The webinar will begin shortly

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Welcome

Perry Fri
Senior Vice President
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HDMA

Webinar sponsored by axway
HDMA Education Webinar  
Serialization, Pedigree and Traceability: The Path to Data Exchange  
Wednesday, June 19, 2013 • 2:00 PM-3:00 PM (EDT)

Before we get started...

- Today’s webinar is being recorded
- Formal presentation, followed by time for Q&A
- Evaluation Survey
- Presentation and audio-replay will be e-mailed following the conclusion of the webinar
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Q&A: Submit Your Questions

1. Type your question into the Q&A box located on the right-hand side of your screen.

2. Click the SEND button to submit your question.

Speaker Disclaimer

This Webinar is for information and educational purposes only.

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Federal Pedigree Efforts

2013 Hill Progress

- Effort to produce a balanced product in an effort to consider stakeholder priorities
  - Factors include California delegation concerns with preemption and TNT
  - FDA desire to preserve “pedigree” AND get to a more robust, more transparent track-and-trace
  - Industry stakeholders generally united in ultimate goal but various opinions about how to get there, various niche issues in play and pharmacy concerns linger
  - Imminent California deadlines
Congressional Proposals

**Phase I**  Preemption of state activity

- Pre-serialization pedigree requirements
- Serialization and Lot Level “product tracing”
- “Product Identifier” applied by manufacturer to include SNI, lot # and expiration date
- “Verification” of suspect and illegitimate product and saleable returns
Congressional Proposals

<table>
<thead>
<tr>
<th>Phase II</th>
<th>Unit Level “Traceability”</th>
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<tr>
<td></td>
<td>Elimination of need for pedigree</td>
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<td>Self-effectuating vs. FDA regulations</td>
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<td>FDA authority</td>
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<td>Licensure</td>
<td>Preservation of role for state agencies</td>
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<td>“Floor” vs. “ceiling” regarding requirements</td>
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<td>Separate licensure status for 3PLs</td>
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Expectations

- House Markup ✓/Committee Vote ✓/Full House Vote ✓
- Senate Markup ✓/Committee Vote ✓/Full Senate consideration by July recess
- Goal is Q1 or Q2 – after that, does interest wane?
- Potential for consensus and reconciliation of differences
- Political challenges
Big Ticket Issues

- Full pedigree vs. interim provisions
- Returns
- Exemptions
- Licensure floor or ceiling
- Dispenser activity
- Implementation dates
- Phase II

Presenter

Ruby Raley
Director, Healthcare Solutions
Axway
In a time of uncertainty, it can be challenging to sort out what can be planned and known from what may change. Yet, gaining clarity on the foundations of serialization and traceability can reduce both cost and risk.

This webinar will focus on:
- Identifying guide rails for the project;
- Project charter, the foundations; and
- Ensuring resilience under certainty.

Note: Always consult your organization’s compliance and government affairs team before finalizing requirements for regulatory projects.

Guide rails are not only boundaries, but principles that will guide the team in decision making and issue resolution:
- Production & Physical Material Handling
- 3rd Party Relationships
- IT Architecture
- Compliance
- Strategic Reach
Production and Packaging Constraints

- Global or U.S. only?
- Outsourced manufacturing, packaging and logistics?
- How many plants? How many lines?
- Packaging?
  - Identifying the saleable units
  - Selecting or enhancing a PES
- Implementation
  - Acceptable downtime
  - Configuration

IT Architecture

- **Master Data Management**
  - Lot, expiration, product characteristics
- **Capabilities of Strategic Partners**
  - Role of the ERP
  - System of Record: PO, ASN, Invoice
- **Gateway / Portal**
- **Standards Support**
  - Standards reduce cost of integration
- **Resources**
  - Analysts, Developers and IT Operations
Example: Impact of Data Architecture Decision

- **Data Architecture is Fundamental**
  - Centralized vs. Distributed
    - 1+ instances, 3rd party relationships
  - Serial Number generation
    - Country issued (China)
    - Brand protection
  - Network bandwidth
    - Limitation or risk
  - Repository
    - What events? Scale?
    - Compliance Artifacts?
    - Access? 3rd party

Compliance

- **Validated Systems**
  - Cost of change makes defining scope critical
- **Trusted Trading Partner**
  - ADR (Authorized Distributor of Record)
  - Know Your Customer
  - Required for certification / verification
- **Archives and Regulatory Inquiries**
  - 3-6 years, 24-48 hour response time
- **Reporting Culture**
  - Automated or manual

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What you don't know can't hurt you. But it's what you suspect that screws up everything.
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Strategic Reach
Lead / Follow? Brand / Compliance? Investment / Tax?

• Manufacturers
  - Global packaging requirements - next 3 to 5 years
  - Turkey, China, Korea, Brazil, Argentina, India, Europe and Mexico?

• Distributor
  - Business processes
    o Trusted trading partner programs
    o Certification, Verification
    o Returns
  - Paper or Electronic
    o Transaction history or pedigree?

• Dispenser
  - Who do you buy from?
  - Where will you source solutions?
  - How will you certify and validate purchases?

Strategy without tactics is the slowest route to victory. Tactics without strategy is the noise before defeat. - Sun Tzu

Project Charter, The Foundations

1. Define the Scope
2. Define the Approach
   - Boundaries are your friend!
3. Define the Architecture
4. Identify the Risks
Global Harmonization vs. Local Autonomy

Provide a core system that can be locally adapted

- **Global Core**
  - Consistent architecture
  - Global data management
  - Productized, not customized
  - Global scope
  - Corporate IT support
  - Scalable
  - Repeatable deployments
  - IT interfaces managed centrally
  - Test/Simulation environment
  - Leadership/Resources

- **Local Autonomy**
  - Regulatory requirements
  - Local workflow and process
  - Plant device preferences
    - MES/PES servers
    - OEM equipment
    - Cameras/Line speed
    - Manual/Automated
  - Product packaging types
  - Outsourced/Owned
  - Leadership/Resources

Pedigree Requirements: Recommended Shopping List

**Sunny Day Requirements**

1. **Create pedigree**
   - Ship product & create pedigree
   - Include Aggregation

2. **Receive / authenticate pedigree**
   - Receive inbound pedigree from trading partners
   - Publish pedigree data to receiving systems

3. **Repack**
   - Commission the repacked product SN
   - Support M:1 and 1:M
   - New pedigree inherits from source

4. **Kits**
   - Multiple item serial #'s, multiple LOTs → 1 kit, new LOT#

5. **Returns**
   - Saleable/ Non-saleable

6. **Drop Shipments**
7. **Emergency Shipments**
8. **Item / Case Status Changes**
   - Commissioned
   - Aggregation
   - Decommissioned
Pedigree Requirements: Recommended Shopping List

1. Mass Maintenance
   - Change a data element
   - Across multiple items or multiple pedigrees

2. Pedigree Corrections
   - SN on hand, missing Pedigree
   - Request revised pedigree from upstream partner
   - Swap case / item between pedigrees

3. Item Status Change
   - Embargoed
   - Quarantined
   - Cleared
   - Recalled

4. All Scenarios
   - Audit Log of events
     - Admin changes logged
   - Pedigree archived once published
   - Retention / Archive
     - 3-6 years

5. Additional Questions
   - Organization
   - Change Management / Compliance
   - Resource availability

Uncertainty Requires Modular Approach

Local Repositories, Caches may be necessary
- response time, process, minimizing event noise

Isolate Regulatory Interfaces
- simplify management, increase agility, protect assets
Integration modules
- enable partners, role-based access, innovate
Risk Management

# 1 Risk: Regulatory Uncertainty
- Regulatory change
- Organizational commitment

# 2 Risk: Human Resources
- Skilled resources: Ops, IT, Vendors
- Operational acceptance and change management

# 3 Risk: Plant / Line Costs
- Local variations or future state plans
- Unplanned outages or slowdowns
- Validated systems

# 4 Risk: Business Process
- Impact on existing process
- Alignment with outsourced processes

Ensuring Resilience

- Find common patterns
  - Regulatory and Trading Partner
  - Product labeling
  - Certification and verification

- Isolate component efforts
  - Separate pedigree from serialization
  - Validated / Reporting / Supply Chain

- Size the problem and build for scale
  - How many?
  - How much?

- Standardize with reliable partners
  - Compliant doesn’t equal certified
  - Standards reduce costs

Resilience: the ability to resist, absorb, recover from or successfully adapt to adversity or change in conditions. - Homeland Security
Recommendations for Resilience

- **Centralize components with:**
  - Specialized skills
  - Extreme scale
  - Large access communities
  - Audit / discoverable records

- **Decentralize systems to boost business continuity**
  - Manufacturing / Warehousing / Shipping functions
  - Record events locally and batch to central repository

- **Address uncertainty, gain agility**
  - Delineate boundaries: validated systems
  - Configurable integration
  - Query and report builders
  - Modular purchase options

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Upcoming HDMA Seminars

Trade Management Seminar
Formerly known as Product Life Cycle Management
September 23-24, 2013
The Umstead Hotel • Cary, NC

Contract and Chargebacks Seminar:
Perspectives on Process Improvement
October 21-22, 2013
Hotel du Pont • Wilmington, Del.

Track-and-Trace Technology
November 11-13, 2013
Renaissance Arlington Capital View Hotel • Arlington, Va.

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