EPCglobal
Healthcare & LifeSciences Business Action Group
State of Pedigree and EPC/RFID Standards

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AGENDA

- Background -- EPC in the Healthcare Industry
- Organizational Alignment
- HLS Progress and Capabilities
- EPCglobal Medical Devices Summit
- Summary of Critical Issues
## EPCglobal Community

<table>
<thead>
<tr>
<th>Established</th>
<th>Nov-2003</th>
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| **Mandate** | - Develop user-driven technical standards for EPC  
  - Support adoption and implementation of EPC  
  - Leverage 30+ year expertise in managing globally unique numbers (UPC and barcode) |
| **Principles** | - Not for profit standards organization  
  - User driven and governed (all supply chain roles)  
  - Public policy and regulatory support  
  - Direct, practical support for industry initiatives  
  - Key value driver is standardized data exchange  
  - Global implementation support (103 offices)  
  - Committed to working with government, industry associations, other standards bodies  
  - Support large, medium and small companies |
| **Standards Work** | 1,600+ global participants |
| **Subscribers** | 800+ global subscribers |
EPCglobal Community

<table>
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<tr>
<th>Region</th>
<th>Jun-04</th>
<th>Dec-05</th>
<th>Current %</th>
<th>% Increase</th>
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<td>17</td>
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<td><strong>805</strong></td>
<td><strong>2.1%</strong></td>
<td><strong>421.5%</strong></td>
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</table>

- 30 of top 40 global **pharmaceutical manufacturers**, 16 of top 20 US manufacturers
- 3 of top 4 **retail pharmacies** and 4 of top 6 **supermarket pharmacies** are part of EPCglobal (20,000 locations in total)
- 4 of top 5 **medical devices** companies are current subscribers
EPC in the Healthcare Industry

• EPCglobal Healthcare Action Group formed in 2004
  – US members represent 38 of 40 largest manufacturers
  – 3 largest distributors
  – Major retailers
  – Formed in association with HDMA, NACDS and others
  – FDA involvement
• Active participation in all key supply chain roles
  – Manufacturers, Distributors, Retailers, Hospitals
  – Medical Devices RFID Summit – March 2, 2006
• Focused on addressing critical needs:
  – Pedigree Management (including a Pedigree Messaging Standard)
  – Air Interface Standard for item level tagging
  – Serialization (the format of the EPC on the tag)
  – Decommissioning of tags
  – Network Security
• EPCglobal helped form and supports the Unified Pedigree Coalition
Initial Key Industry Drivers for HLS

Why would we spend our time doing this?!?!

• Patient Safety
• FDA
• State pedigree

However, these are only initial focal points…. 
Safe and Secure Supply Chain

EPC/RFID

- Read and authenticate shipments with no “line of sight” needed
  - Confirming inbound receipts of item level product
  - Identifying expired items w/o handling each item
  - Receipt of pallets and cases with out disassembly
  - Reduced physical handling = reduced risk/increased security
- EPC takes advantage of best practices for data sharing
  - Distributed data (data is held by owner)
  - Lower cost to supply chain
- Industry actively moving towards standardization
  - Item Level Requirements identified
  - EPCglobal Technology Demonstration March 23-24
  - Development of new/modified standard
  - Serialization formats proposed
Safe and Secure Supply Chain

**EPC and Public/Private Leadership**

- Current EPC implementations by global leaders indicate long-term commitment
- RFID/EPC has the capability to solve critical regulatory issues
- Physics and standards challenges are being addressed
  - Not all products are RFID candidates at this time – Biologics, proteins, metal & glass
- Tag and reader prices are coming down
- Pilots are underway and learnings are contributing to standards efforts

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HLS Work Group & Task Force Alignment

HLS Top Priorities – 2006
On-Going HLS WGs

On-Going EPC WGs
HLS Top Activities – 4Q05

Initiate Discussion Groups
Cold Chain Med Devices Biologics

Strategy Work Group
Information Work Group
Technology Work Group
R&D Work Group
Joint Public Policy Steering Committee
Process Work Group
Industry Adoption

HLS Strategic Plan
Auto-ID Labs

Joint HLS/EPCIS Pedigree
EPC global Applied Tag Performance
ILT JRG

Serialization 1A
Authentication & Data Exchange
Security Work Group
Joint Item Level Tagging
Decommission

Serialization 1B

HLS Strategic Plan
Auto-ID Labs

Cold Chain Med Devices Biologics

EPCglobal
Powered by GS1
HUG/HLS Areas for Collaboration

HUG/HLS Opportunity

- HLS Top Priorities – 2006
- On-Going HLS WGs
- HLS Top Activities – 4Q05

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Overview to HLS Progress and Capabilities

• Item Level Tagging

• ePedigree

• Serialization

• 2006 Focus Areas
HLS Areas for Standards

State of the Standards

1. Pedigree Management Use Cases
2. Pedigree Messaging Standard
3. Item Level Tagging
4. Serialization
5. Decommissioning
6. Track & Trace

Requirements
Architectural Review
Standards Development
Ratification

Vendor Adoption
Industry Adoption
Item Level Tagging Joint Requirements Group Progress – To Date

- Jan 13 – Final draft of Requirements & Business Scenarios delivered to HAG
  - ILTJRG Requirements Document – 32 pages spanning 60+ Scenarios
- Jan 16-17 – HAG, FMCG & HLS identified 7 critical scenarios to be demonstrated
  - Hanging Garments on Mobile Metal Hanger Rack
  - Dock Door Portal
  - Apparel Point of Sale
  - DVD in Adjacent Shelf Slots
  - Vial & Ampoules in Case
  - Vial & Ampoule Write
  - Retail Pharma Mixed Tote
- Jan 18 – Proceed to Phase 2; gathered requirements from key external stakeholders – FMCG/HLS/DoD
- Jan/Feb – HAG confirmed technology supplier & scenario match-ups to ensure demo completeness
ILTJRG - Next Steps

- Feb/Mar – Technology suppliers to build/test solutions
- Mar 23-24 – HAG/ Technology suppliers demonstration
- April / May – HAG/SAG/ILTJRG Face-To-Face

Outcome of March demo should determine timeline for HAG to provide technology recommendation
E-Pedigree Standards
Key Objectives and Process Requirements

Objectives:
• Provides universal interchange format to express pedigree requirements of varied state regulations as drug products flow from one state to another
• Enable trading partners to send and receive pedigrees in a secure and interoperable manner that leverages existing B2B technologies and processes

Process Requirements:
• Each party engaged in the wholesale distribution of prescription drugs must provide a pedigree to the recipient for sales, returns, and transfers of prescription drugs
• Pedigrees must contain a certification (via signature) by the sender that the information is true and accurate
• Pedigrees must be authenticated by the recipient prior to receipt of drugs
• Recipient must add receipt and authentication signature to pedigree
• A pedigree received by or provided by an organization is a subject to recordkeeping requirements for record retention and record availability
E-Pedigree Standards
E-Pedigree Interchange Requirements

• Common format that meets FDA’s PDMA and state needs
  • Supports all required data elements for PDMA and states
  • Extensible format supports future state requirements
• Supports regulatory and business requirements
  • Serialized items (Could potentially support Non-serialized items with additional study – not RFID dependent)
  • Repackaged products
  • Sales, transfer, and return transactions
  • Creating electronic pedigree from paper pedigree
  • Digital signatures and electronic authentication
• Enables interoperability among trading partners
  • Representation of pedigrees in a common portable format
  • Exchange using existing business data transfer mechanisms
• Supports Standard Security Protocols
  • Public Key Infrastructure (PKI)
ePedigree and RFID Challenges

**Industry Challenges:**
- Data Sharing Issues
- Non-serialized Items
- Patient Privacy
- Public Policy
- Regulatory Considerations
- Cost/Benefits Differ by Stakeholder
- End-to-End Supply Chain Implementation Essential for Mass Adoption
- Lack of Universal Pedigree Agreement

**Technology Challenges:**
- Serialization
- Tag Frequency
- Performance
- Package Size
- Physical Characteristics
- Event Vocabulary
Serialization

• Two options developed
  – sGTIN - NDC code with random serial number
  – Company identifier with random serial number

• Concerns have been raised about each option
  – Privacy
  – Efficiency and effectiveness at every read point

• Next Steps
  – Review feedback from market research on privacy and RFID
  – Obtain input from DEA and FDA
  – Ensure standard is carrier independent
  – Leverage full GS1/EPCglobal capabilities
2006 Focus Areas - Capabilities

- **Track & Trace**
  - Intended to utilize EPC to track material where pedigree is not going to be required

- **Reverse Logistics**
  - Return of product initiated by Manufacturer, Wholesaler, Retailer or Hospital. The overall intent is to design processes and standards regarding the “reverse” flow of healthcare product across the Supply Chain.

- **Authentication**
  - Intended to utilize EPC to authenticate individual product, information and identification

- **Patient Care Management (Future)**
  - Intended to utilize EPC to increase the effectiveness of patient care management.
Medical Devices Summit

- HLS original intent is to cover medical devices and pharmaceuticals
- Medical Devices RFID Summit – March 2, 2006
  - Collaboration between EPCglobal and Medical Devices Supply Chain Council
- Agreed to draft charter for EPCglobal HLS Medical Devices workgroup
Summary of Critical Issues

- **Policy**
  - Privacy and Security
  - State and FDA – ePedigree model
  - Adoption Approaches – Getting to a “Tipping Point”
  - Data Network (Central vs. Distributed)
  - Data Ownership vs. Data Sharing

- **Technology**
  - Tag Frequency Standard
  - Serialization Standard – carrier independent
  - Item Level Tagging – performance, materials, volume…
  - Technology maturity – evolution/$$$

- **Industry Adoption**
  - Uniform Implementation Standards
  - Conflicting Industry Group Requirements
Next Steps – Managing Expectations
Beyond Standards Ratification

• Capital Planning
• Process Reengineering
• Systems Integration
• Infrastructure Build-Out
• Scale-Up
Thank You!!