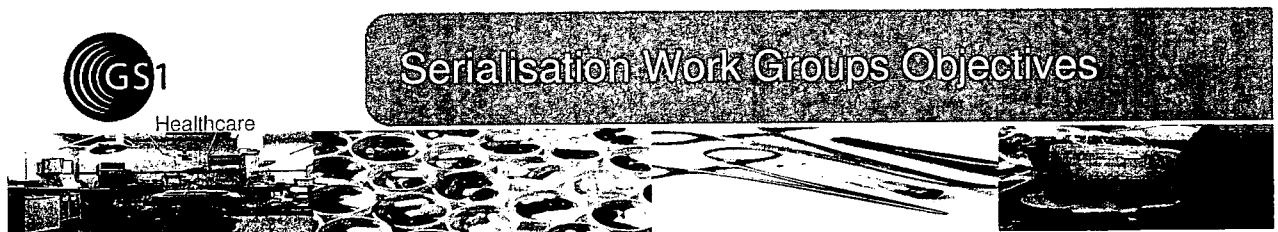


# Serialisation Work Group

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**To determine the size and structural requirements  
for lot numbers and serial numbers to support  
patient safety and product authentication  
for healthcare products**

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## SCOPE HEALTHCARE PRODUCT AREA



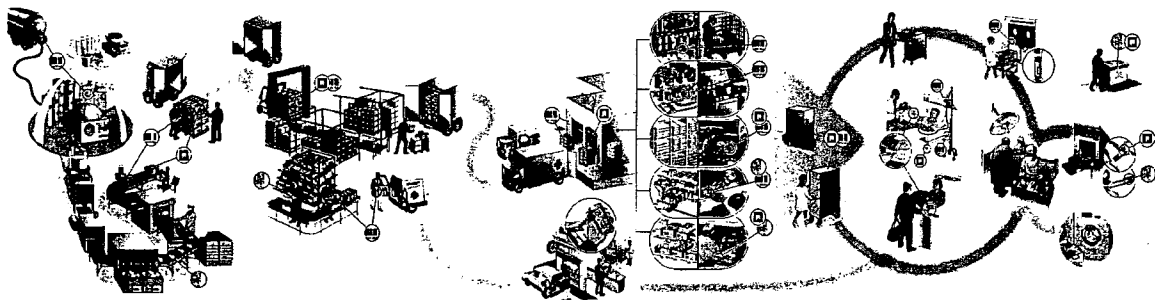
- Vaccines
- Biologics
- Therapeutic nutritional products
- Pharmaceutical
- Medical Devices (e.g., Instruments, Implants)

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## Scope Supply Chain Boundaries



Manufacturing → Distribution → Care Facility

From: Finished Goods

To: End of Treatment

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## SCOPE

The Serialisation WG will review and document business and regulatory requirements for serialisation by:

- Meaningful numbers versus randomization & capacity affect
- Decentralization/centralization of allocation & affect on capacity
- Structure
  - Numeric length
  - Alpha-numeric length



## Scope Review

The Serialisation WT will review and document business and regulatory requirements *for serialisation by Size (capacity needed).*

Number	Product	Company	Industry
Serial #	all	one	any
Serial#	all	one	healthcare
Serial#	largest	one	healthcare
Lot #	largest	one	healthcare

### **Number Structure and Capacity Data Collected**



- ✓ By Company
- ✓ By Product Types
- ✓ By Number (Lot number & Serial number)
- ✓ By Number Selection (Intelligent number or Random number)
- ✓ By Number Assignment (Centralized or Decentralized)
- ✓ By Number Structure (Numeric or Alpha-numeric)

### **Over 39 Responses**

#### **Representing:**

- ✓ **All product types**
- ✓ **Manufacturers**
- ✓ **Distributors**
- ✓ **Hospitals**
- ✓ **North America**
- ✓ **Europe**
- ✓ **Australia**
- ✓ **New Zealand**

## Largest Numbers Collected

**Number of serial numbers needed if 1 is assigned to every product “instance” produced for:**

	any channel	healthcare	highest volume
<b>vaccines</b>	2 Billion	2 Billion	2 Billion
<b>biologics</b>	5 Billion	3 Billion	400 Million
<b>therapeutic nutritional</b>	2 Billion	2 Billion	1 Billion
<b>pharmaceuticals</b>	4 Billion	50 Billion	50 Billion
<b>medical devices</b>	2 Billion	50 Billion	50 Billion
<b>instruments</b>	10 Million	10 Million	20 Thousand
<b>implants</b>	10 Million	10 Million	20 Thousand



## STATUS

Data Collection Is Closed

Data Study Started

- Serialisation Factors

Conclusions To Be Reported



# Thank You

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**GS1 Healthcare**  
**Global Data Synchronisation & Classification**

UCONNECT Conference - June 6, 2007

MJ Wylie, GS1 Global Office

The global language of business

www.



***Focused on patient safety!***

**Primary focus**

Develop global standards for electronic product identification, using GS1 barcodes and RFID

**Future projects are now**

- Medical catalogue**
- Data synchronisation**
- Classification**
- E-commerce
- And more ...



**Why Data Synchronisation in Healthcare?**

- **Healthcare continues to uncover more inefficiencies in the supply chain due to incorrect product data not aligned with all trading partners.**
- **Healthcare is similar to other sectors, however the errors that occur because of incorrect product data, can result in patient death.**

Because of these points, GS1 Healthcare User Group (HUG™) has accelerated the development roadmap to extend Global Data Synchronisation for Healthcare. In 2007, GS1 HUG approved two new work teams to address:



- ✓ **Global Data Synchronisation for Healthcare**
- ✓ **Product Classification for Healthcare**

***If you do business with a partner that is global, you are a part of the global supply chain!***





## Approved Work Teams with Leadership

### Approved Work Teams

#### ■ Global Data Synchronisation Work Team

- ❖ Joe Pleasant, Premier Inc.
- ❖ Tom Werthwine, Johnson & Johnson

u3

#### ■ Global Classification Work Team

- ❖ Leighton Hansel, Abbott Healthcare
- ❖ Dave Turner, Novation

✓ MJ Wylie serves as GS1 Resource for both teams. u2



- u2 MJ Wylie, GS1 GO facilitates both work teams.  
ulrike.kreysa, 6/1/2007
- u3 I have taken the countries out - this looks otherwise as a US only activity and Abbott as well as J&J are global companies and do this under a global perspective  
ulrike.kreysa, 6/1/2007

## Global Data Synchronisation Work Team

## The Data Sync Work Team in a nutshell



- Compile, review and assimilate current pilots and production initiatives
- Compile and condense the list of required healthcare data attributes
- Deliver a phased approach for static healthcare product data attributes in GDSN

The approved attributes and business requirements will be used to establish a GS1 GDSN Healthcare extension

## Global Data Synchronisation Work Team *A closer look*

### Scope

Leverage and utilize Global Data Synchronisation Network's (GDSN) existing infrastructure and processes to define new healthcare business and data requirements for static product data.

### Objectives

- ❖ Define global business requirements to adapt to GDSN.
- ❖ Develop implementation roadmap and facilitate local and global adoption.
- ❖ Ensure a business case is documented for healthcare industry-wide education.

### Deliverables

- ❖ Collect and document all current (local and global) data synchronization initiatives as a gap analysis,
- ❖ Ensure a business case is documented for industry wide education,
- ❖ Define global business requirements to adapt to GS1 GDSN,
- ❖ Deliver roadmap for requirements, development and implementation timelines.
- ❖ Define adoption plan with timelines.

**Compare requirements for product data worldwide – find alignments, gaps, and work to assimilate data elements against the GDSN elements....**

- Australia
- Canada
- France
- Greece
- Netherlands
- Spain
- Sweden
- Switzerland
- USA

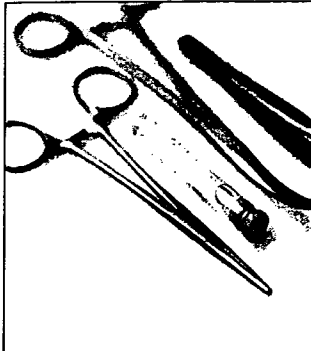
**Special Thanks**  
**Valerie Marchand**  
**GS1 France**  
**&**  
**Christian Hay**  
**GS1 Switzerland**

*If you do business with a partner that is global, you are a part of the global supply chain!*



**Product Classification Work Team**  
**(a subteam of Data Synchronisation Work Team)**

## The Classification Work Team in a nutshell



- Compile, review and assimilate current and key classification systems used in healthcare
- Define healthcare-specific product groups within the GS1 GDSN
- Determine implementation roadmap for publishing and maintaining classification in GDSN
- Deliver the GDSN healthcare classification system and processes to ensure mass adoption

**Goal:** Leverage and utilise GDSN's existing infrastructure and processes

## Global Classification Work Team *A closer look*

### Scope

Leverage the **GDSN** classification structure of **GPC** and **UNSPSC** for static healthcare product data, including the minimum participation of that taxonomy for use in global data synchronization – to ensure the proper classification of healthcare items in **GDSN**.

### Objectives

- ❖ Agree upon potential classification structures for which **GDSN** might leverage in addition to **GPC** and **UNSPSC** for static healthcare product data, including the minimum participation of that taxonomy for use in global data synchronization – to ensure the proper classification of healthcare items in the **GDSN**.

### Deliverables

- ❖ By end of June meeting in Orlando, define the terms: taxonomy, classification, nomenclature and ontology for Work Team use in global data synchronization classification project and future **GDSN** educational initiatives.
- ❖ Identify global, regional, and country classification systems currently in use.
- ❖ Analyze existing systems to identify and prioritize those that should be considered for assimilation/integration into **GDSN**.
- ❖ Deliver a roadmap with high level implementation and stakeholder adoption plans, with recommended timelines.

## Primary Use for Classification in Data Synchronisation

- **In scope: Navigation and Search Capabilities**
- **Not in scope: Procurement & Sourcing Activities:**
  - Sourcing, Contracting and Spend Analysis
  - Financial and Commercial analysis



## Questions & Discussion

*If you do business with a partner that is global, you are a part of the global supply chain!*



## Contact details

### GS1 Healthcare

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David Turner - [DTURNER@novationco.com](mailto:DTURNER@novationco.com)

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[www.gs1.org](http://www.gs1.org)



## Drug Pedigree 1.0, Software Certification

Chris Adcock, EPCglobal

6th-June, 2007

EPCglobal



# Goals of the Pedigree Standard

- Provide a standard, interoperable platform for supply chain partner compliance with state, regional and national drug pedigree laws
- Provide flexible interpretation of existing and future pedigree laws
- Provide a standard today that can operate with other EPCGlobal standards in the future (item-serialization, EPC-IS, etc.)



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# ePedigree Timeline

Activity	Date(s)
Drug Pedigree WG started	<b>February 20<sup>th</sup>, 2006</b>
Drug Pedigree ratified	January 5 <sup>th</sup> , 2007
Beta-Testing	April 30 – May 10, 2007
Certification Testing / Pre-Testing*	May 14 – May 31, 2007
First Suppliers Certified	<b>June 6, 2007</b>

\* Ongoing certification program, may apply anytime after the program is launched



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# Certified Drug Pedigree 1.0 products as of 6<sup>th</sup> June 2007

Company	Product	Representative(s)
Axway, Inc.	Synchrony ePedigree	Dale Moberg Binu Jacob
rfXcel Corporation	rfXcel Active ePedigree Management	Jim Chiang
SupplyScape Corporation	SupplyScape E-Pedigree	Lucy Deus Peter Spellman

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# Drug Pedigree Software Certification, June 6<sup>th</sup> 2007



**Synchrony ePedigree**



**rfXcel Active ePedigree Management**

# SupplyScape

SupplyScape E-Pedigree

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# Summary

- Thank you goes to a great number of people that participated in the work groups:
- Special Thank you to the co-chairs:
- *Work or Interest Group Co-Chairs*
  - Dirk Rodgers, SupplyScape
  - and Eli Perlman, Tibco

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Tag Data JRG  
Summary of User and TID Memory Requirements  
presented to Healthcare and Life Sciences IAG





## Tag Data Joint Requirements Group (TD JRG)

- **JRGs Overview:** Joint Requirements Groups brings together the End Users and the Technology Providers for dialogue to reach a common understanding on the needs of the End Users and the capabilities of the technology.
- **TD JRG Questionnaire:** Tag Data Joint Requirements Group (TD JRG) created a questionnaire and requested that all EPCglobal end users complete the on-line tool to describe their application and convey requirements for user memory and tag ID.
- **TD JRG Requirements Doc:** The TD JRG requirements document has been posted for comment for the past two weeks. The comment period has now closed, **but additional IAG input is welcomed.**



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## Summary of Questionnaire Results

- 56 Distinct use cases were submitted and described representing 8 different industry groups
- **HLS submitted just over 10% of the use cases**
- While the questionnaire was designed to gather requirements from End Users who intend to use User Memory and/or Tag ID, the results clearly specify that not all End Users have such a need:
  - The Tag Data Standards shall support tags with no user memory
  - **The Tag Data Standard memory format shall support a mixed tag population of tags with varying amounts of user memory (including tags with no user memory).**



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## Questionnaire Results - Summary

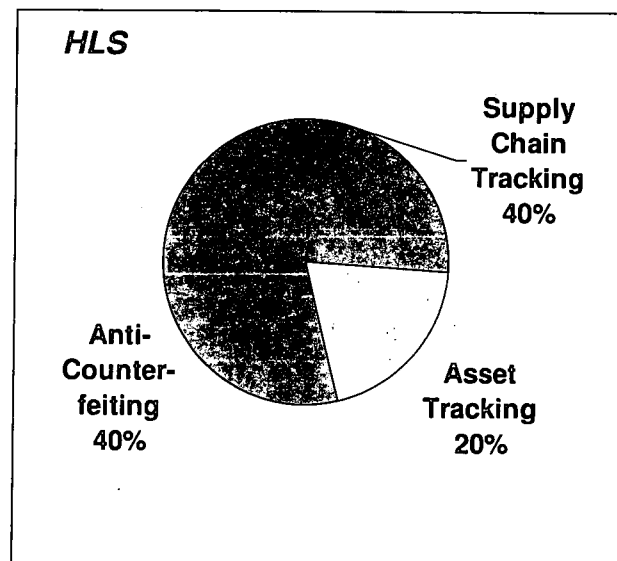
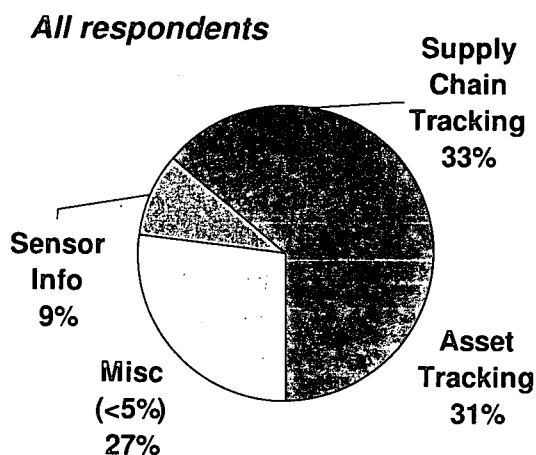
- Actual results of all respondents follow
- HLS results are compared to all respondents
- TD JRG still welcomes your comments, [jrg\\_td-chair@lists.epcglobalinc.org](mailto:jrg_td-chair@lists.epcglobalinc.org)
- Your input and ideas are requested for HLS

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## What application are you referencing in answering the User Memory Questionnaire?



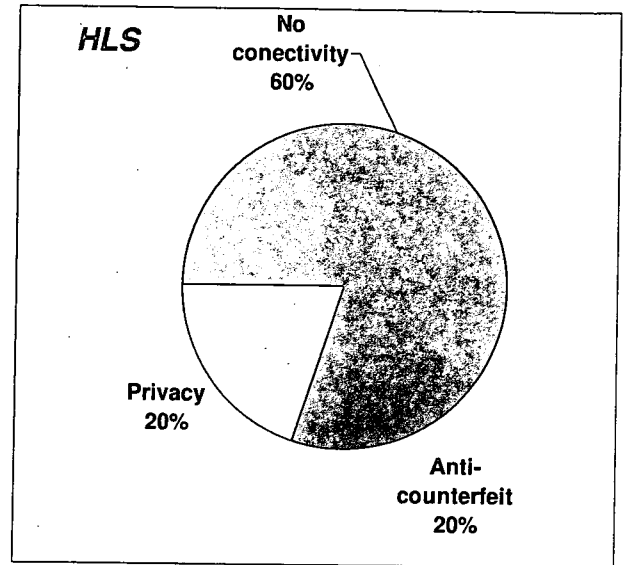
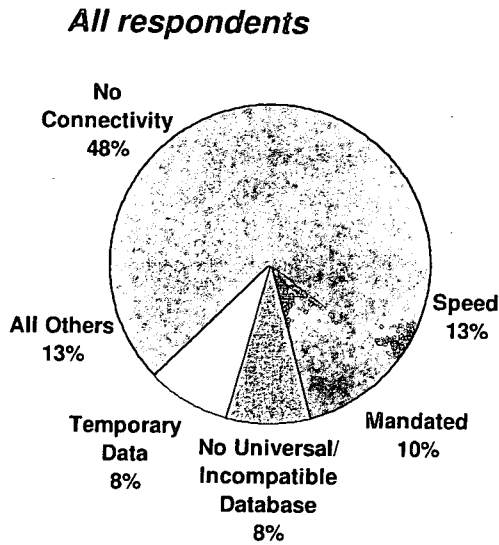
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## Why should the information reside on the tag rather than accessing it via lookup?



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## What data standards are you currently using (select all that apply)

- The majority of all respondents indicated they are currently using AI's, followed closely by DI's and/or the requirement for a mixed environment.
  - Aerospace uses TEIs and many use open system standards (IATA, AAR, UPU, etc.).
  - A few respondents use proprietary standards.
- HLS identified AI's and DI's, with the vast majority (80%) indicating they are currently using AI's only

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