EPCglobal HLS Update

Healthcare User Group

September 2006
Paris, France

EPCglobal

Initial Key Industry Drivers

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

- Patient Safety
- FDA
- State pedigree

However, these are only initial focal points….

EPCglobal

Safe and Secure Supply Chain

EPC

- Read and authenticate business transactions
  - **Confirming inbound receipts of item level product**
  - **Identifying expired items**
  - **Receipt of pallets and cases**
  - **Reduced physical handling = reduced risk/increased security**
- EPC takes advantage of best practices for data sharing
  - **Determine how to leverage GS1 product identification and data exchange**
  - **Lower cost to supply chain**
- Industry actively moving towards standardization
  - **Item Level Requirements identified**
  - **Pedigree standard**
  - **Serialization formats proposed**

EPCglobal

Safe and Secure Supply Chain

EPC – State of Industry Progress

- Current EPC implementations by global leaders indicate long-term commitment

- EPC has the capability to solve critical regulatory issues

- Pilots are underway and learnings are contributing to standards efforts

EPCglobal

Healthcare & Life Sciences Update

- Overview to HLS History & Organization

- HLS Workgroup Overview

- Workgroups Status

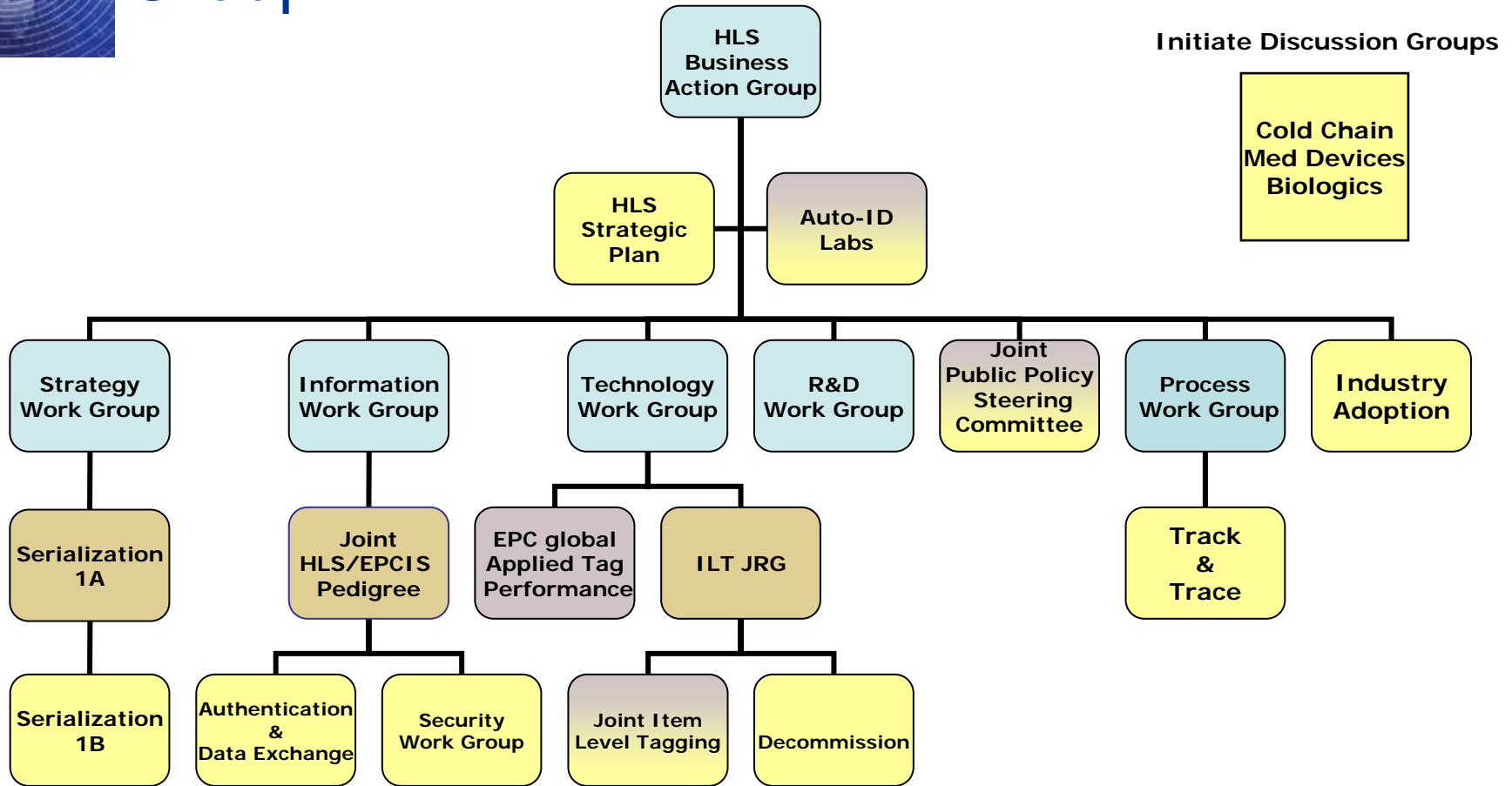- Coordinating within GS1

EPCglobal

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, PhRMA and others**
- Active participation in all key supply chain roles
  - **Manufacturers, Distributors, Retailers, Hospitals**
- Focused on addressing critical needs:
  - **Pedigree Management (including a Pedigree Messaging Standard)**
  - **Serialization - the format of the Electronic Product Code (EPC)**
  - **Network Security**
- RFID
  - **Air Interface Standard for item level tagging**
  - **Decommissioning of tags**
- EPCglobal helped form and supports the Unified Pedigree Coalition (State and Federal Regulatory Agencies)

EPCglobal

Healthcare & Lifesciences Business Action Group

Initiate Discussion Groups

- HLS Business Action Group
  - HLS Strategic Plan
  - Auto-ID Labs
- Strategy Work Group
  - Serialization 1A
    - Serialization 1B
- Information Work Group
  - Joint HLS/EPCIS Pedigree
    - Authentication & Data Exchange
    - Security Work Group
- Technology Work Group
  - EPC global Applied Tag Performance
  - ILT JRG
    - Joint Item Level Tagging
    - Decommission
- R&D Work Group
- Joint Public Policy Steering Committee
- Process Work Group
  - Track & Trace
- Industry Adoption

Cold Chain Med Devices Biologics

Legend:
- ☐ HLS Top Priorities – 2006
- ☐ On-Going HLS WGs
- ☐ On-Going EPC WGs
- ☐ HLS Top Activities – 4Q05

EPCglobal

Serialization

James Hickland – GSK
Steven Addante - Walgreens

Charter:

Define the HLS requirements that will lead to a viable mechanism for mass-serialization of pharmaceuticals at various packaging levels, including item level

EPCglobal Confidential and Proprietary

EPCglobal

Item-Level Tagging
Tom Pizzuto – Wyeth
Tim Marsh - Pfizer

Charter:

- **Item Level Tag JRG represents end-users from Fast Moving Consumer Goods, Healthcare and Life Sciences & Department of Defense. It is chartered to define a comprehensive set of item-level requirements**

- **Comprised of three different groups**
  - **Joint Requirements Group (JRG)**
  - **Air Interface HF**
  - **Air Interface UHF**

- **Examine the interoperability of data carriers**

EPCglobal

Pedigree
Dirk Rodgers – Cardinal
Eli Perlman

Charter:

- The SAG Drug Pedigree work group inherited a set of requirements from the form Pedigree Messaging **JWG**

- **Objective- create a pedigree document specification and usage guidelines** that provides a platform for the pharmaceutical supply chain to comply with the various state and federal pedigree laws

EPCglobal

Industry Adoption
Ted Ng – McKesson
Grant Hodgkins – Alcon Labs

Charter:

Define a strategy for adoption by the healthcare industry of EPC and RFID technologies, contributing to a safer and more secure supply chain.

- FDA efforts, along with multiple state regulatory agency initiatives, are being drafted to ensure appropriate safe guards will be implemented.

- Regulatory efforts have heightened the awareness and sense of urgency that industry plans and timelines must be developed more expeditiously.

EPCglobal
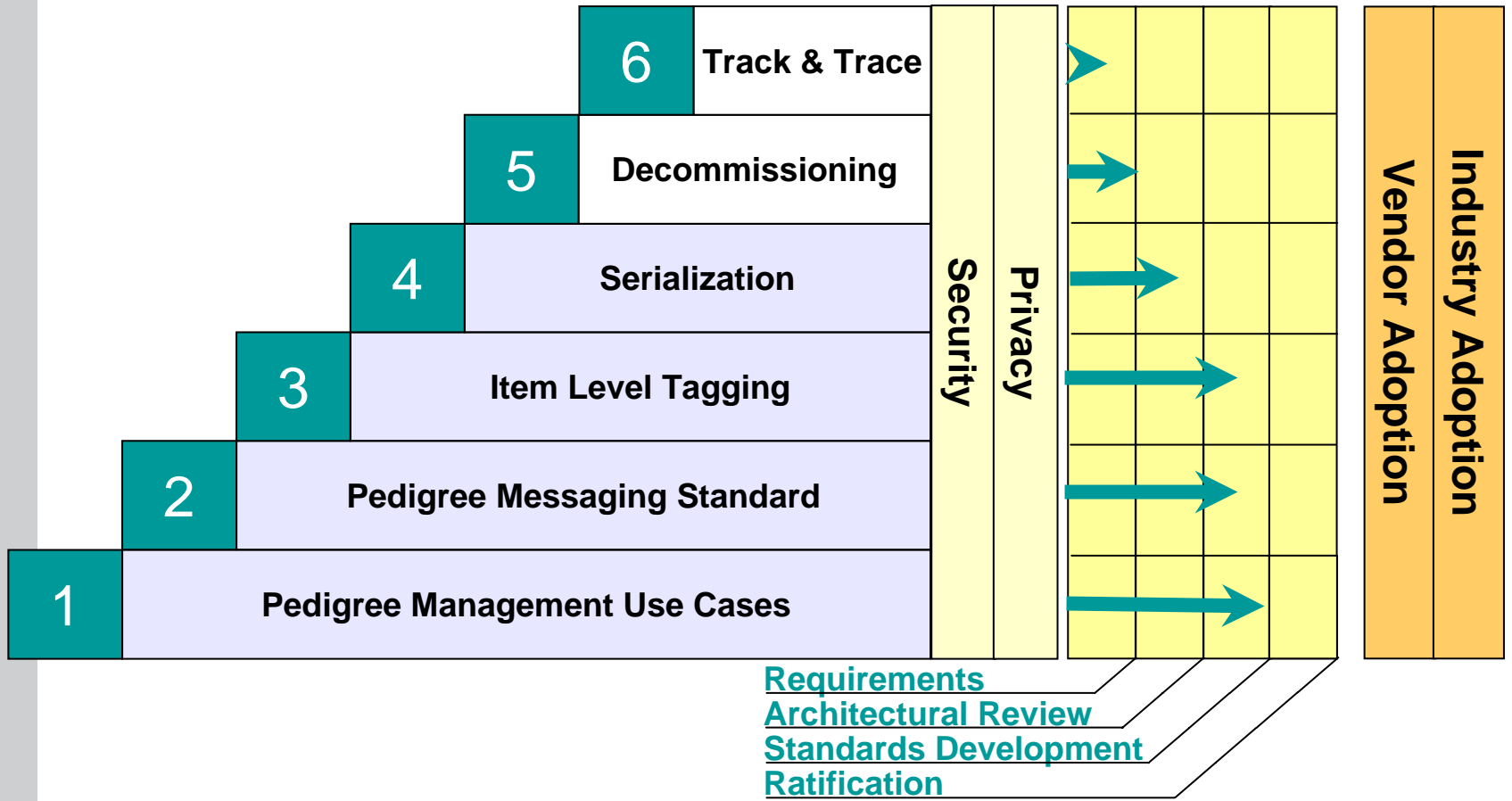
Track & Trace
John Howells – HDMA

Charter:

- **Create the business requirements essential to delivering an RFID enabled HLS Track & Trace**

- **Both, forward and reverse logistics business processes, will be defined as scenarios with associated use cases and possible variants.**

EPCglobal

ePedigree Standards
State of the Standards – Foundational Capabilities

6	Track & Trace			
5	Decommissioning			
4	Serialization			
3	Item Level Tagging	Security / Privacy		Vendor Adoption / Industry Adoption
2	Pedigree Messaging Standard			
1	Pedigree Management Use Cases			

Requirements
Architectural Review
Standards Development
Ratification

EPCglobal

Coordinating within GS1

GS1 Healthcare User Group

Mission and Vision

Our **mission** is to lead the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.
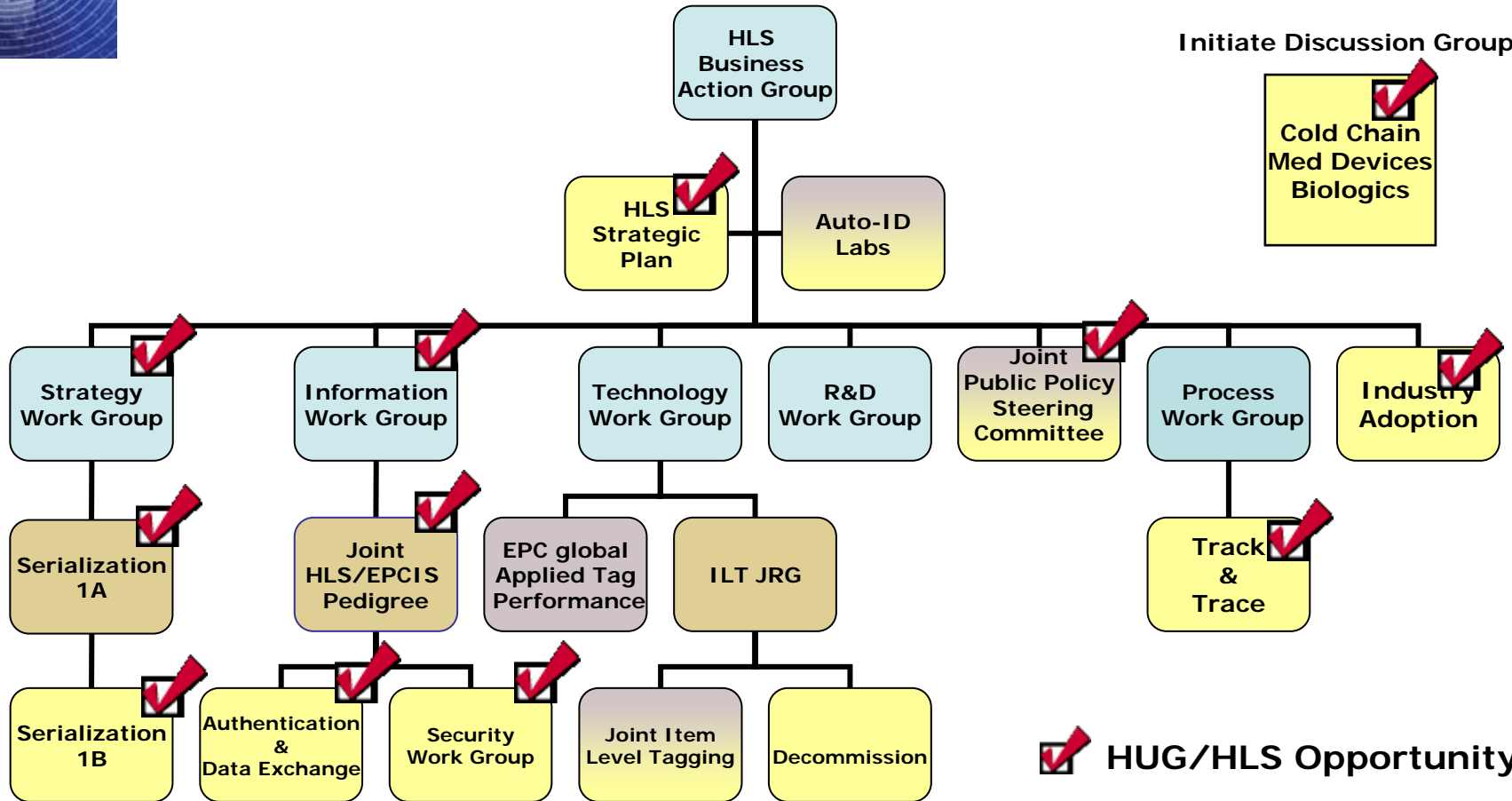
Our **vision** is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

HUG/HLS Areas for Collaboration

Initiate Discussion Groups

- HLS Business Action Group
  - HLS Strategic Plan ✓
  - Auto-ID Labs
- Cold Chain Med Devices Biologics ✓

- Strategy Work Group ✓
  - Serialization 1A ✓
    - Serialization 1B ✓
- Information Work Group ✓
  - Joint HLS/EPCIS Pedigree ✓
    - Authentication & Data Exchange ✓
    - Security Work Group ✓
  - EPC global Applied Tag Performance
- Technology Work Group
  - ILT JRG
    - Joint Item Level Tagging
    - Decommission
- R&D Work Group
- Joint Public Policy Steering Committee ✓
- Process Work Group
  - Track & Trace ✓
- Industry Adoption ✓

✓ **HUG/HLS Opportunity**

Legend:
- ☐ HLS Top Priorities – 2006
- ☐ On-Going HLS WGs
- ☐ On-Going EPC WGs
- ☐ HLS Top Activities – 4Q05

EPCglobal

Next Steps

- Joint Working Group on Serialization in Paris with members from HUG and HLS

- Integration Meeting between the Leadership Teams of the HUG and HLS

- Joint HUG/HLS Meeting at uConnect in June

- Invite HUG Members to Participate in the Active Working Groups

EPCglobal

Questions?