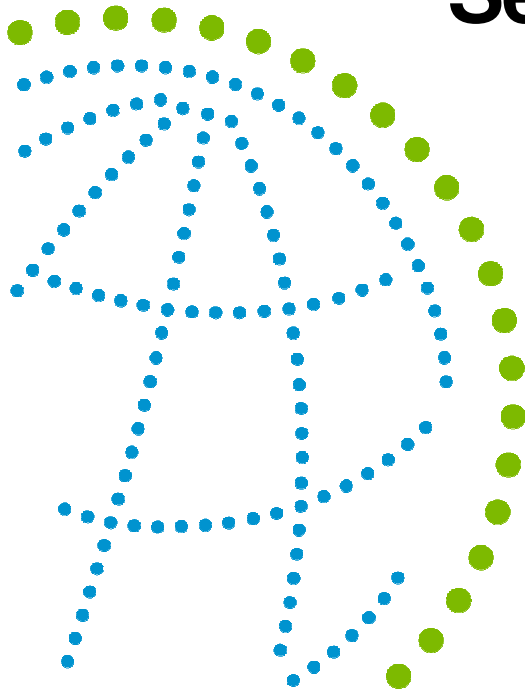




Delivering a Comprehensive Serialization Traceability Program

Peggy Staver - Pfizer



Overview



- Pfizer History
- What it Takes
 - Strategies
 - Organization
 - Solutions
 - Business-as-Usual
- Summary



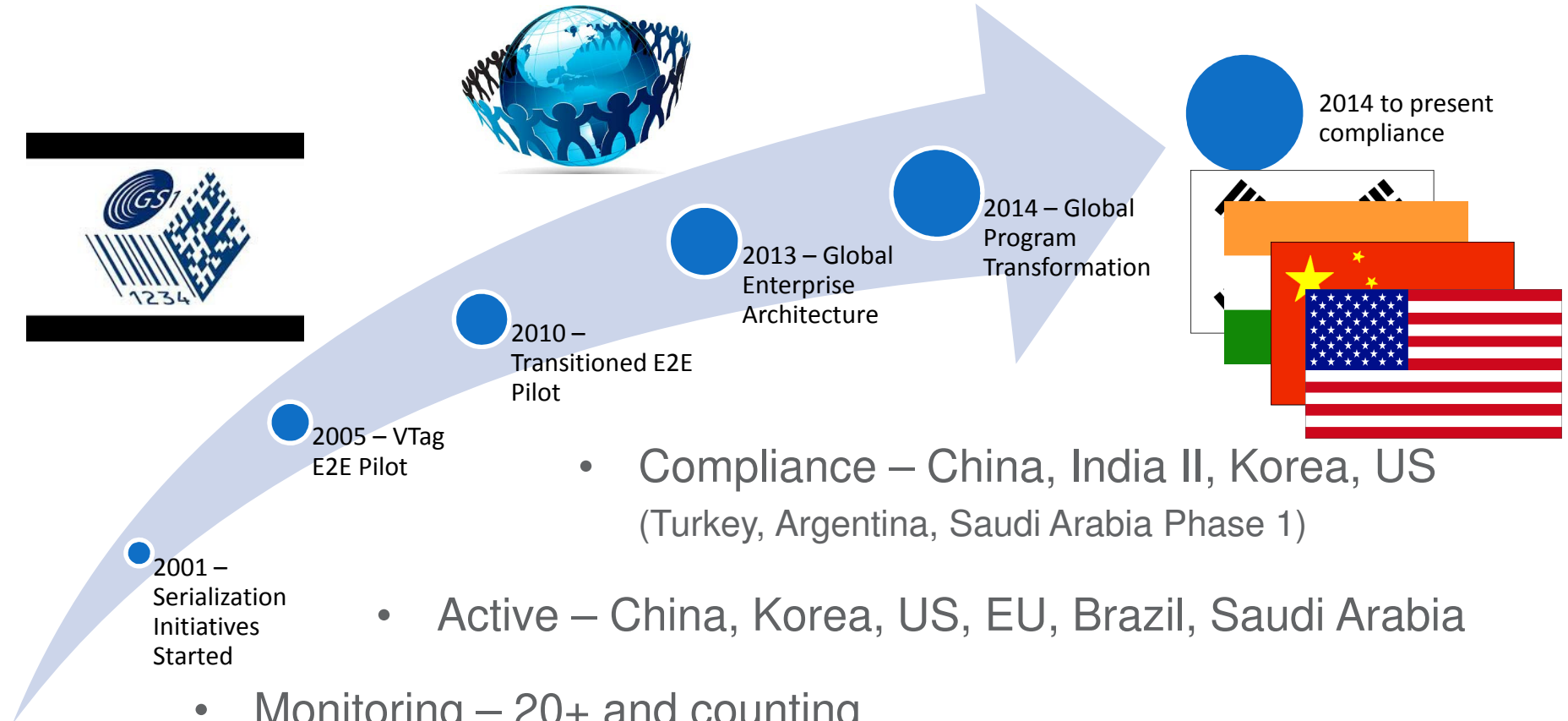
Pfizer History

Serialization Myth #1



“There’s Plenty of Time”

Pfizer's History



2001 –
Serialization
Initiatives
Started

2005 – VTag
E2E Pilot

2010 –
Transitioned E2E
Pilot

2013 – Global
Enterprise
Architecture

2014 – Global
Program
Transformation

2014 to present
compliance

- Compliance – China, India II, Korea, US
(Turkey, Argentina, Saudi Arabia Phase 1)

- Active – China, Korea, US, EU, Brazil, Saudi Arabia

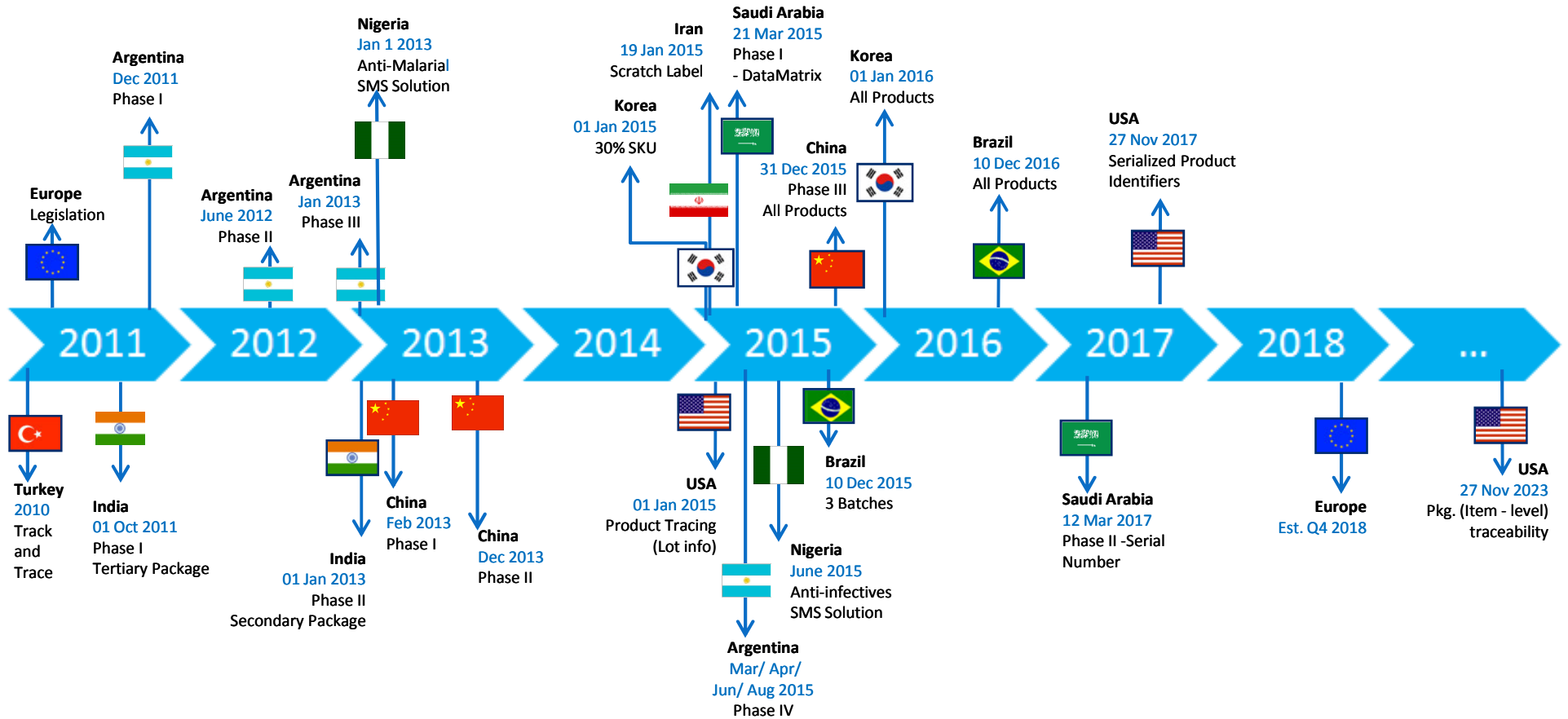
- Monitoring – 20+ and counting

- 20+ live sites/CMOs (50+ lines), 6 logistics facilities and 50+ active ongoing implementations

- Collaboration – GS1, Rx-360, regulators, trade associations, trading partners

April 21, 2015

Serialization Compliance Timeline



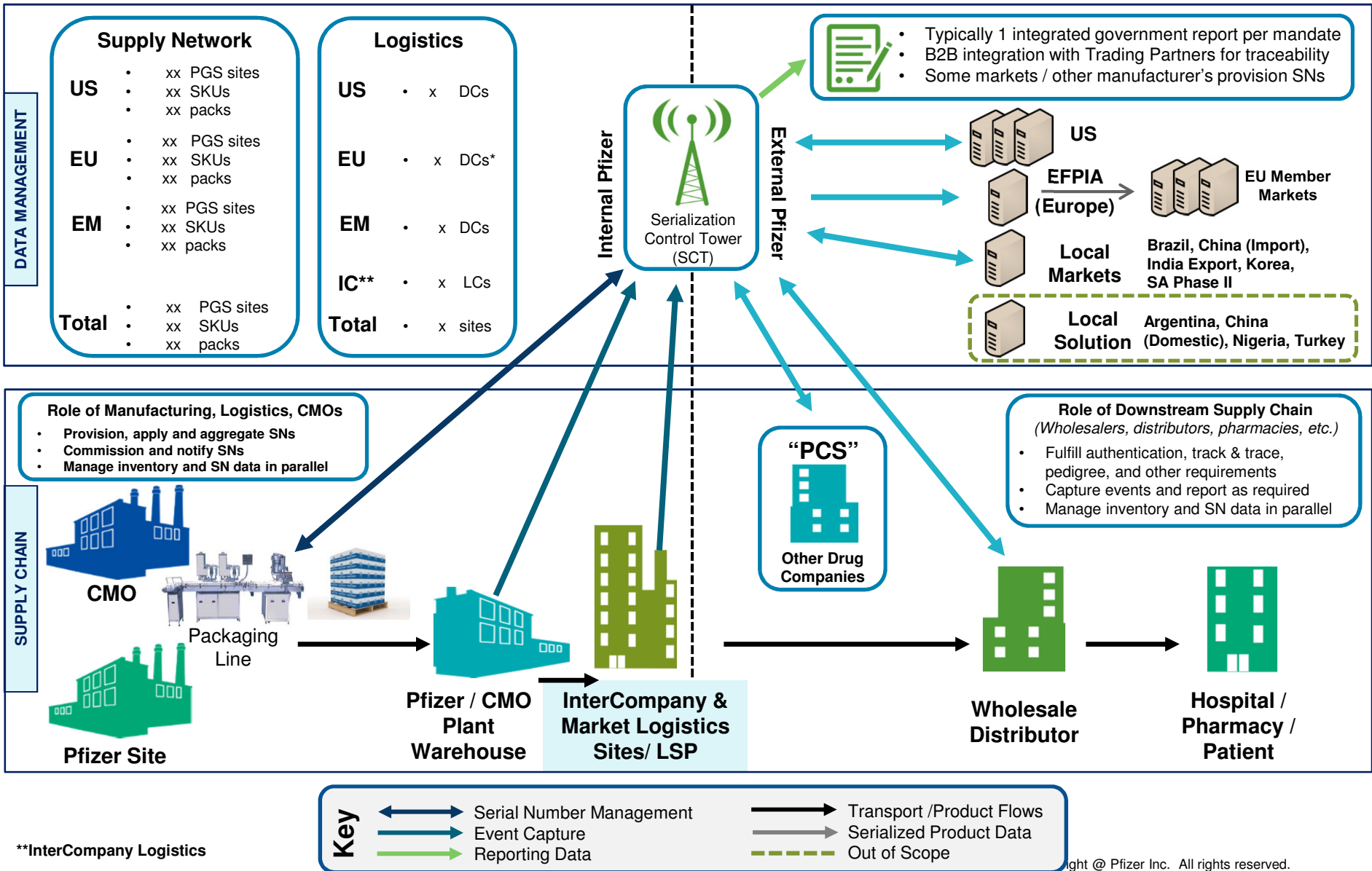
Actively Monitoring



No Confirmed Law

Draft Law

Serialization Enterprise Solution Overview



**InterCompany Logistics

Strategy

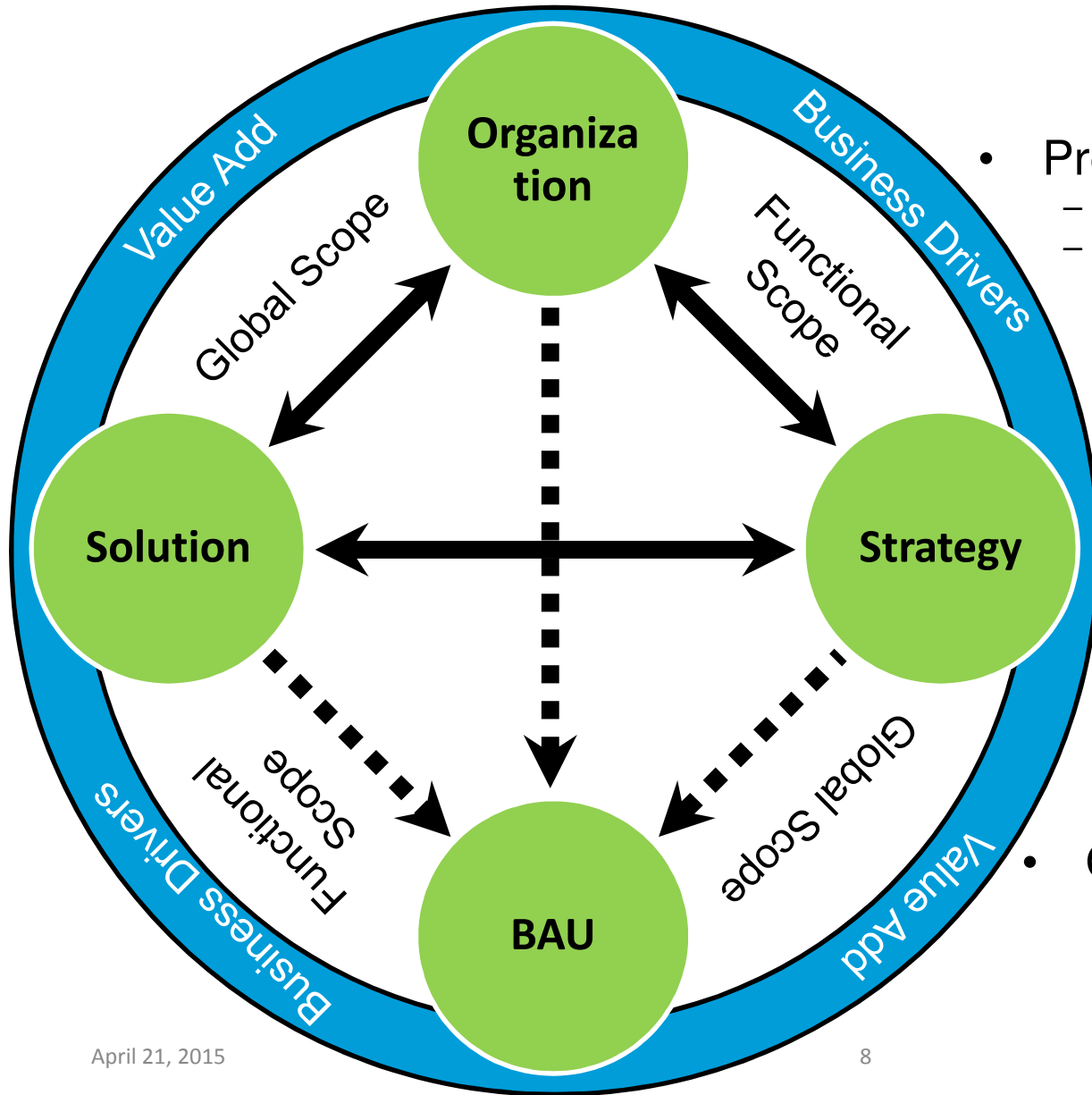
Serialization Myth #2



“Serialization is really just setting up your packaging lines with some bar code printers and scanners”



What Does It Takes?



- Program Breadth?
 - Global / Regional / Market
 - Supply Planning / Manufacturing / Logistics / Commercial
- Participants?
 - Direct / Indirect
 - Global / Local
- What to Implement?
 - Regulation Interpretation
 - Line Technologies
 - Material Handling
 - Data Management
- Ongoing Operations?
 - Operationalize
 - Enterprise Support
 - Maintenance

Strategies & Methodologies

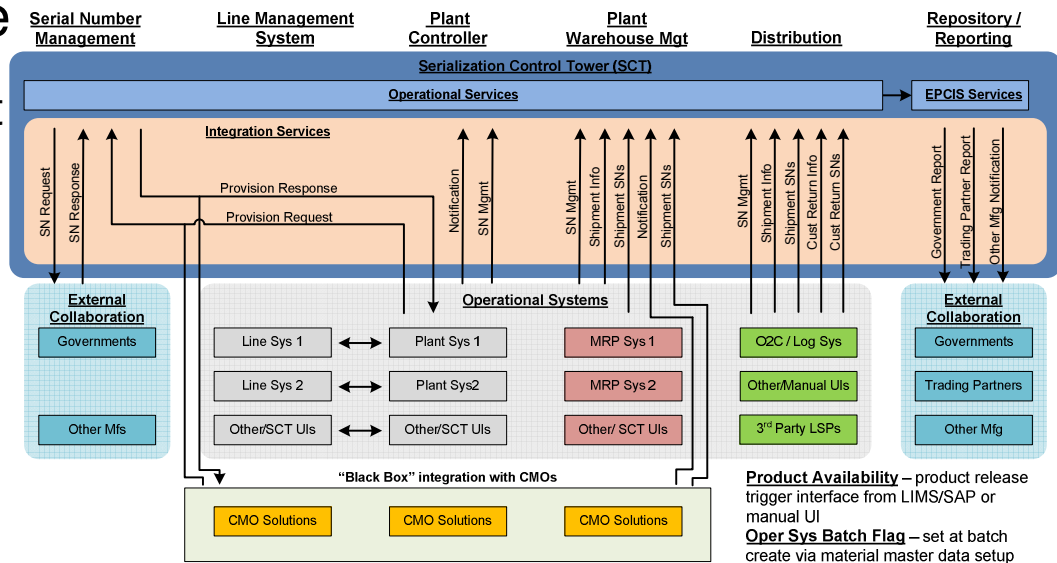


- Alignment with business and investment plans
 - Packaging network optimization (insource/outsource strategies, hubs, etc)
 - Postponement and source strategies
 - Work center, deferred aggregation or enable line
- Harmonized standards, modular build and consistent timing



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- Global solution architecture
 - Enterprise data management
 - Agile and flexible
 - Leverage existing solutions
- Compliance fulfillment
 - Program Operating Model
 - Holistic project management



Note: Only certain shipments will require serial number tracking
 • 1) Any customer sale shipments, 2) Product redirect shipments and 3) PCS shipments
 Typically intercompany shipments do not require serial number tracking

- Learning & continuous improvement

“Commoditize” Mandates



Mandate Classification

Mandate Requirements

- Import
- Authentication
- Export
- Track & Track

Common Enablers

- Serial number provisioning
- Notification / commissioning
- Aggregation
- Serial number management

Event Driven Reporting

- Government
- Trading Partners
- Other Manufacturers

Business Events

Provision & Apply

Creation / Aggregation*

Product Availability

Tracked Receipts

Tracked Shipment

Compliance Reporting

Serial Number Management (e.g. provision, commission, ship, rework, destruction, returns)

Mandate

– China

Requirements

Import
SN Management
Track

– India

Export

– Brazil

Import
SN Management
Track

– US

Track
SN Management
Authentication

– EU

Event Combination

ProvApply→Notify→Prod Avail→Report

Modifications→Report

Ship→Report

Prov/Apply→Notify→Prod Avail→Report

Notify→Prod Avail→Receipt→Report

Modifications→Report

Ship→Report

Prov/Apply→Notify→Ship→Report

Modifications

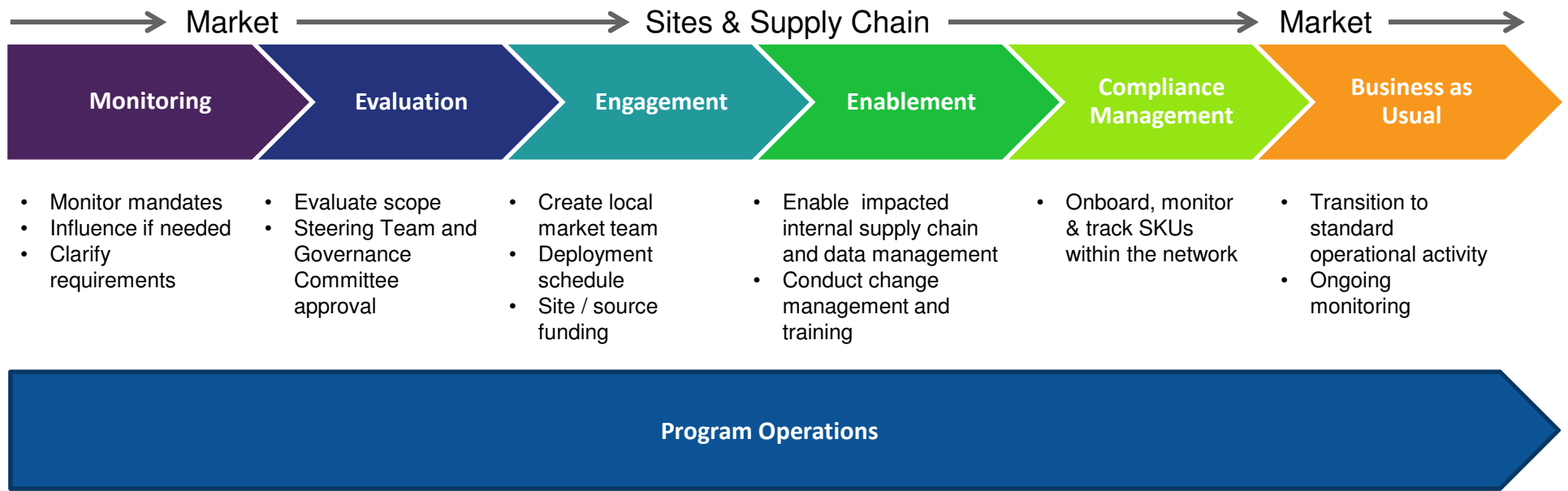
Prov/Apply→Notify→Prod Avail→Report

April 21, 2015

10

* Aggregation is often needed for supply chain efficiencies

Program Operating Model



- **Focus:** Market → Site & Supply Chain → Market
- **Enablement Projects:** driven by market requirements
- **Manage Supply:** impact of executing enablement projects
- **Ongoing Operations:** execute on a strategy allowing the company to operate post program

Operational Learnings



THEMES (Origin)

- Incorrect configuration of master data
- Required functionality delayed
- Serialization data commissioning processes missed or delayed
- Readability of barcode
- Serial number out of sequence
- Label misprint / damaged barcode
- Product incorrectly handled
- Serialization data upload
- Improper handling during shipment
- Reports not accepted from the government
- Data matching issues

CORRECTIVE & PREVENTATIVE ACTIONS

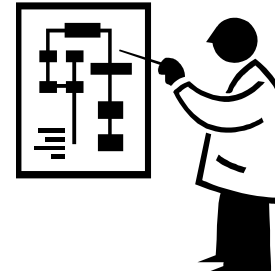
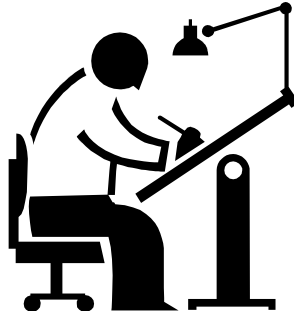
- Reinforce stakeholder engagement and understanding
- Migrate from manual to automated processes
- Outfit intercompany distribution with serialization education
- Update operating procedures
- Submit system enhancement request

Low volume and criticality of issues

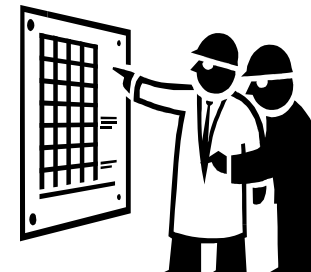
Medium volume and/or criticality of issues

High volume and/or criticality of issues

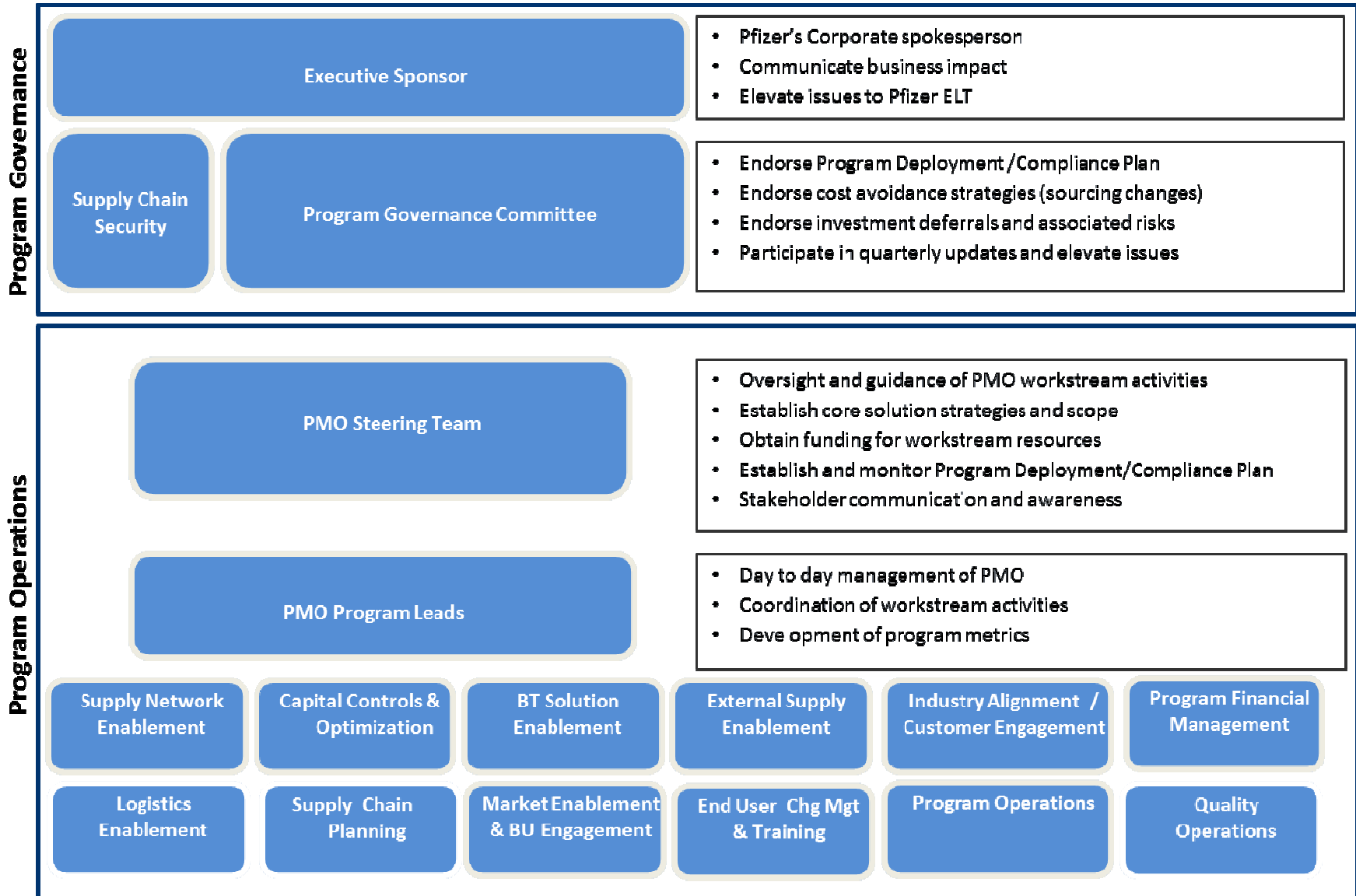
Organization Serialization Myth #3



“Give it to Engineering They will get it done”



Program Governance

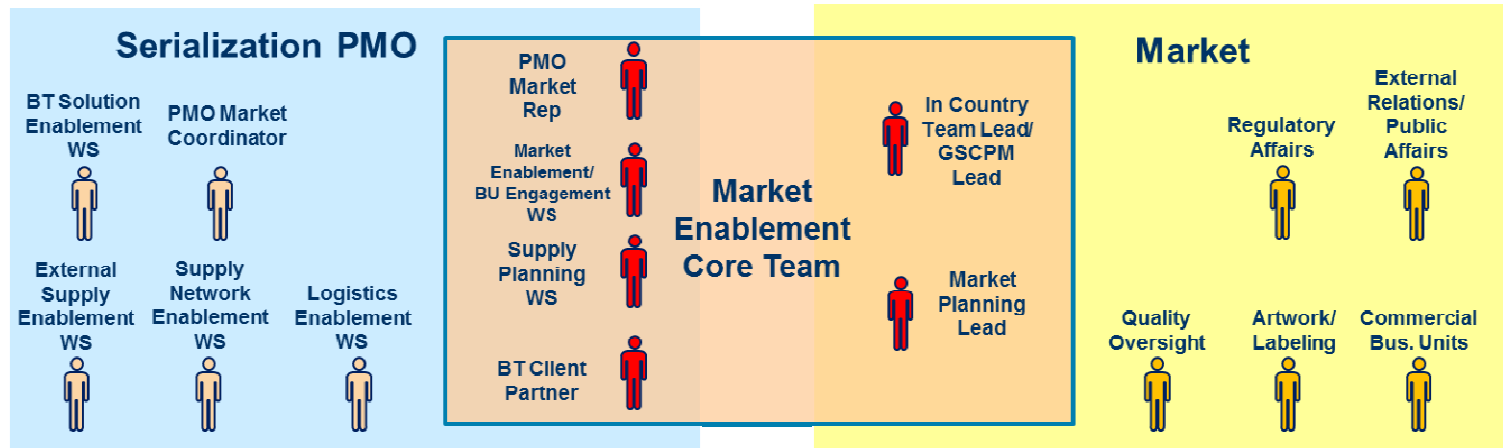


Blended Teams



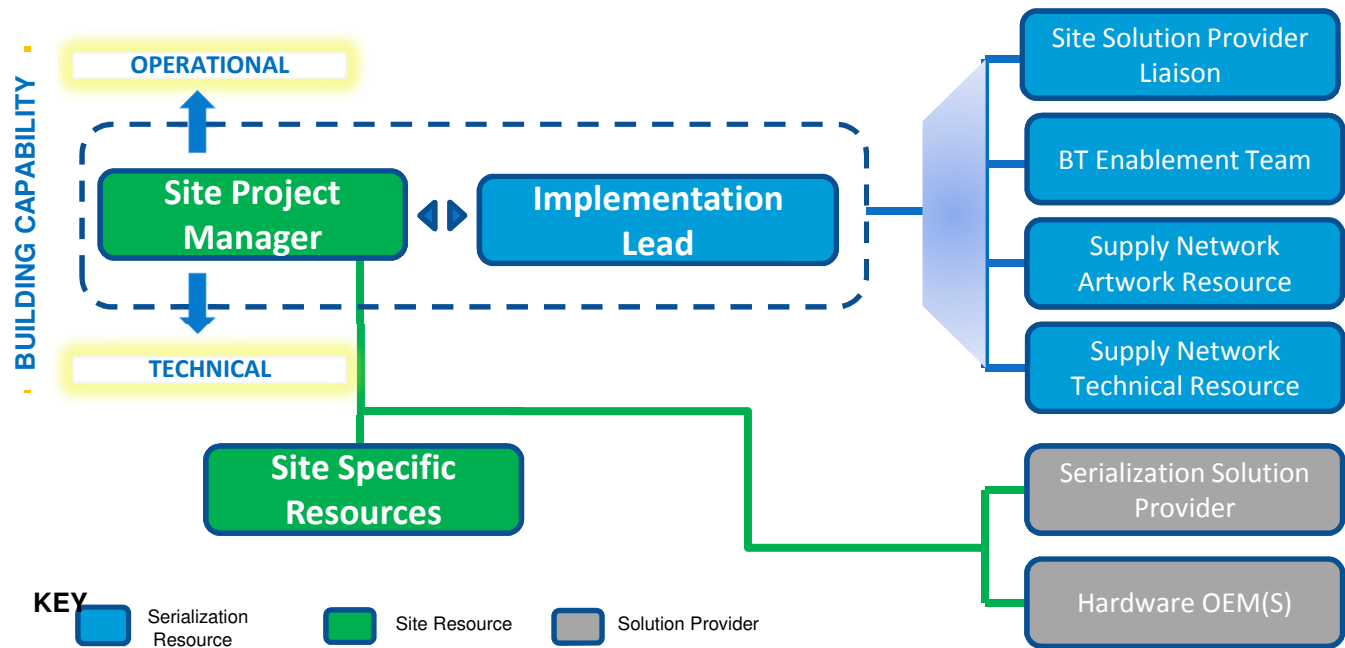
Market:

- In-country team key to success
- Partnership & Influence



Source Location:

- Ownership
- Drive operational & technical capability
- Sustainable operations



Solution

Serialization Myth #4



“One size fits all”



Modular Building Blocks

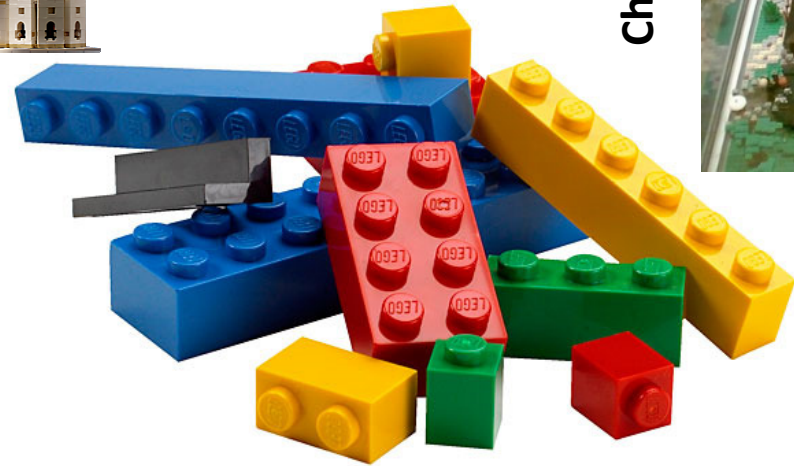
India DGFT



China EDMC



US DSCSA



Reusable Parts

- Simple / versatile / agile
- Fulfill different independent functions
- Put together to address higher level needs

EU FMD



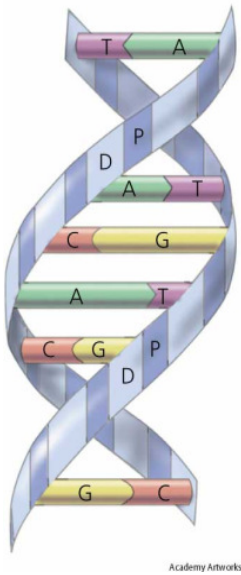
Standard Operational Processes



- Analyze overall network for event capture points in operations
 - Lines / CMOs
 - Plant warehouses
 - Logistics network
 - Market distribution network
- Identify operational requirements to meet / maintain compliance
 - Normal “go-forward” process
 - “Exception” handling
- Define Operations Requirement Flows
 - Operationally “agnostic” to mandates
 - Minimize operations impacts
 - Automated and / or manual



Master Data

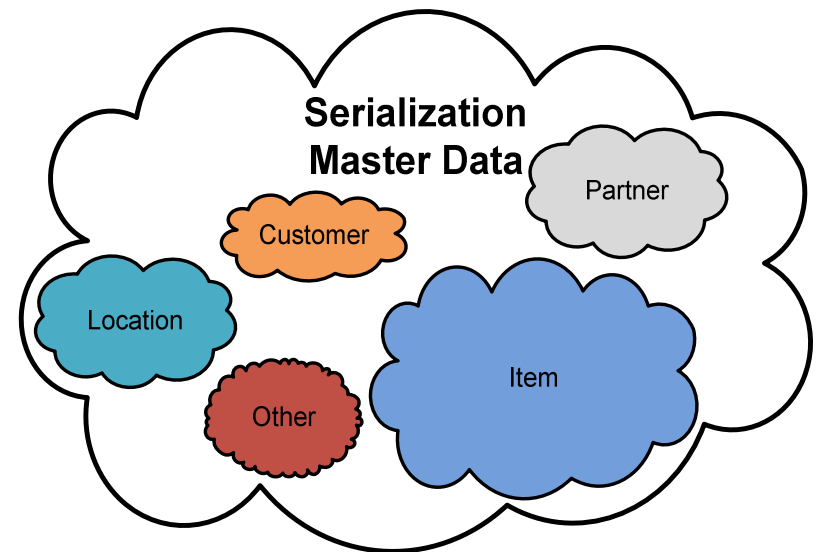


Master Data is the “DNA” for the Serialization Program

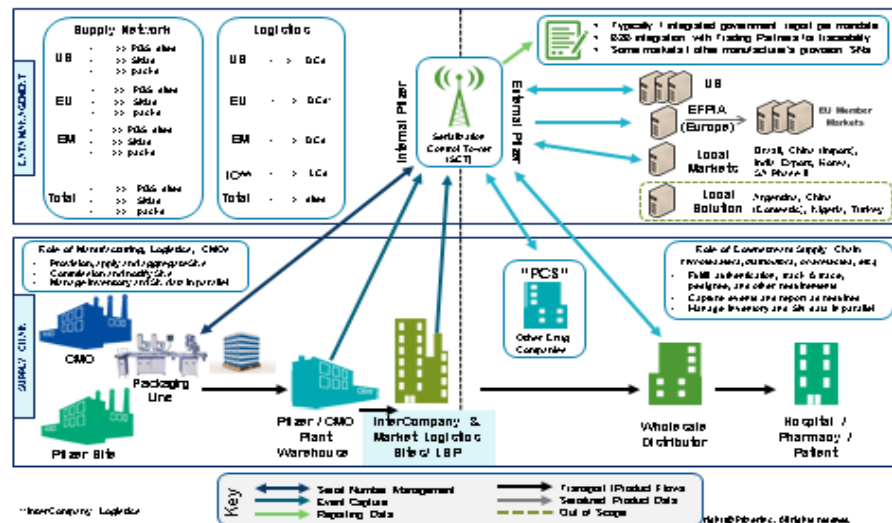
- It is the “Identity” of the Product and Company Data with necessary elements
- It is the “Bond” that ties all internal and external supply chain solutions together

Serialization Program Key Components

- Business processes are the work flows to be executed
- Master Data is the definition / identity of what the business processes are to be acted on and how



Serialization Enterprise Solution Overview



Business Process Integration

- Many internal and external business systems need to be able to work interactively
- The master data serves as the bond that enables the different solutions to talk in a common language

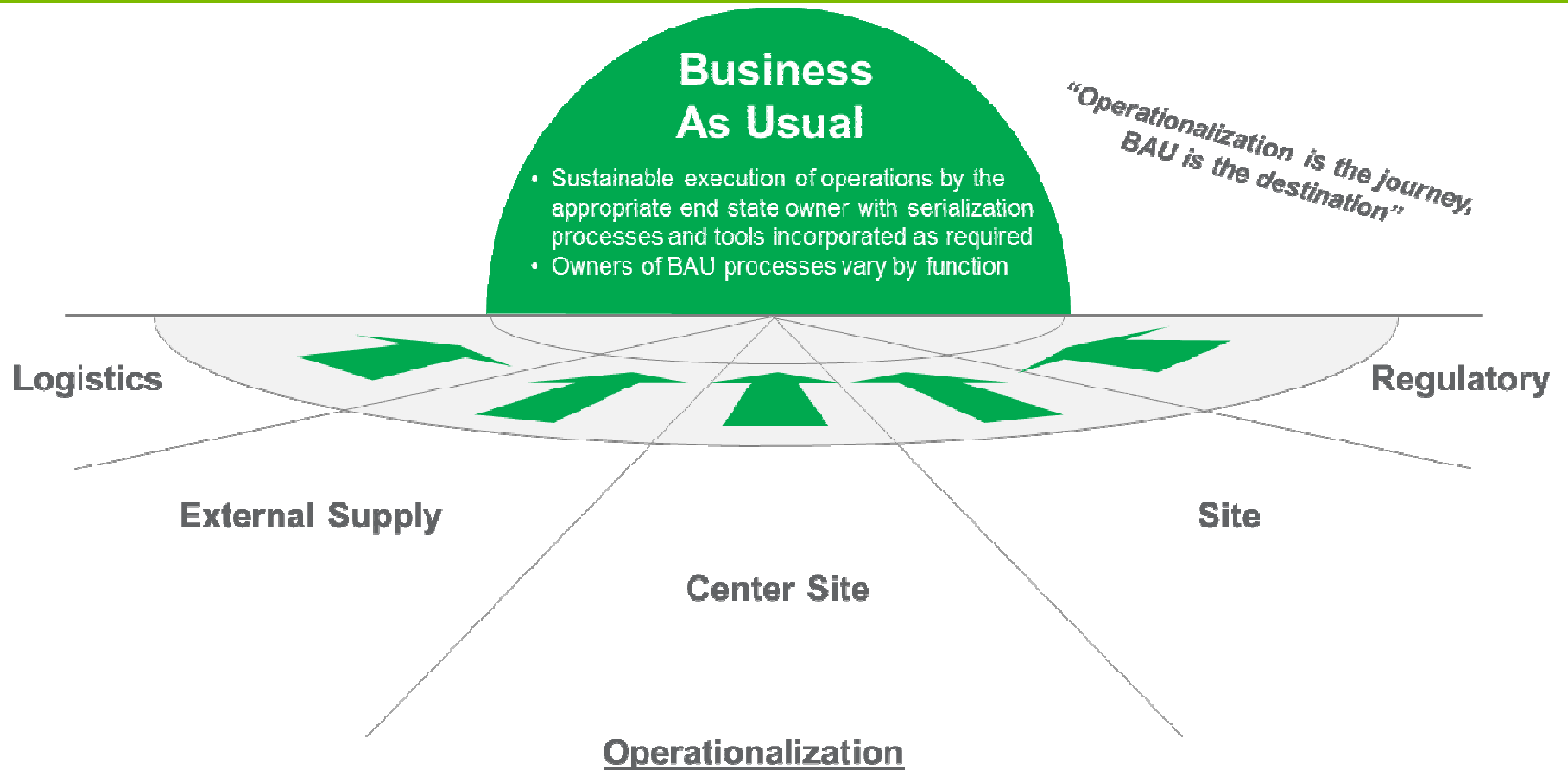
Business-As-Usual Serialization Myth #5



“Serialization only adds to product cost and does not create business value”



BAU vs. Operationalization



- Processes and activities needed to transition the network from non-serialized to serialized operations
 - Each respective functional area undergoes the transition to a serialized state, with some starting at a different point along the maturity curve than others
 - Operationalizing includes process enhancement to improve efficiencies
 - NOTE: New requirements or functionality will go to BAU

How to Support?



Challenge

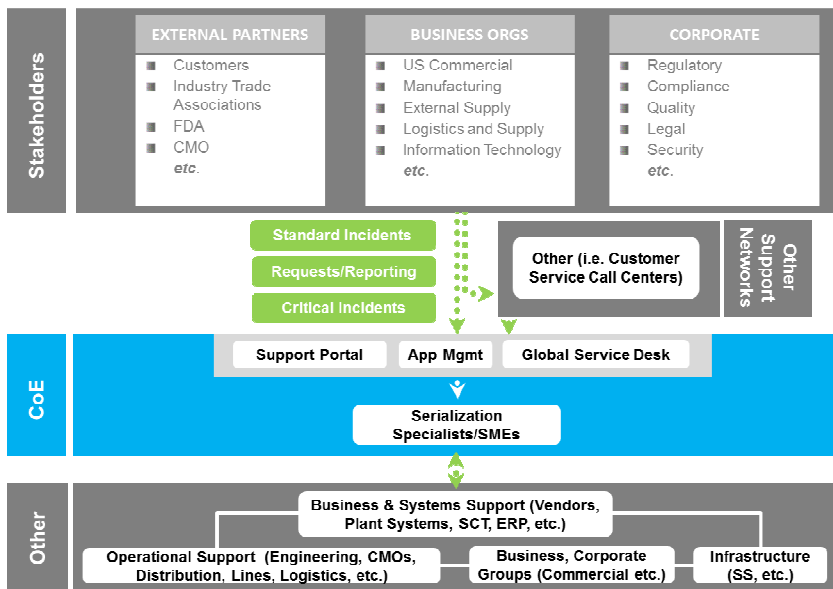
- Many potential supply chain points of failures
- Efficiently find issue source
- Capture/manage issues traversing the supply chain
- Harmonizing business partners / tech teams
- Regulatory time constraints
- Explicit knowledge management

Problem	Reported By
Serial number does not match the electronic data sent downstream	Customer (Wholesaler)

Solution Route:



S.N.	Cause of problem	Resolution Provider
1	Label was printed incorrectly	Manufacturing Site Operation
2	Data was corrupted	Plant System or SCT
3	Label reading issue at the customer	Customer



Challenge

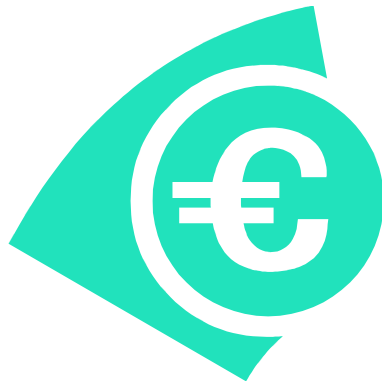
- **Enterprise support:**
 - Learning solution, gluing existing support networks
 - Support internal or external stakeholders
 - Incident and Problem Management
- **Routing mechanism:**
 - “Fastest” routing / resolution of issues traversing groups
- **Enterprise Support (COE):**
 - Mgmt & SMEs for performance and stakeholder mgmt
 - Learning machine that provides continuous support & solution improvement
- **Accountability:**
 - From opening to closing of incidents
 - Monitoring problem management effectiveness

Summary

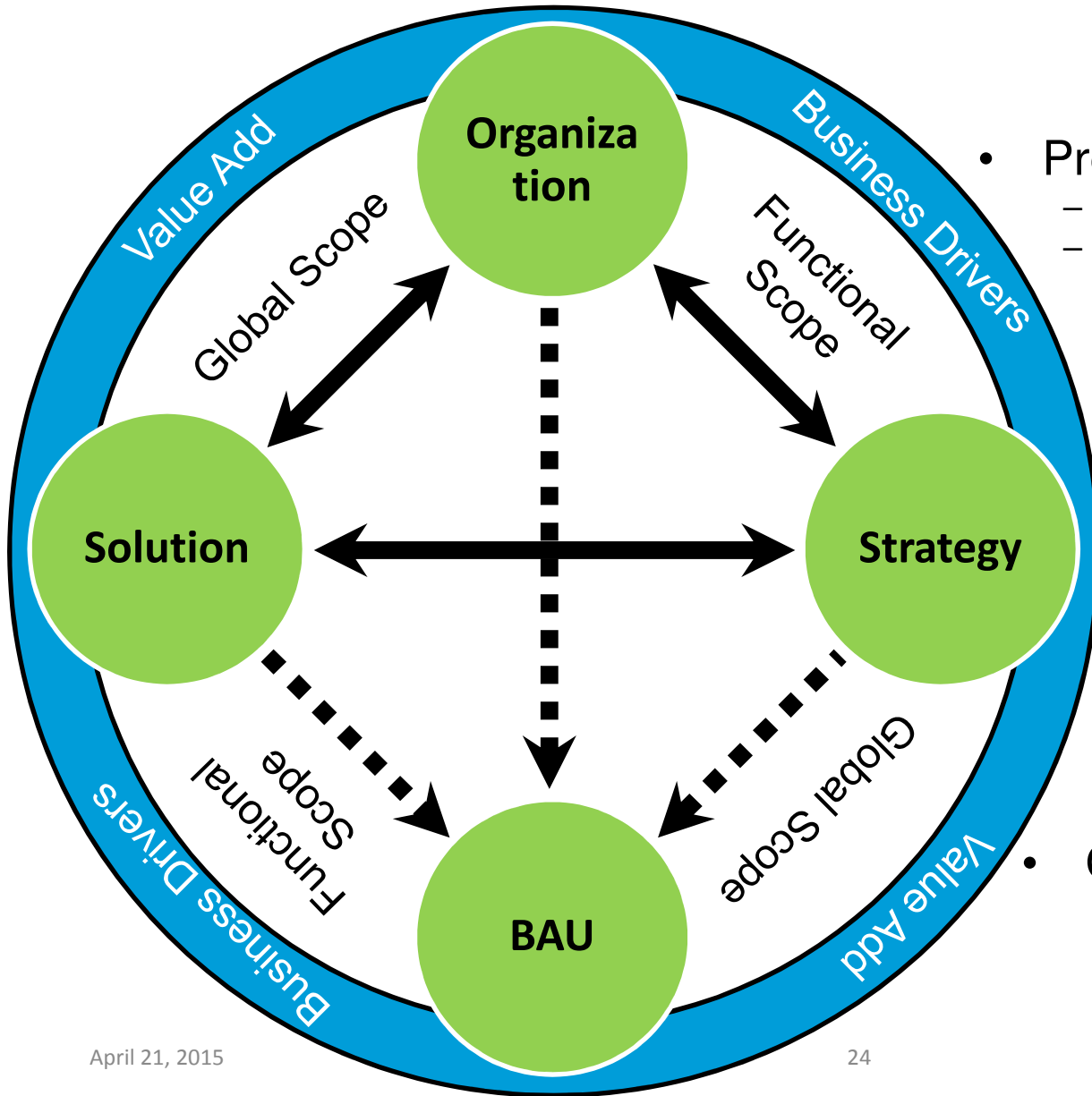
Serialization Myth #6



“Once I have funding approved, I can get this done in a couple of months”



What Does It Takes?



- Program Breadth?
 - Global / Regional / Market
 - Supply Planning / Manufacturing / Logistics / Commercial
- Participants?
 - Direct / Indirect
 - Global / Local
- What to Implement?
 - Regulation Interpretation
 - Line Technologies
 - Material Handling
 - Data Management
- Ongoing Operations?
 - Operationalize
 - Enterprise Support
 - Maintenance

Thank You!!!

