

# Taking steps to

*A voluntary healthcare user group is bringing together stakeholders to develop standards to enhance efficiency and patient safety. **Janice Kite** explains*

**GS1 is a leading global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world (see [www.gs1.org](http://www.gs1.org)).**

## **About GS1 Healthcare**

GS1 Healthcare is a voluntary, global healthcare user group bringing together all related healthcare stakeholders – pharmaceutical and medical devices manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, government and regulatory bodies, and associations (<http://www.gs1.org/sectors/healthcare/index.html>).

It was formed in 2007 when the GS1 EPCglobal HLS Industry Action Group (HLS) and the GS1 global Healthcare User Group (GS1 HUG) joined forces into one global healthcare user group, called GS1 Healthcare.

## **Mission and vision**

The mission of GS1 Healthcare is to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in healthcare for patient safety, supply chain security and efficiency, traceability and accurate data synchronisation.

Some examples of how GS1 Healthcare is working internationally were presented at a recent meeting of the WHO IMPACT Technology work team in Singapore. Authorities of Hong Kong, Italy, Spanish regions (Andalusia and Galicia) and Turkey shared their ongoing projects at the conference in Granada. Japan will soon issue revised barcode guidelines for medical devices, recommending the continued use of GS1 Standards, but with some changes to align with global standards.

The global standards development roadmaps of the two groups have also been integrated and updated and there are now three main work streams:

- AIDC Application Standards
- Traceability in healthcare
- Data synchronisation and product classification.

The GS1 Healthcare Work Team 'Traceability in Healthcare' was established in support of the GS1 Global Healthcare Roadmap. Its objectives are in two phases.

**PHASE 1** is that by the end of June 2008 the Traceability in Healthcare Work Team will have developed the Traceability in Healthcare Standard that:

- Enables improvement to patient safety
- Meets national and/or international legal and regulatory requirements
- Addresses business and interoperability needs
- Has been validated against the GS1 Global Traceability Standard (see [http://www.gs1.org/docs/gsmpt/traceability/GS1\\_Global\\_Traceability\\_Standard\\_i1.pdf](http://www.gs1.org/docs/gsmpt/traceability/GS1_Global_Traceability_Standard_i1.pdf)), and any resulting change requests will then be

# traceability

submitted to GS1 Global Standard Management Process (GSMP).

**PHASE 2** is that by the end of December 2008 the Traceability in Healthcare Work Team will have:

- Developed Traceability in Healthcare Implementation Guideline
- Collected and documented case studies
- Collected and documented best practices.

The work team has an active membership of 98 and 280 have opted in to receive work team communications. It is truly international with representation from Turkey, Australia, Germany, US, Ireland, Austria, Canada, UK, Hong Kong, New Zealand, Norway, China, Brazil, France, Netherlands, Croatia, Chile, India, Tunisia and Sweden and represents all healthcare stakeholders: distributors, regulatory bodies, pharmaceutical and medical device manufacturers, industry associations, hospital procurement, clinicians, academia, ministries of health and wholesalers.

The scope is **'from finished goods to end of product life'** and includes:

- Pharmaceuticals including vaccines, biological and therapeutic nutritional products
- All risk levels of medical devices
- Patient safety
- Visibility (logistics)
- Brand protection (authentication, anti-counterfeiting, grey market)
- Process and technologies

## But out of scope are:

- Traceability of non-medical products supplied to healthcare providers, such as food, information technology, staff
- Traceability of blood and blood products (as there is a Memorandum of Understanding in place between GS1 and ISBT (International Society of Blood Transfusion – see [www.isbt-web.org](http://www.isbt-web.org)) and work is being done to harmonise standards)
- Traceability of patients
- End of life related to environmental regulations (e.g. European WEEE Directive)

The work team is co-chaired by Tim Marsh, senior manager – global package technology, Pfizer Global Manufacturing Services (US-based global manufacturer) and Frédérique Fremont, organisation engineer, C.H.I Robert Ballanger (French hospital) and is facilitated by Janice Kite, GS1 Global Office.

The work team is on track in Phase 1 and has completed collection, analysis and agreement of 114 traceability business requirements. These came from the existing Global Traceability Standard, HLS and work team members.

A business requirement is defined as '... a statement of need concerning the business area or business process under study. It is something that the system must do or a quality that the system must have. A requirement exists either because the type of product demands certain functions or qualities, or the client wants the requirement to be part of the delivered product.'

The 114 business requirements fell into one of five groups, defined as 'Traceability Principles' in the Global Traceability Standard:

**0. Traceability System:** The requirement for a Traceability System

**1. Unique Identification:** of products, logistic units, locations and assets

**2. Data Capture and Recording:** Capturing and recording traceability data

**3. Links Management:**

Linking in-bound materials through changes to new out-bound traceable items and

**4. Data Communication:** Sharing traceability data between trading partners

The objective of this review is to ensure that all business requirements provided to the work team are given adequate consideration. The analysis process results in one of three possible outcomes for each business requirement:

• **CLOSED:** A business requirement is CLOSED when the work team has agreed/approved the wording of the business requirement and includes re-approval of business requirements already in GTS

• **DELETED:** A business requirement is DELETED (but the data is retained) if it has been combined with another business requirement or replaced by two or more new business requirements

• **OUT OF SCOPE:** A business requirement is OUT OF SCOPE if it is a national requirement or not related to traceability; it may be moved to a 'parking lot' for future consideration.

At completion of this stage 80 business requirements were closed (i.e. approved), nine business requirements were deleted and 25 business requirements were Out of Scope and one business requirement was determined

to be a business rule rather than a business requirement. Broadly, the closed business requirements were found to be addressed by the 20 business requirements already included in the Global Traceability Standard, with a few wording changes.

This is a significant achievement and is testament to the commitment of the work team members as the majority of the activity undertaken is via weekly conference calls. These calls alternate between 14:00 GMT and 21:00 GMT in an effort to accommodate members in different time zones.

Meetings face to face take place at the global GS1 Healthcare conferences that happen three times per year; the last one being in Granada, Spain; the next one is scheduled for Toronto, Canada from 17-19 June 2008.

The work team followed the same process for Business Rules. A Business Rule is defined as a

"...statement of fact concerning the business area or business process

under study that must survive changes to process or data. Business Rules are a constraint, in the sense that a business rule lays down what must or must not be the case. Business Rules define what must be the case rather than how it comes to be. As with the Business Requirements review, at completion of this stage 27 of the 28 existing GTS Business Rules were closed (i.e. approved), one was split to form two separate business rules and one new rule was added, making 30 business rules in total, with a few wording changes."

Any changes agreed during these activities will be incorporate into a change request to the Global Traceability Standard and, ultimately, submitted to GS1's GSMP. At the end of the GSMP process the Traceability in Healthcare standard will be published.

While the change request is progressing through GSMP the work team will move into **PHASE 2** activity.

For more information or if you would like to join the Traceability in Healthcare Work Team, contact Janice Kite at [janice.kite@gs1.org](mailto:janice.kite@gs1.org) •

## About the author

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