



Traceability in Healthcare

Status update 10 October 2008

GS1 sets roadmap to state-of-the-art Global Traceability Standard for Healthcare

GS1 commits to facilitate the development by the user community of a Global Traceability Standard for Healthcare (GTSH) as well as a suite of technical standards as an efficient and effective architecture for all Healthcare supply chain stakeholders. A complete suite of standards for global traceability is targeted for mid 2010 enabling compliance with ongoing legislative and regulatory developments worldwide as well as industry business process needs. GS1 recommends all Healthcare stakeholders to build-in the necessary flexibility and upgradeability while developing traceability solutions, taking the GTSH into account.

The need for global traceability in Healthcare

Safety, security and traceability of pharmaceuticals and medical devices are currently at the forefront of government regulations and industry concerns around the world. Traceability regulations and solutions are being (or have already been) proposed to the national and international supply chain stakeholders. Several states in the U.S. have passed pedigree legislations, notably in California. Recognising the vast effort it will take for industry to “implement electronic technologies to track the distribution of dangerous drugs within the state,” the California State Board of Pharmacy recently announced a delay in the implementation of its pedigree law to 2015. In its written announcement, the Board stated that “innovations and applications would benefit greatly from additional time to mature.” Furthermore, the U.S. Food and Drug Administration is charged under the FDA Amendments Act of 2007 with developing standards for numerical identifiers and for authentication tools for drugs by April 2010. A pending bill could cause the FDA to write regulations that would pre-empt State Pedigree laws. The European Commission is currently drafting a regulation for anti-counterfeiting legislation in E.U. Member States.

GS1’s vision on the Global Traceability Standard

GS1 aims to define a portfolio of standards that will enable traceability in Healthcare to ensure that the business needs of the industry are fulfilled, including ensuring global traceability in an efficient, secure and reliable way, addressing restrictive legal requirements, addressing authentication from manufacturer to patient, and achieving cross-industry interoperability.

The Global Traceability Standard for Healthcare (GTSH) will ultimately enable supply chain stakeholders to reconcile national legislative and regulatory requirements. Implementation of the GTSH will be enabled by a supporting suite of technical standards.



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Roadmap to Global Traceability Standard for Healthcare

While taking into account differences imposed by diverse legislative and regulatory requirements and diverging expectations in terms of enabling technologies, the GS1 Healthcare community is committed to develop the GTSH enabling improvements to patient safety in an efficient and effective way.

GS1 facilitates a work team 'Traceability in Healthcare' that was established in December 2007 and builds on the work that was already done by the Global Traceability Standard work group and the EPCglobal Healthcare and Lifesciences (HLS) Track and Trace work group. The work team has finalised a draft GTSH and submitted it into the GS1 Global Standards Management Process (GSMP). The GTSH is expected to be ratified early 2009. This work team will then also have developed an implementation guideline that references contemporary, documented case studies and best practices.

GS1 facilitates the development by the user group of a portfolio of standards that enable traceability across the global healthcare supply chain for all stakeholders. This portfolio of standards will include both process standards such as the GTSH and technical standards such as EPC Information Services Standard (EPCIS), Object Naming Service Standard (ONS) and Discovery Services Standard, and is targeted to be available by mid 2010. These standards will be applicable to the full range of GS1 members of any size and to all levels of organisational complexity and system sophistication. The necessary resources and budget have been secured to facilitate the development process. Ongoing work from local user groups, including GS1 Healthcare France, Spain, and US, will be taken into account during the development.

GS1 recommends all Healthcare stakeholders to develop traceability solutions taking the GTSH into account by building in the necessary flexibility and upgradeability. GTSH will provide a global, comprehensive and future-proof traceability standard to the benefit of all stakeholders. It will supersede the current Pedigree Ratified Standard V1.0, which was developed to comply with document-based pedigree laws in the U.S.

A handwritten signature in blue ink, appearing to read 'V. Heijden'.

Michel van der Heijden
President Healthcare & New Sectors

A handwritten signature in black ink, appearing to read 'Miguel A. Lopera'.

Miguel A. Lopera
President & Chief Executive Officer

GS1 aisbl
Blue Tower, Avenue Louise 326, bte 10
B-1050 Brussels
T +32 (0)2 788 78 00
F + 32 (0)2 788 78 99
E contactus@gs1.org
www.gs1.org



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Frequently Asked Questions

Q. How is GS1 related to traceability?

A. Because of GS1's ability to provide globally unique identification of items, parties and locations (GS1 Identification Keys, GS1 BarCodes and GS1 EPCglobal RFID), GS1 Standards are particularly well suited to be used for traceability purposes in Healthcare. GS1 eCom provides global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners. EPCIS provides a standard interface for supply chain partners to share and exchange information efficiently.

Q. What is the Global Traceability Standard?

A. The GS1 Global Traceability Standard is a process standard that defines the Traceability business process and the minimum data management requirements for all traceability systems independently from the technology.

Read more at www.gs1.org/productssolutions/traceability/overview/

Q. What is the Global Traceability Standard for Healthcare (GTSH)?

A. GTSH is being developed to meet emerging national and/or international legal and regulatory requirements and to address healthcare-specific business and interoperability needs on a worldwide basis.

Q. What is the suite of technical standards and how is it related to the GTSH?

A. The suite of technical standards for Healthcare includes Discovery Service standard, EPCIS standard, Core Business Vocabulary Standard, and ONS standard along with guidelines to illustrate how these standards are used to implement a system of global traceability based upon the GTSH.

Q. When will the GTSH be available?

A. The next version of the GTSH along with an implementable suite of technical standards will be available by mid 2010. The necessary resources and budget have been secured to achieve this.

Q. Will GS1 continue to support the Pedigree Ratified Standard V1.0?

A. GS1 and EPCglobal, Inc., a subsidiary of GS1, will continue to support the Pedigree Ratified Standard V1.0 in its current version, until the GTSH can replace it. All future traceability related standards development work will be focused on the GTSH and related technical standards. GS1 recommends all stakeholders to develop traceability



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solutions taking the GTSH into account by building in the necessary flexibility and upgradeability.

Q. What is EPCIS?

A. The EPC Information Service (EPCIS) is a standard used to track the progress of objects as they move through the supply chain. The data shared at each read point in the supply chain provides WHAT, WHEN, WHERE and WHY of each read. EPCIS provides the Information Services necessary for the storage, communication and dissemination of EPC data. It provides standard event capture and query interfaces for obtaining and sharing data about unique objects in the supply chain within and across organisations. EPCIS provides a way for supply chain partners to share and exchange information efficiently, because a standard interface allows trading partners to use the same functions or methods for querying data across the supply chain, leading to reduced time to integrate with partners if everyone uses the same interface, even though they may store the information in different types of underlying databases.

The EPCIS Standard v. 1.0 was ratified by the EPCglobal community in April 2007.

Q. What are Discovery and ONS?

A. The Discovery Services Standard currently under development will enable trading partners to discover all of the other participants who may have visibility data that is captured and stored via EPCIS. It will ensure each party retains rights of ownership of its visibility data and that queries are authorised and authenticated. The Discovery Services Standard will enable trading partners to exchange data in a secure way with parties that they may not have a prior direct business relationship and to obtain data when and where it is needed.

Object Name Service (ONS) is an automated lookup service that locates the EPCIS of the issuing authority for a specific EPC. The ONS Standard v. 1.0 was ratified by the EPCglobal Board of Governors in October 2005 (v. 1.0.1 in May 2008).

Q. What is GS1?

A. GS1 is a global, not-for-profit Standards Development 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.

GS1's Global Office is based in Brussels (Belgium) and in Princeton, NJ (US) and facilitates the development of global supply chain standards. GS1 has Member Organisations in 108 countries.

For more information, visit www.gs1.org