourceBergen

Scenario List of Saleable Returns Options

	Number	Scenario Description
Live Pilots	1	Manufacturer sends purchased unit product identifiers to respective wholesale distributor
	3	Central repository – manufacturers send all data to central database which the distributors accesses for verification
	7	Distributors scans product on outbound
	9	Verification Discovery Router Service – distributor query is routed to appropriate manufacturer database
Desktop Pilots	5	Distributor accesses each manufacturer's database through portal
	8	Distributor manually confirms with manufacturers at time of return via phone or email
White Papers	2	Manufacturer sends product identifiers for all units shipped within the U.S. to all direct purchase distributors
	4	Verification services – Distributor builds point-to-point interfaces to each manufacturer's verification service, which automatically returns a verification response
	6	Distributor scans all purchased product identifiers on inbound receipt

AmerisourceBergen

Internal and HDA Sponsored Pilots: ABC Key Learnings

- AmerisourceBergen:
  - **What worked well?**
    - > Executed end to end process flow.
    - > Coordination and execution with our partners.
    - > Captured 90,000 inbound GS1 EPCIS SNI's for Commissioning Events, ~700 Scans within our DC's
  - **Where were there bumps?**
    - > GS1 EPCIS Data Exchange.
    - > Some scanning challenges.
  - **What did we learn?**
    - > Not all labeling is equal.
    - > Operational impacts were significant.
    - > Exceptions WILL be a challenge in both data and processes.
    - > Data exchange… Test. Test. Test.
- **SAP:**
  - ATTP performed better than expected and allowed for the flexibility necessary to process transactional files
  - Pharma Network performed as expected directing electronic traffic as needed

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Packaging “Shipper/Case” Current State

Huge variations in conformance to guidelines and standards

AmerisourceBergen

DGFT… impact on US Supply Chain Management

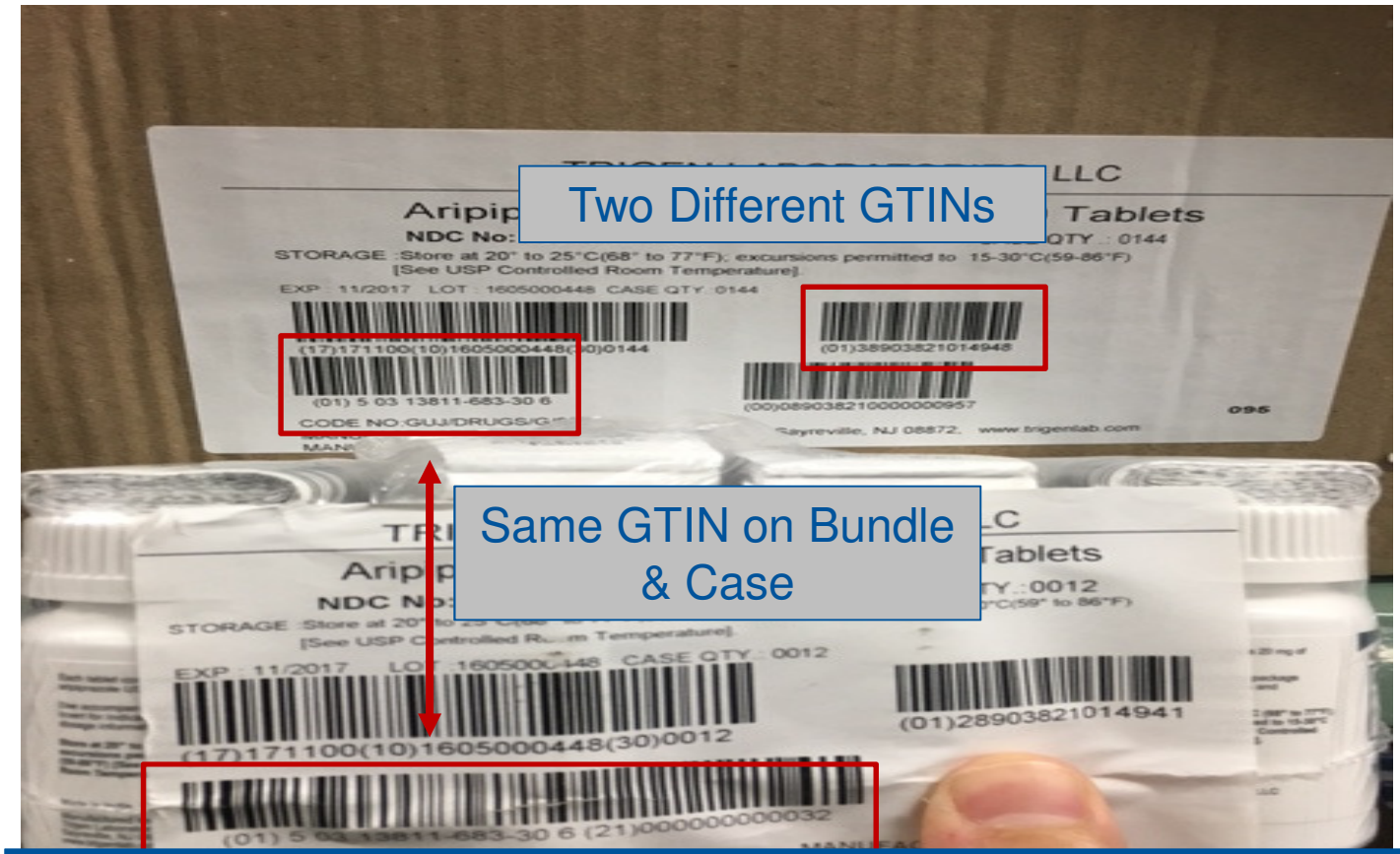
Tertiary and Secondary GTIN on Same Homogenous Case

Per SNI & GS1 Standards you can have only ONE GTIN per Current Trade Item &
SSCC Contained on case that was NOT a logistic unit

AmerisourceBergen

DGFT… impact on US Supply Chain Management

Tertiary and Secondary GTIN on Same Homogenous Case, Tertiary GTIN ALSO on Inner pack



You can not have the same GTIN on different levels of packaging
SSCC Contained on case that was NOT a logistic unit

AmerisourceBergen

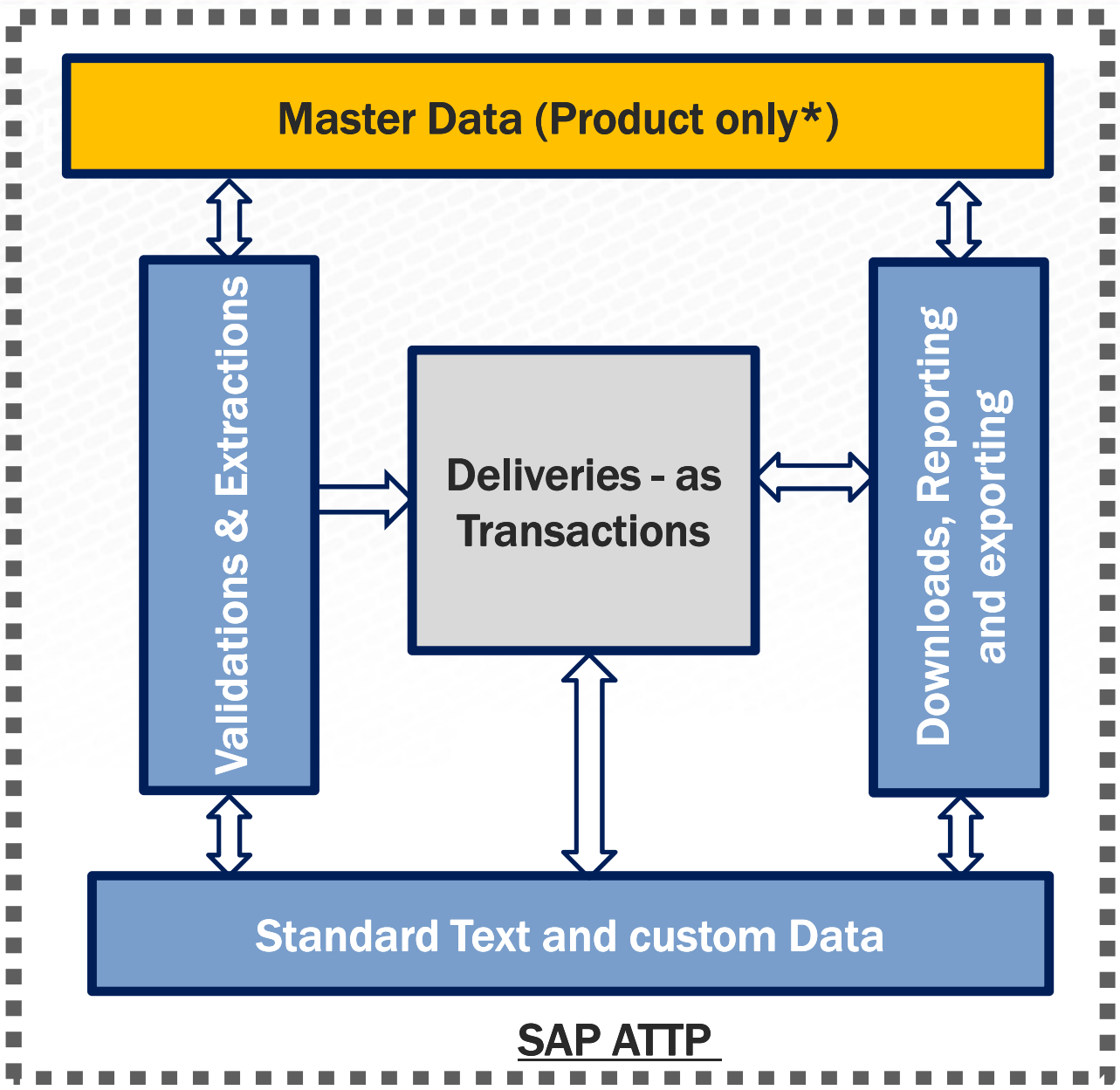
DGFT… impact on US Supply Chain Management

Duplicate GTIN on Case

Same GTIN Printed Twice??? And
SSCC Contained on case that was NOT a logistic unit

AmerisourceBergen

How do you function with “standards"?
✓ Flexibility while keeping end state in focus!



Legends

ATTP Release 2

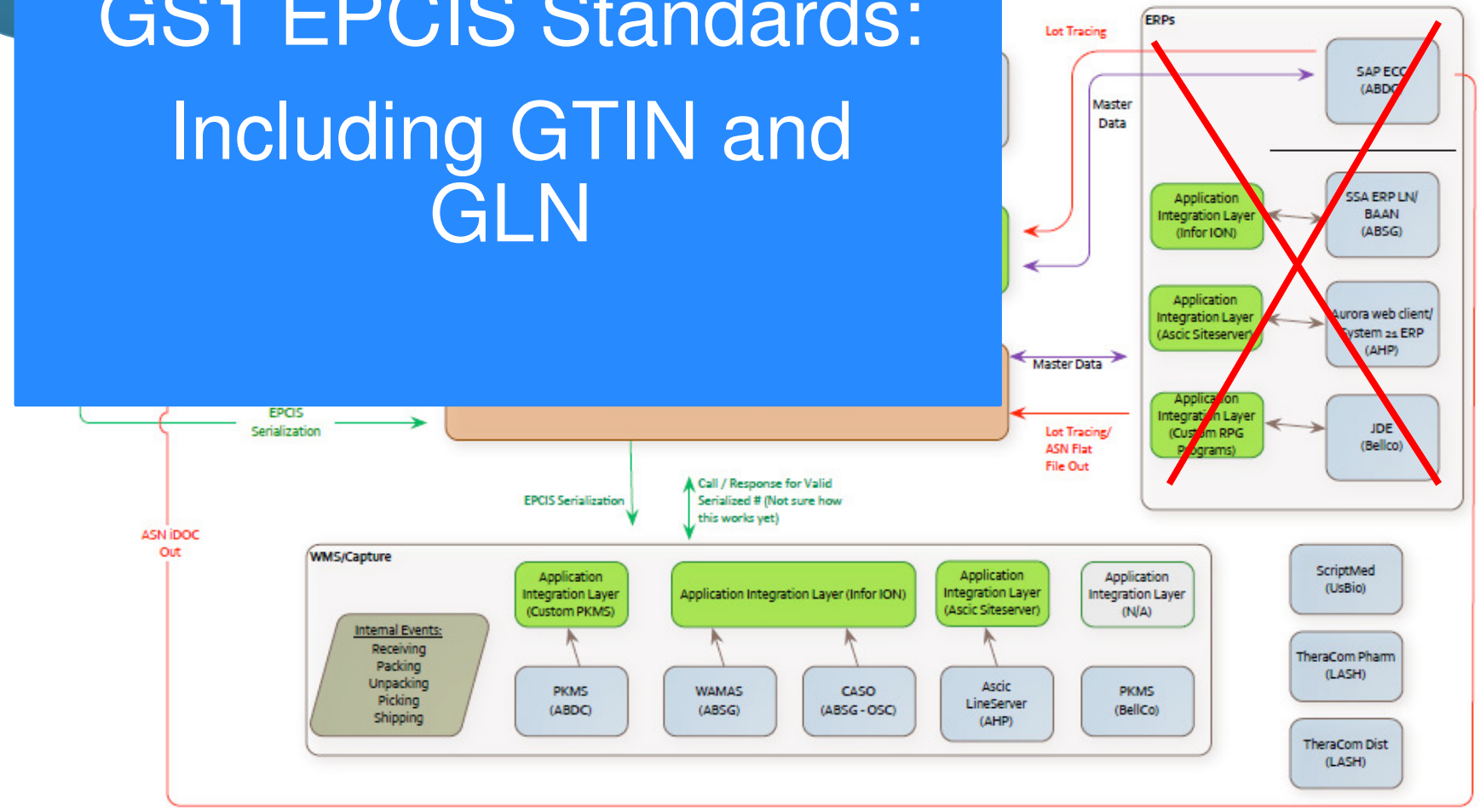
Standard ATTP with additional enhancements

Custom ABC

AmerisourceBergen®

IT: Service Model – GS1 Standards Based Approach

GS1 EPCIS Standards: Including GTIN and GLN



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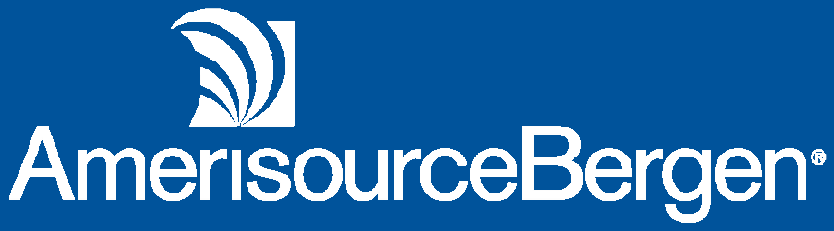


Where knowledge,
reach and partnership
shape healthcare delivery.

Johnson & Johnson SUPPLY CHAIN

Johnson & Johnson Supply Chain's Experience:
Pharmaceutical Traceability – what does it mean for a pharmaceutical manufacturer

Mike Rose
Vice President, Supply Chain Visibility
October 25, 2016

Johnson & Johnson

Global Presence

- Global leader in Health Care
- More than 275 operating companies in 60 countries
- Selling products in more than 175 countries
- Approximately 128,000 employees worldwide

Johnson & Johnson Aspiration

Caring for the world, one person at a time, inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Johnson & Johnson Credo

COMMON SET OF VALUES UNIFYING DIVERSE BUSINESS

- Created in 1943
- Drives deep commitment to ethical principles
- The Four Tenets
  - Customers
  - Employees
  - Communities
  - Stockholders

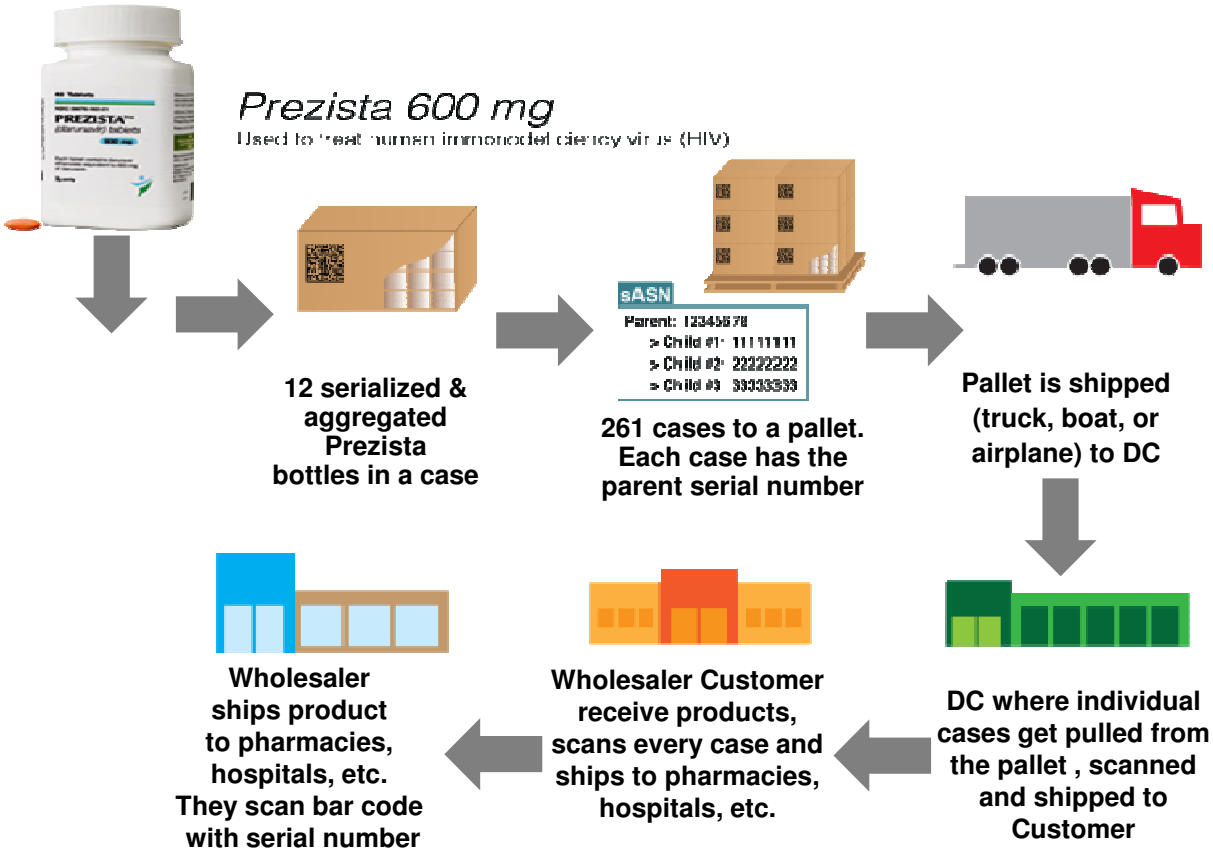
Serialization

Item level serialization using GS1 standards

A **unique identification number** is assigned to **each item** identifying it with a product number and associated serial number. It's applied at every package level (bottle, case, and pallet).

Track & trace

Traceability using GS1 and EPCIS standards



Regulatory mandates are demanding visibility of products from point of packaging to point of dispense.

- These mandates demand improved supply chain visibility
- Products are identified, serialized, authenticated, tracked & traced
- What product? Where has it been? Where is it going? How long has it been there?
- Using data captured as product moves through the supply chain, answers questions as to the disposition of inventory

The importance of standards

- Ability to make and deliver anywhere
- More efficient and cost effective infrastructure
- More efficient product handling
- Consistent look for our products
- Enable quick searches to track serialized product status

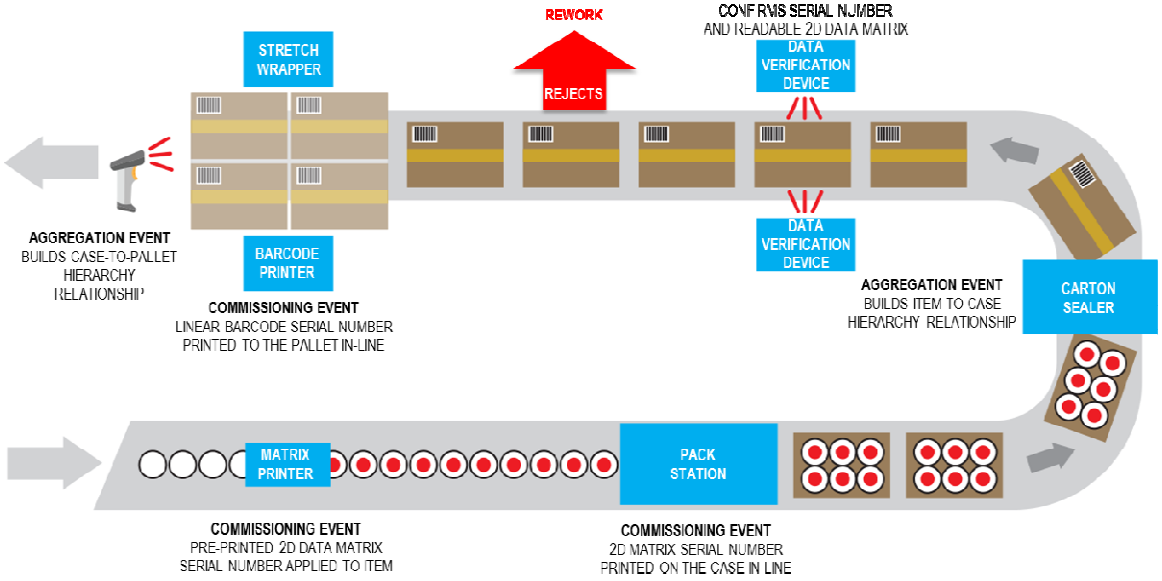
Practical lessons learned

Manufacturing benefits realized through standards, process improvements and information

- Reduction of manual work, increase in productivity
- More precise data aids investigations of deviations
- Increased efficiency in product issue resolution
- Improvements in label print quality
- Reduction in amount of disposable materials and waste

Practical lessons learned

Distribution center operations

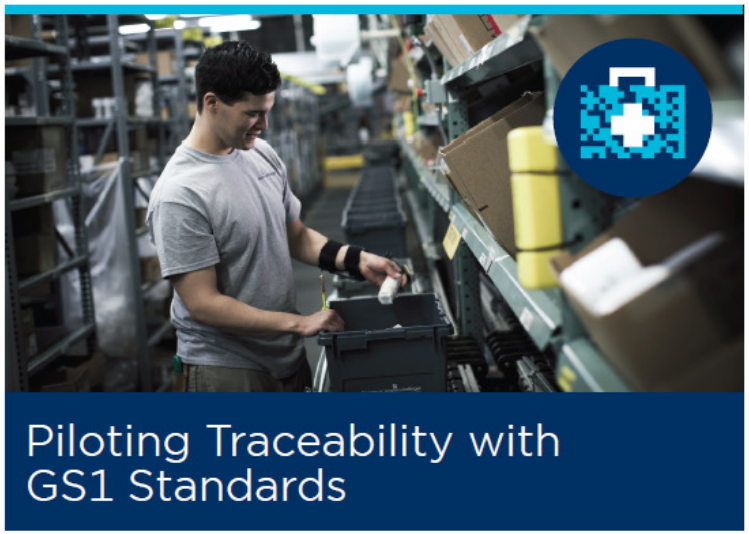


- **NO** additional headcount was necessary
- Savings from better accuracy and standardized labelling for error correction
- Higher fidelity inventory accuracy and visibility
  - Reduced need for checks and counts
  - Reduction in claims and credits

Practical lessons learned

Customer track & trace pilots

CASE STUDY



Piloting Traceability with GS1 Standards

AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings

CHALLENGE

The Federal Drug Administration (FDA) regulation requires that the pharmaceutical industry implement end-to-end traceability by 2023. Trading partners throughout the supply chain must implement and test GS1 Standards-based solutions in real-world pilots to meet the deadline for interoperability.

SOLUTION

- Collaboration pilots is critical
- Enabled through GS1 standards
- Clear interpretation of standards
  - E.g., expiry date, unit of measure
- Process alignment
  - E.g., data must arrive before physical product
- Opportunities for value creation

Brazil pharmacy pilot

Regional pilot to test feasibility of scanning

- Internal and external collaboration
- Identify suspect or illegitimate product
- Scanned and verified serial number

EU Falsified Medicines Directive

Product safety seatures

Authenticity

Pack Identity

Tamper evidence

Medicines Verification System

Feb 9, 2019

Good distribution

Wholesalers & Brokers

GDP

2013-Q1

Active substances

GMPs for excipients

Jan 2, 2013

Registration API activities

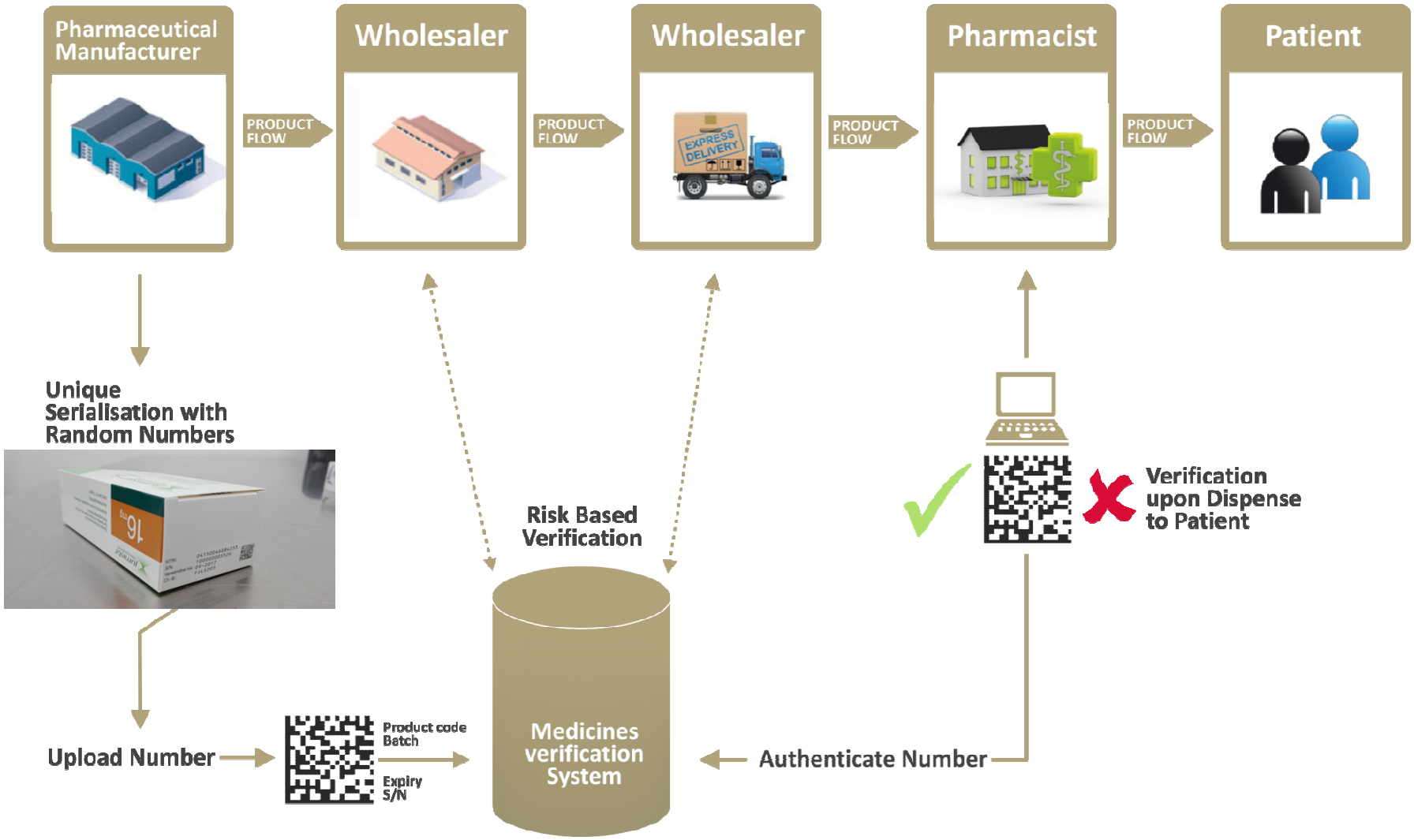
July 2, 2013

Internet sales

Community logo

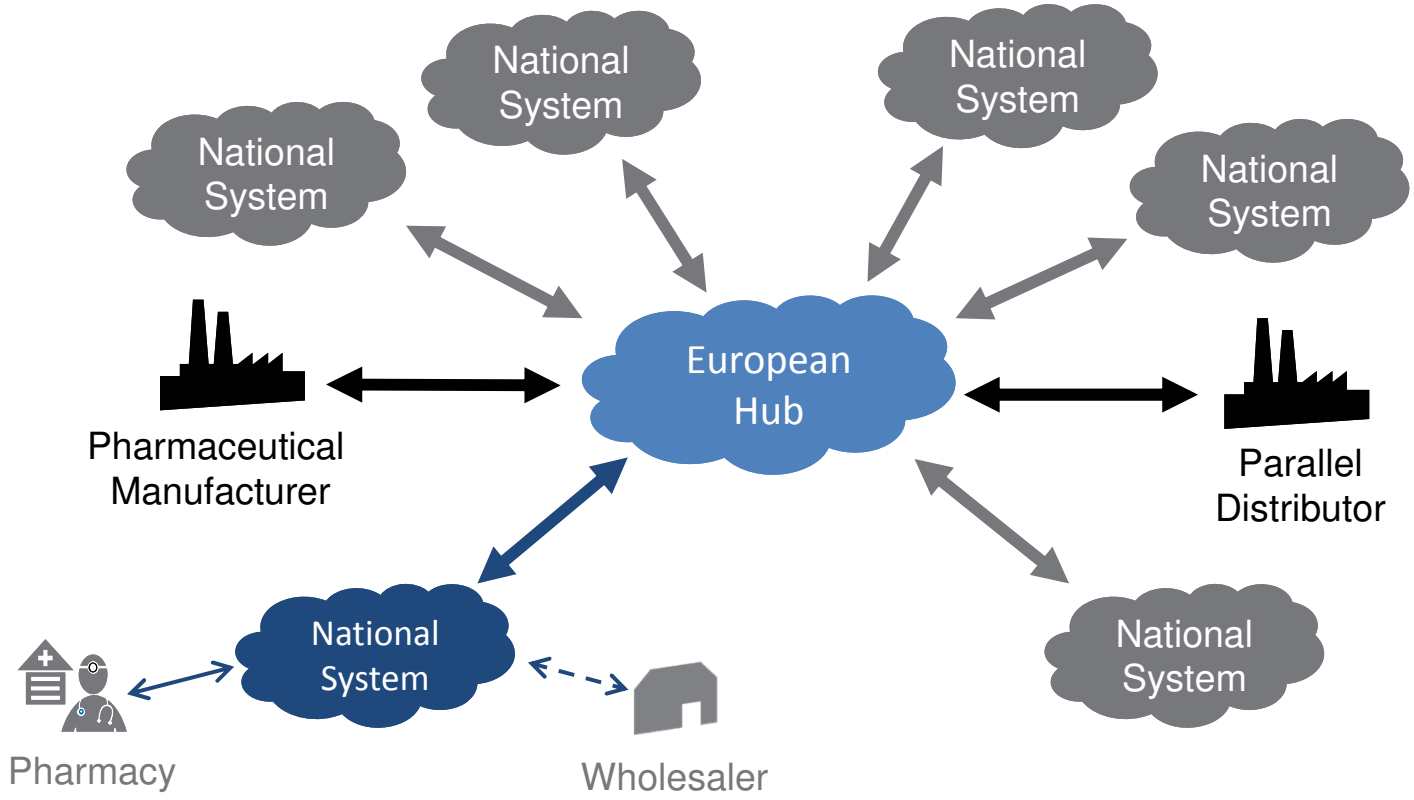
2015

Point of dispense verification



Pan-European System

National verification Systems (NMVS) connected by the European Hub



European Stakeholder Model

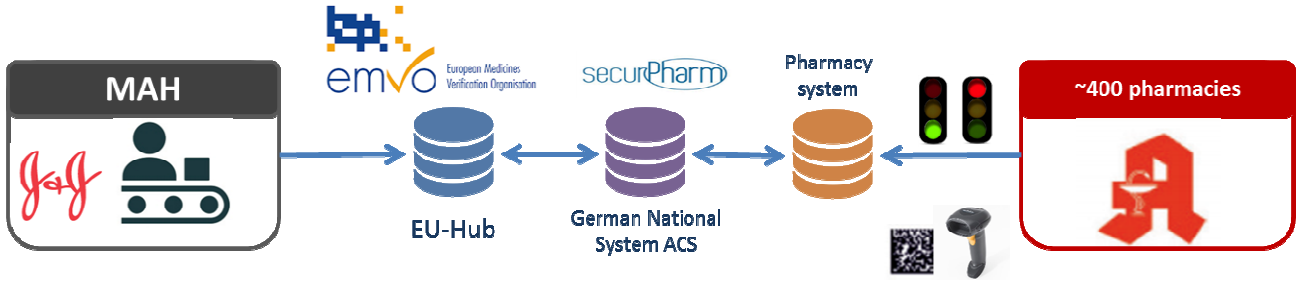
Aligned to a Common vision to protect patients

- Protect patients
- Secure the legitimate supply chain
- Be proactive as market partners
- Formed a stakeholder-governed model that is
  - ✓ Functioning
  - ✓ Harmonised
  - ✓ Cost-effective
  - ✓ Inter-operable
- Established the European Medicines Verification Organization (EMVO)

German securPharm pilot

Pharmacy point of dispense verification

- Approximately 400 pharmacies
- Partnership between pharmacies and manufacturers
- Receive scan confirmation



Traceability challenges encountered

- Serialization adds extra layer of complexity
- Aggregation adds ~50% cost and implementation time
- Protecting impact to overall equipment effectiveness (OEE)
- Alignment with external manufacturers

Solutions implemented

Critical components to manage risk and drive consistency

- Utilize GS1 standards
- End-to-end view
- Multi-tiered governance structure
- Vendor management program
- Serialization training centers
- Change management program
- Customer collaboration pilots

7 Billion Reasons to Care

Serialization and track & trace will benefit patients and consumers around the globe

EU – 2011, 2016
Falsified Medicine Directive (FMD)

Status: Directive 2011/62/EU on prevention of the entry into the legal supply chain of falsified medicinal products

Scope: Pharmaceuticals – prescription drugs

Purpose: Counterfeiting

Requirements : composition, format & carrier of the unique identifier **fully harmonised**

- Packaging level: secondary level packaging
- Data elements: Unique identification number, Batch/Lot number, Expiry date, Serial number, national reimbursement number (if applicable)
- Data carrier: DataMatrix for unique identification (possible QR for marketing purposes)
- Deadlines:
  - 2011: Adoption of a new Directive on falsified medicines (FMD)
  - 9 Feb. 2016: Publication of the Delegated Acts on harmonised safety features
  - 2019 (+ 6 years if preexisting measures : EL, IT, BE): requirements implementation

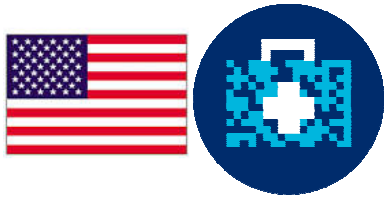
Data Submission Portal: Stakeholder model – EMVO

Traceability Model: Authentication model

Open point(s)/upcoming dev.: Delegated Acts adopted on 2 Oct. 2015 and published on 9 Feb. 2016 (date of publication is to be taken into account for the calculation of the implementation deadlines).

FAQs released by EC (not mandatory) and Implementation plan released by EMA on 9 Feb. 2016.

USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)



Status: Legislation

Scope: Pharmaceuticals (prescription drugs)

Purpose: Traceability, combat counterfeit

Requirements as applicable:

- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines:

- First phase lot based (2015) – delayed to 1 March 2016 for dispensers
- Serialisation (SNI) after four years (2017)
- Full track & trace after 10 years (2023)

Data Submission Portal: Not determined, under discussion

Traceability Model: First lot based traceability, full track & trace in 10 years

Open point(s)/upcoming dev: US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance

GS1 US Rx Guideline for DSCSA(www.GS1US.org/RxGuideline): includes application of EPCIS for serialized item-level traceability

PP Database Dossier #: 738USAPH140430

Argentina 2011, 2012, 2013, 2015, 2016 Serialisation

Status: Regulation on traceability system for the control of pharmaceutical products from the manufacturer to the patient
Scope: Pharmaceuticals
Purpose: Supply chain efficiency

Requirements as applicable:

- **AIDC**:
- Packaging level: Secondary packaging
- Data elements: GTIN, Serial Number - AI (21)
- Data carrier: GS1-128, DataMatrix, RFID tag
- Deadlines: different for product classes (2011, 2012, 2013, 2015)
- **Data Submission Portal :** Central database hosted by ANMAT
- **Traceability Model :** Track & Trace

- **Open point(s)/upcoming dev.:**

Disposición 963/2015 expends the ANMAT drug traceability system to 33 more drugs by 2 March 2015.

Circular 0002-15 provides 3 deadlines for implementation for products already regulated by previous ANMAT requirements: 30th April 2015, 30th June 2015 and 30th August 2015.

ANMAT released a new Regulation on drug traceability: Disposition 10.564/2016 published on September 23, 2016.

This Regulation is not amending the current traceability system but its scope.

Wholesaler Perspective on Traceability

October 25, 2016

Scott Mooney
Vice President Distribution Operations

McKESSON

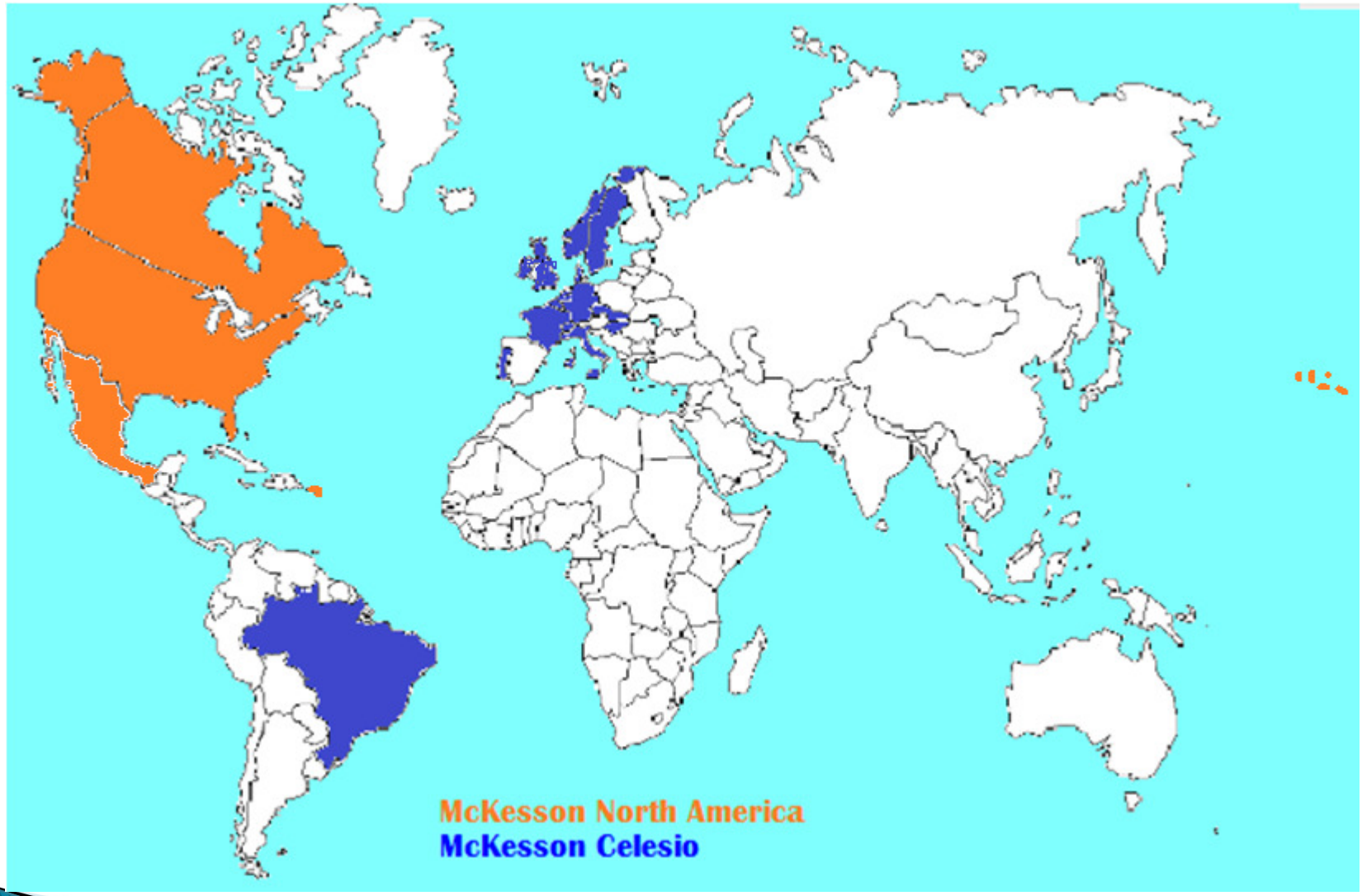
McKesson Distribution Solutions

- U.S. Pharmaceutical
- McKesson Canada
- Celesio (Europe and South America)
- McKesson Medical-Surgical
- McKesson Specialty Health
- McKesson Pharmacy Systems and Automation
- * McKesson Packaging Solutions

McKesson Technology Solutions

- McKesson Health Solutions
- Imaging and Workflow Solutions
- Connected Care and Analytics
- Business Performance Solutions
- Enterprise Information Solutions

#5 on Fortune 500


McKesson North America
McKesson Celesio

McKESSON

McKesson is an industry leader in:

- Pharmaceutical distribution in the U.S.,Canada and Europe
- Medical-surgical distribution to alternate care sites
- Generics pharmaceutical distribution
- Medical-management software and services to payers
- Business and clinical services for providers
- Connectivity services

More than **200,000** physicians use our technology and services

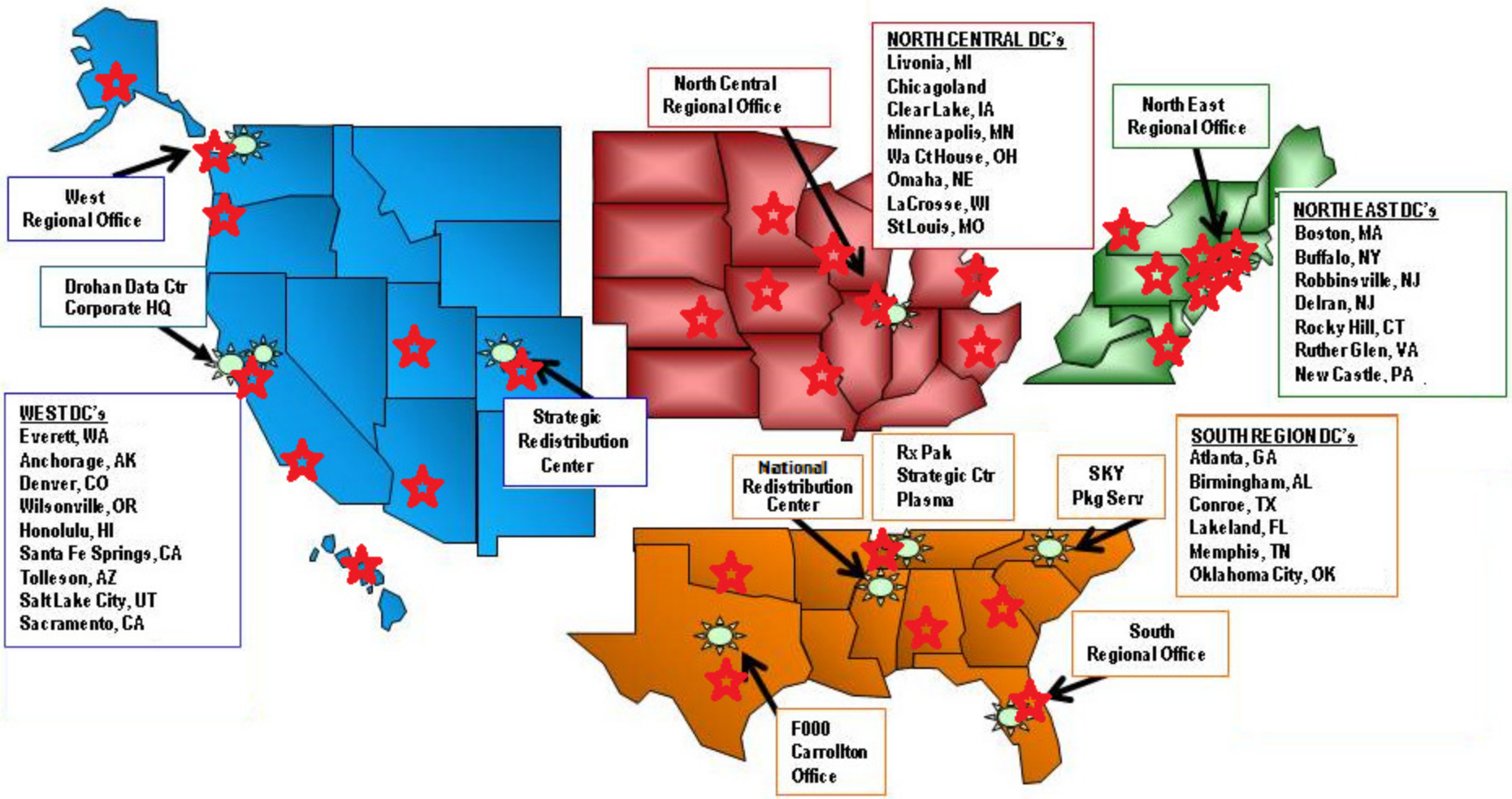
1/3 of all pharmaceuticals used each day in North America are delivered by McKesson

4th largest pharmacy chain

3,000+ retail pharmacies are members of our Health Mart® franchise

76% of hospitals with >200 beds are McKesson customers

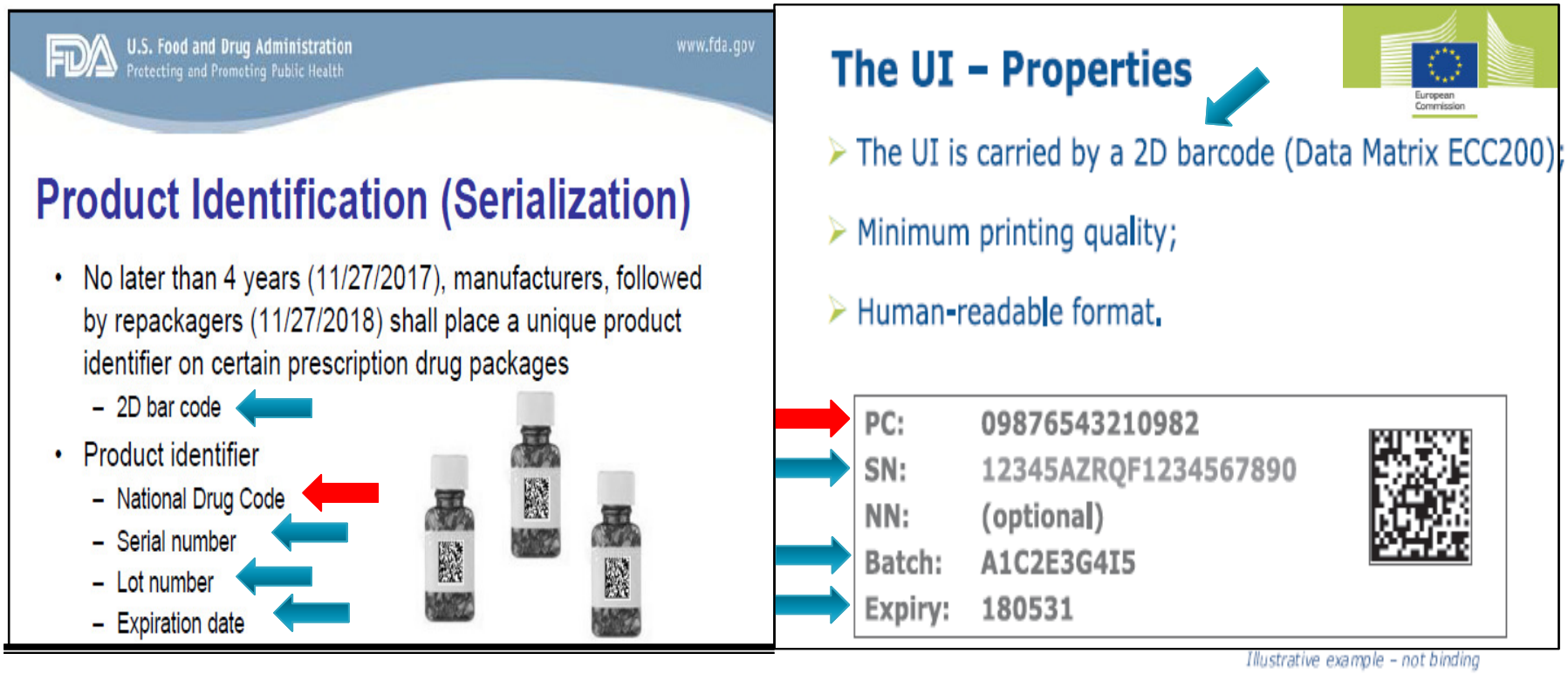
100% of the top 25 health plans are McKesson customers


West
Regional Office
Drohan Data Ctr
Corporate HQ
WEST DC's
Everett, WA
Anchorage, AK
Denver, CO
Wilsonville, OR
Honolulu, HI
Santa Fe Springs, CA
Tolleson, AZ
Salt Lake City, UT
Sacramento, CA
Strategic
Redistribution
Center
North Central
Regional Office
NORTH CENTRAL DC's
Livonia, MI
Chicagoland
Clear Lake, IA
Minneapolis, MN
Wa Ct House, OH
Omaha, NE
LaCrosse, WI
St Louis, MO
North East
Regional Office
NORTH EAST DC's
Boston, MA
Buffalo, NY
Robbinsville, NJ
Delran, NJ
Rocky Hill, CT
Ruther Glen, VA
New Castle, PA
National
Redistribution
Center
Rx Pak
Strategic Ctr
Plasma
SKY
Pkg Serv
SOUTH REGION DC's
Atlanta, GA
Birmingham, AL
Conroe, TX
Lakeland, FL
Memphis, TN
Oklahoma City, OK
South
Regional Office
F000
Carrollton
Office

Network Statistics

- 33,000 Customers Delivered Daily
- 23,000 Products Stocked (Rx and OTC)
- Order cut offs as late as 9pm local
- 90% Deliveries before 11am local
- 4800 Purchase Orders received daily
- 1.8 Million cases per month transferred
- 840 Thousand cases delivered to customers per month

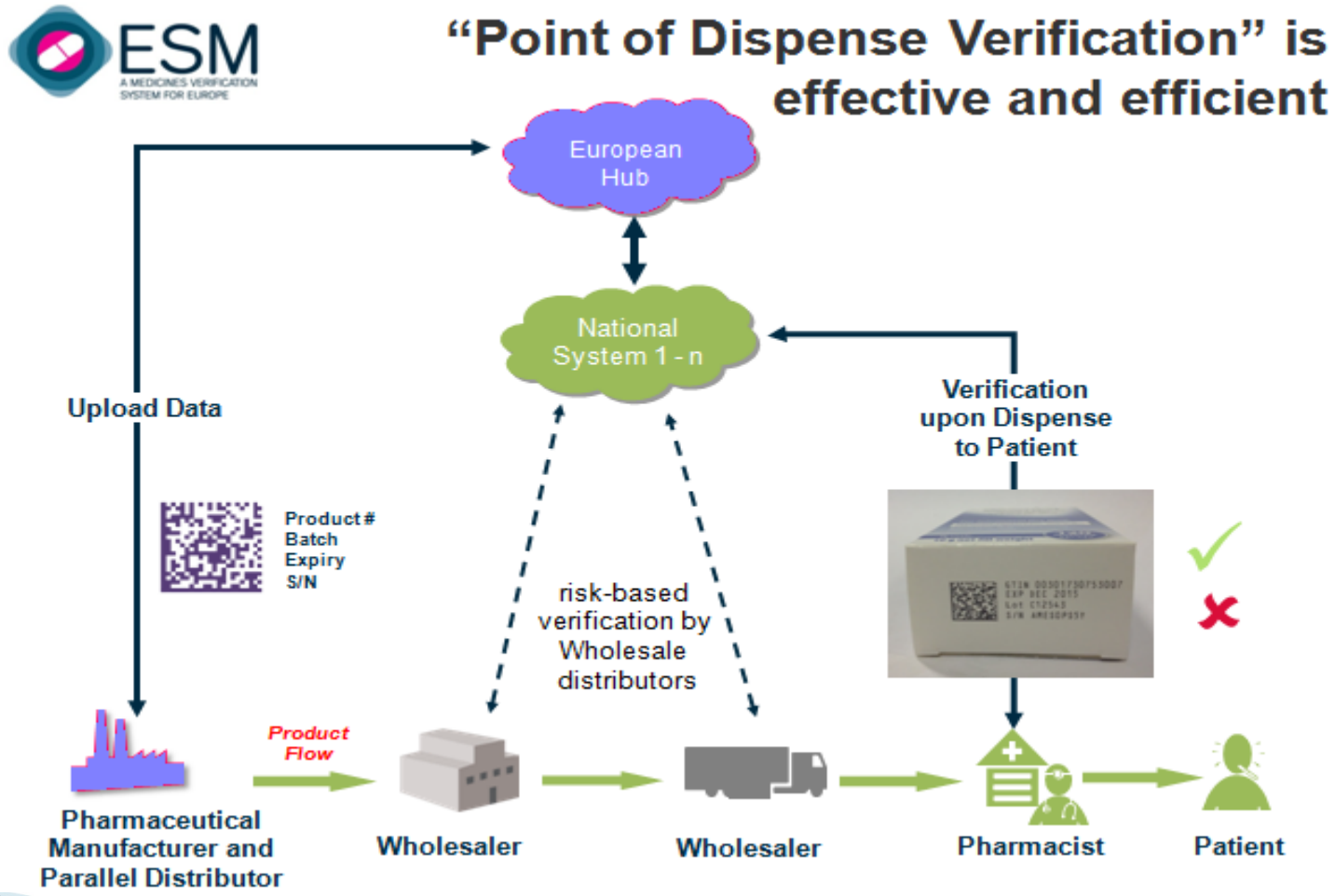
Product Encoding



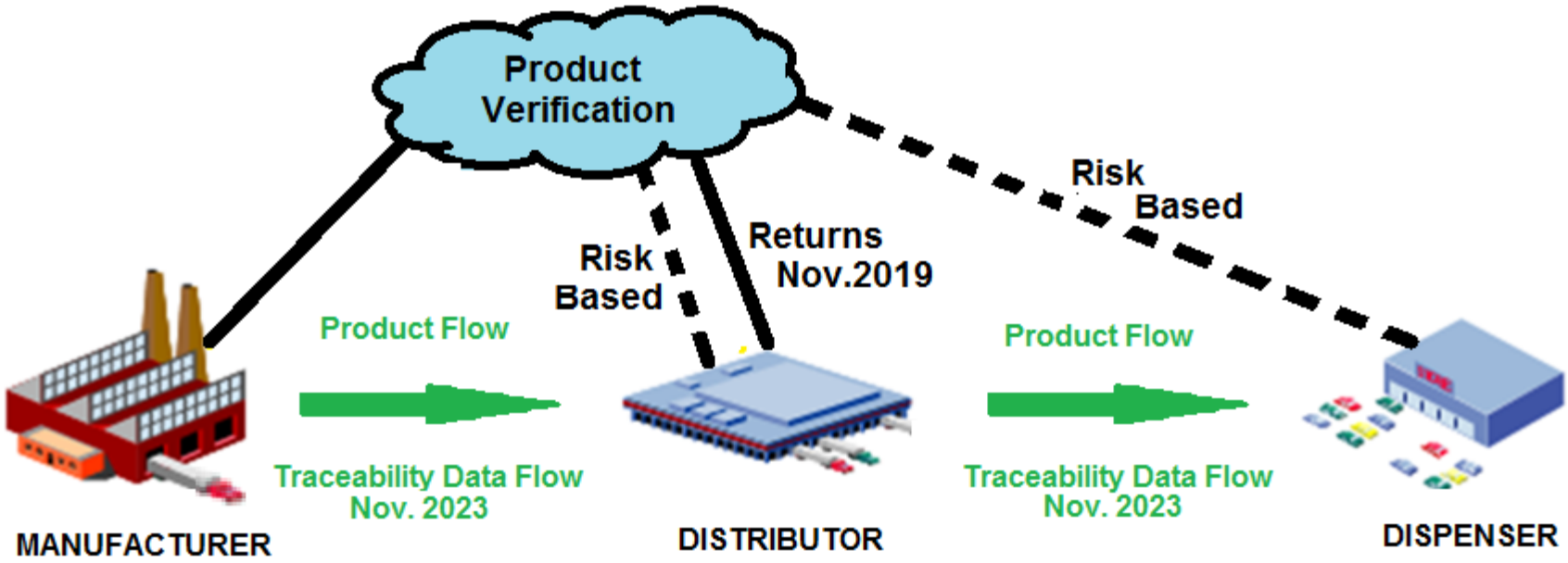
Encoding is nearly the same in the US and EU

US requires NDC embedded in GTIN

EU FMD Model


ESM
A MEDICINES VERIFICATION SYSTEM FOR EUROPE
"Point of Dispense Verification" is effective and efficient
European Hub
National System 1 - n
Upload Data
Product #
Batch
Expiry
S/N
risk-based verification by Wholesale distributors
Verification upon Dispense to Patient
Product Flow
Pharmaceutical Manufacturer and Parallel Distributor
Wholesaler
Wholesaler
Pharmacist
Patient

US DSCSA Model



Model Requirements

- Manufacturers identify who serial products are sold to and send DSCSA data
- Distributor to receive/send DSCSA data for every transaction with a trading partner
- Distributor must verify returned goods before restocking
- Dispenser may verify on a risk based approach but is not required

- Manufacturers post commissioned serial products to European Hub
- Distributors to verify on a risk based system
- Dispenser must verify before dispensing to patient

Distributor Implications

- Distributors will transact twice as much data as manufacturers and dispensers
- Distributors fulfill both full case and each unit sales with dispensers
  - The knowledge of the relationship between inner and outer packaging will be critical to capture serial numbers
  - Customer often purchase full cases and return an each
  - Aggregation would answer this for US

- Case, bundle and each serials may be posted to European Hub
- Aggregation unnecessary to post serials for verification

Readiness

- 2D Barcodes beginning to appear on packaging
- Estimate no more than 15% of selling units currently have 2D bar code on them
- Lots of issues with data formats at this time
  - Incorrect GTIN for intended country
    - Origin country and intended country standards differ
  - Date formats not following GS1 standards
- Scanning technology requires upgrading to imagers
  - White on Black vs. Black on White
  - 2D vs. Linear capability
- Not all 2D bar codes are serialized

Resources

- "A European Medicines Verification System" presentation by Grant Courtney at Global GS1 Healthcare Conference, Copenhagen, Denmark, April 2014

- "EU Falsified Medicines Directive – EU Commission, DG Health and Food Safety" presentation by Patrizia Tosetti, Policy Officer at GS1 Global Healthcare Conference, Dubai, UAE, April, 2016

- "Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act) Taking a Step To Further Protect Public Health" presented by Connie Jung, RPh, PhD, U.S. Food and Drug Administration, Silver Spring, MD June 4, 2014

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Panelists

Pharmaceutical Traceability for Manufacturers & Wholesa

- Ms. Peggy Staver, Pfizer

  Director, Product Integrity

- Mr. Jeffrey Denton, AmerisourceBergen Corporation

  Senior Director, Secure Supply Chain

- Mr. Michael Rose, Johnson & Johnson Supply Chain

  Vice President, Supply Chain Visibility

- Mr. Scott Mooney, McKesson

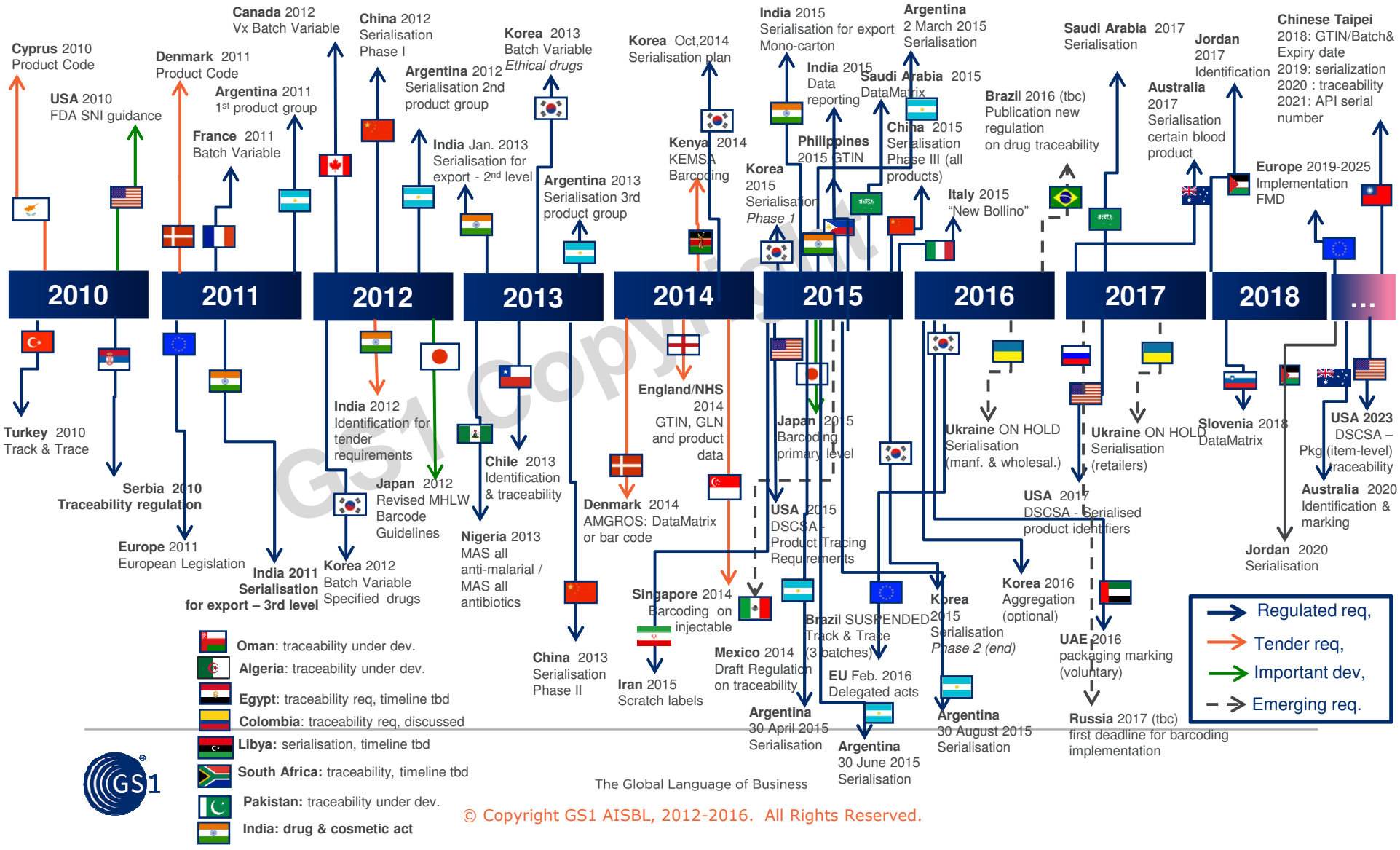
  Vice President Distribution Operations

- Dr. Maximiliano Derecho, ANMAT

  Legal Advisor

Pharma – World (including Europe)

coding & serialisation requirements



The Global Language of Business