Delivering a Comprehensive Serialization Traceability Program

Peggy Staver - Pfizer
Overview

• Pfizer History
• What it Takes
  – Strategies
  – Organization
  – Solutions
  – Business-as-Usual
• Summary
“There’s Plenty of Time”
Pfizer’s History

- 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

- **Turkey**: 2010 - Track and Trace
- **USA**: 01 Jan 2015 - Product Tracing (Lot info)
  - 27 Nov 2017 - Serialized Product Identifiers
- **Korea**: 01 Jan 2015 - 30% SKU
- **Brazil**: 10 Dec 2015 - 3 Batches
- **Saudi Arabia**: 21 Mar 2015 - Phase I - DataMatrix
  - 19 Jan 2015 - Scratch Label
- **China**: 31 Dec 2015 - Phase III All Products
- **Saudi Arabia**: 01 Jan 2016 - All Products
- **Korea**: 01 Jan 2016 - All Products
- **Europe**: Legislation
- **India**: 01 Oct 2011 - Phase I Tertiary Package
  - 01 Jan 2013 - Phase II Secondary Package
  - 2011 - Anti-Malarial SMS Solution
- **Argentina**: Dec 2011 - Phase I
  - June 2012 - Phase II
  - Jan 2013 - Phase III
- **Nigeria**: Feb 2013 - Phase I
  - Dec 2013 - Phase II
- **USA**: 01 Jan 2015 - Product Tracing (Lot info)
- **Brazil**: 10 Dec 2016 - All Products
- **Saudi Arabia**: 12 Mar 2017 - Phase II - Serial Number
- **Argentina**: Jan 2013 - Phase I
  - June 2015 - Anti-infectives SMS Solution
- **Nigeria**: March/April/June/Aug 2015 - Phase IV
- **USA**: 27 Nov 2017 - Serialized Product Identifiers
- **Europe**: Est. Q4 2018 - Phase IV
- **Argentine**: June 2012 - Phase II
- **China**: Feb 2013 - Phase I
- **USA**: 27 Nov 2017 - Serialized Product Identifiers
- **Argentina**: Mar/Apr/Jun/Aug 2015 - Phase IV
- **Nigeria**: June 2015 - Anti-infectives SMS Solution
- **Europe**: 27 Nov 2023 - Pkg. (item-level) traceability

**Actively Monitoring**

<table>
<thead>
<tr>
<th>UAE</th>
<th>Jordan</th>
<th>Taiwan</th>
<th>Colombia</th>
<th>Mexico</th>
<th>Ukraine</th>
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<td>🇺🇦</td>
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<table>
<thead>
<tr>
<th>No Confirmed Law</th>
<th>Draft Law</th>
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<tbody>
<tr>
<td>Copyright © Pfizer Inc. All rights reserved.</td>
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</table>
“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

- Global solution architecture
  - Enterprise data management
  - Agile and flexible
  - Leverage existing solutions

- Compliance fulfillment
  - Program Operating Model
  - Holistic project management

- 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
  - Import
  - SN Management
  - Track
- India
  - Export
- Brazil
  - Import
  - SN Management
  - Track
- US
  - Track
- EU
  - SN Management
  - Authentication

**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

* 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

- 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
“Give it to Engineering …. They will get it done”
Program Governance

Executive Sponsor
- Pfizer's Corporate spokesperson
- Communicate business impact
- Elevate issues to Pfizer ELT

Program Governance Committee
- Endorse Program Deployment/Compliance Plan
- Endorse cost avoidance strategies (sourcing changes)
- Endorse investment deferrals and associated risks
- Participate in quarterly updates and elevate issues

PMO Steering Team
- Oversight and guidance of PMO workstream activities
- Establish core solution strategies and scope
- Obtain funding for workstream resources
- Establish and monitor Program Deployment/Compliance Plan
- Stakeholder communication and awareness

PMO Program Leads
- Day-to-day management of PMO
- Coordination of workstream activities
- Development of program metrics

Program Operations
- Supply Network Enablement
- Capital Controls & Optimization
- BT Solution Enablement
- External Supply Enablement
- Industry Alignment / Customer Engagement
- Program Financial Management
- Program Operations
- Quality Operations

Logistics Enablement
Supply Chain Planning
Market Enablement & BU Engagement
End User Chg Mgt & Training

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Blended Teams

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

Source Location:
- Ownership
- Drive operational & technical capability
- Sustainable operations

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“One size fits all”
Reusable Parts

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

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
“Serialization only adds to product cost and does not create business value”
BAU vs. Operationalization

Business As Usual

- Sustainable execution of operations by the appropriate end state owner with serialization processes and tools incorporated as required
- Owners of BAU processes vary by function

“Operationalization is the journey, BAU is the destination”

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 enhancements to improve efficiencies
  - NOTE: New requirements or functionality will go to BAU

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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

Solution Route:

<table>
<thead>
<tr>
<th>Problem</th>
<th>Reported By</th>
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<tbody>
<tr>
<td>Serial number does not match the electronic data sent downstream</td>
<td>Customer (Wholesaler)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Cause of problem</th>
<th>Resolution Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Label was printed incorrectly</td>
<td>Manufacturing Site Operation</td>
</tr>
<tr>
<td>2</td>
<td>Data was corrupted</td>
<td>Plant System or SCT</td>
</tr>
<tr>
<td>3</td>
<td>Label reading issue at the customer</td>
<td>Customer</td>
</tr>
</tbody>
</table>

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