GS1 Healthcare Newsletter
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GS1 Healthcare: one unified User Group

GS1 and its Healthcare User Community have already made significant accomplishments. I want to thank everyone involved for their unfailing devotion. The Global Standards development processes have resulted in some standards being ratified and more are in progress. To make this process more efficient, the two existing User Groups within GS1 (the GS1 Global Healthcare User Group and the EPCglobal Healthcare & Life Sciences Industry Action Group) have agreed to join forces and form one united group “GS1 Healthcare”. This means: one governance charter, one roadmap, a single group for our users to contribute to and to follow up and a single source for regulatory bodies and associations to work with. This integrated group will kick-off on 28 October 2007 at our next GS1 Healthcare Conference in Windsor (near London). In the meantime, it is of course ‘business as usual’: the standards development process keeps on going.

Michel van der Heijden, President Healthcare, GS1

GTIN Allocation Rules Standard ratified for Healthcare

The GTIN (Global Trade Item Number) Allocation Rules Standard for Healthcare has been ratified by the GS1 Community. “With this global standard we can assure that GTIN’s are assigned consistently within the Healthcare industry”, says Mark Walchak, Pfizer and Work Team Leader, “This moves the industry one step closer to automatic data capture and helps all of us achieve our goal of improved patient safety”. “This is the first major milestone in defining the Healthcare Application Standards for Automatic Identification and Data Capture. The achievement certainly confirms the GS1 Global Healthcare User Group’s commitment in delivering a standard designed for Global harmonisation to improve patient safety” says Mark Hoyle, Covidien (formerly Tyco Healthcare) and Work Team Leader. For more information, see:

www.gs1.org/docs/gsmp/HUG/HUG_GTIN_Allocation_i4.6.pdf

Specific needs of Automatic Identification in Healthcare require camera-based bar code scanners

The GS1 Global Healthcare User Group has issued a Position Statement with a strong recommendation to invest in camera-based bar code scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain, in particular when using GS1 DataMatrix, a 2-D bar code.

For more information, see:

www.gs1.org/hug/about/news/GS1_HUG_ps_Camera_Based_Scanners.pdf

EPCglobal ratifies Global Standard for secure, real-time data sharing

EPCglobal Inc announced a groundbreaking industry standard providing the capability for unprecedented visibility into the movement, location and disposition of assets, goods and services throughout the world. EPCIS (Electronic Product Code Information Services) allows for the seamless, secure exchange of data at every point in the lifecycle of goods and services.

For more information, see:

www.epcglobalinc.org/about/media_centre/press_re/EPCglobal_ratifies_EPCIS_070416.pdf

In this issue:

• Highlights from the GS1 Healthcare Conference in Orlando, including implementations of Auto-ID in Healthcare, EPCglobal/RFID in Healthcare, managing master data in Healthcare, and GS1 collaborating with partners.
• GS1 Healthcare news from around the world, including reports from Australia, Canada, France, Malta, and U.K.
Implementations of Auto-ID in Healthcare

Making the hospital a safer place

In May 1994, St. Alexius Medical Center implemented bar code scanning at their receiving dock. Over the years, they have expanded the application of Auto-ID, all the way to bedside scanning and to RFID. Frank Kilzer, Vice President of Material and Facility Resources, St. Alexius Medical Center in Bismarck, North Dakota, is a strong advocate of how Auto-ID technology not only increases operational efficiencies and reduces the cost of Healthcare, but also more importantly improves patient safety.

Automatic identification technologies (bar coding and RFID) are not used to their full potential, according to Frank Kilzer. These technologies enable improvements in patient care, including reduction of medication errors, nurses have more time to spend with patients and reduction of length of stay. It also allows better utilisation of your resources: professional staff are not involved any more in supply logistics, redundant manual tasks are eliminated and benchmarks measuring performance showed improved staff morale. The programme allowed St. Alexius to transition 7 FTE’s to other responsibilities. The overall supply chain is more efficient: for example the fill rates were improved to over 98% and inventory was reduced by US$2.4 million. Capturing data automatically also enabled St. Alexius to efficiently generate reports on total spend by vendor, department and surgeon. An analysis of these reports allowed cost reductions for example by benchmarking physicians and changing consumption behaviour.

Frank Kilzer concluded: “We are on a journey to improve the safety and efficiency of the health industry supply chain. Let’s work together and make it happen.”

Bar Code Medication Administration: lessons learned by the Veterans Health Administration

VHA (Veterans Health Administration in the U.S.) already started computerising its Healthcare delivery system back in 1982. In 1999, VHA rolled out bar coding for its medication administration throughout their network of medical centres (in total 60,000 beds). About 600,000 medication doses are administered daily or 850 million doses since its inception.

Over the last few years, the VHA Bar Code Quality Program has significantly reduced the number of problematic scans, today 15,600 scans (or 2.6%) remain problematic each day. This can be related to the scanner, bar code, label or printer. Chris Tucker, Director Bar Code Resource Office at VHA, acknowledged that reducing the number of human interventions builds safety into the processes of care, but also highlighted some areas for improvement in the Auto-ID process. These include durability of bar codes on multiple use containers, wristband manipulation, multiple bar codes placed in close proximity making it difficult to scan the right one, no standardised formatting of data for lot number and expiration date and lack of universal verification practices.

Auto-ID of vaccine products in Canada

Over 15 million vaccine doses are provided to Canadians annually. The Public Health Agency of Canada set up a project to improve the safe use of vaccines and to improve immunisation record keeping, by incorporating bar codes into vaccine product labelling.

Lisa Belzak, Public Health Agency of Canada, shared the lessons learned so far. Global standards should be used in national implementation plans. All stakeholders across
the supply chain should be used to advocate for bar code standards. In cases of voluntary implementation, participation and support from the regulatory body is critical. Last but not least, everyone must participate or the desired benefits are not achieved. PHAC is actively supporting the creation of a Local Healthcare User Group in Canada.

For more on this project in Canada, also see “Canada Establishes Advisory Committee for the Identification of Vaccines and Biologics” on page 6.

**EPCglobal / RFID in Healthcare**

**EPCglobal Healthcare and Life Sciences Industry Adoption Task Force**

More than 80 companies and organisations have joined this task force to take the lead in synthesising available material into a coherent, forward looking guidance document for Pedigree and Unique Identification in Rx drug supply chains and products in the USA. This document will provide guidance in meeting current and emerging regulatory expectations and will provide trade associations a starting point in their discussions with their members.

Grant Hodgkins, Alcon, and Ted Ng, McKesson and the Task Force Co-Chairs, explained the next steps. Through a series of face-to-face meetings, task force members will share the developed content with target audiences and solicit feedback. The coordinated exchange of uniquely identified products, using the concept of pedigree transactions, can result in improved supply chain safety and security. Providing trading partners with approved standards and guidance will reduce complexity, barriers to adoption, and lowers the overall cost for all participants.

**EPCglobal Software Certification Programme for Drug Pedigree**

Three companies were awarded the EPCglobal Software Certification Mark: Axway Inc., rFXScel Corp., and SupplyScape Corp.

“Choosing the right EPC/RFID software for your business can be a challenging process, with many factors to consider,” said Chris Adcock, President, EPCglobal Inc. “The EPCglobal Software Certification Programme provides companies with the confidence that the software they implement will work in predictable ways as defined by EPCglobal standards. The program protects the company’s investment and helps them implement EPC/RFID programmes more easily, faster, and for less cost.”

**Managing Master Data in Healthcare**

**The Australian journey towards e-Health**

Australian governments were frustrated about the lack of progress in e-Health: unconnected initiatives, missing pieces of infrastructure, and limited resources. That is why they have established NEHTA (National e-Health Transition Authority). This new entity will provide the necessary standards and infrastructure required to support connectivity and interoperability e-Health information systems across Australia.

One of the NEHTA initiatives is “Supply Chain”, managed by Ken Nobbs. This initiative also encompasses the development of the NPC (National Product Catalogue) in Australia. Ken emphasised that NEHTA fully supports GS1’s efforts in developing a GDSN (Global Data Synchronisation Network) extension for Healthcare. Furthermore, GTIN’s (Global Trade Item Numbers) will be used as the unique product identifier.

The NPC is hosted by the GS1 Australia Data Pool (EANnet - soon to be GS1net). Data requirements cover item data (supply chain data, regulatory data and Healthcare data) as well as pricing data.

Many downstream benefits and increased savings are expected when the NPC is implemented, including reduced errors in purchasing orders, increased reliability of information exchange, improved stock level control, more efficient spend analysis and improved patient outcomes.
The path to data quality at the Department of Defense [USA]

Inconsistent data standards throughout the supply chain result in inaccurate and bad data at all levels and ultimately the customer is paying the price for bad data. The DoD started a programme in 2005 and Kathleen Garvin, Program Manager, DoD/VA Data Synchronisation, shared the lessons learned so far.

In the first phase programme, the DoD synchronised product data from 23 medical manufacturers, two major distributors, 30 military hospitals, and identified US$10.1 million in savings for the hospitals to date. In the second phase, DoD wants to test GS1 GDSN (Global Data Synchronisation Network) as a potential resource for synchronising data for the entire industry. “GDSN is an established network platform for sharing synchronised data by major industries, and many major Healthcare manufacturers already participate in GDSN for retail.” One of the lessons learned so far is that manufacturers need an industry-wide product data strategy and that these decisions have a global impact. GPO’s (Group Purchasing Organisations) can consume GDSN data with minor changes to the current system. DoD now wants to grow the pilot by increasing the number of participants and scenarios and continue to work with standards organisations such as GS1 and CHeS to promote global standards.

A good Item File is the foundation

Poor information makes the job of materials management difficult in Healthcare. Manual data entry, numerous personnel entering product information, last minute notifications all create confusion. This poor information causes incorrect pricing and incorrect product orders or returns, and makes it difficult to effectively manage GPO and local contracts.

Mike Brown, UHC Hospital in Augusta, Georgia and also representing CHeS (Coalition for Healthcare eStandards), explained that the U.S. Healthcare industry is spending millions of dollars on services to make the most out of this poor information (benchmarking, missed contract opportunities). These services add little value to the management of the supply chain because they do not provide any tools for more effective and efficient supply chain management going forward.

GDSN (Global Data Synchronisation Network) can solve these problems. Standardised data eliminates the need for manual data entry. GDSN has a proven track record in multiple industries and allows the addition of attributes specific to Healthcare. Mike Brown expects significant benefits, including ensuring the right prices are loaded correctly, maximising the use of GPO contracts, enforcing advanced notification of price or product changes and leveraging operational efficiencies from bar code or RFID technologies.

GS1 collaborating with partners

Dr. Charles Jaffe, CEO of HL7 (right), and Michel van der Heijden, President GS1 Healthcare (left), announced at the Conference that GS1 and HL7 have signed a Memorandum of Understanding that begins an era of collaboration in developing global standards for improving patient care.

GS1 and HL7 (www.hl7.org) are convinced that this collaboration will be to the benefit of the Healthcare community by aligning standards development and joining forces in promoting global standards in the Healthcare community.

“For the past 20 years, HL7 has been successful in improving interoperability of Healthcare information sharing at the time and point of care, that improves the quality of patient care and reduces errors,” said Dr. Charles Jaffe, CEO of HL7, “The partnership with GS1 will accelerate the development and adoption of global standards for sharing information among our stakeholders.”

U.S. industry associations call for action to track and trace medical products

Several associations in the U.S. have created a coalition to promote the industry wide implementation of track and trace technologies. Participants include HDMA (Health Distribution Management Association), PhRMA (Pharmaceutical Research and Manufacturers of America), NACDS (National Association of Chain Drug Stores), and GPhA (Generic Pharmaceutical Association).
John Howells, Director Industry Relations, HDMA, explained the goals of this coalition: “We want to identify and understand track and trace technologies to increase the safety and security of the Healthcare supply chain. Based on an assessment of the industry readiness and challenges, we want to estimate a realistic date when such track and trace technologies can be implemented.”

AdvaMed supports the development of consensus-based Auto-ID Standards

The Auto-ID Working Group of AdvaMed (Advanced Medical Technology Association) supports the ongoing standards development process of GS1 and EPCglobal. This Working Group represents more than 40 AdvaMed Member Companies.

Jeffrey Secunda, Associate Vice President Technology & Regulatory Affairs, explained that AdvaMed wants to work with all stakeholders to identify specific safety problems that can be mitigated by the application of Auto-ID. A report by the Eastern Research Group prepared for the FDA in 2006 listed those problems, including user errors, device interactions, counterfeiting, analysis of Medical Device Records, and tracking of recalls. AdvaMed wants to propose UDI (Unique Device Identification) solutions to address these patient safety problems, including a clear plan for adoption by device users. The FDA is the most appropriate body in the U.S. for the development and implementation of such UDI solutions.

Mobile applications in Healthcare?

In Japan, McDonald’s customers can already point their mobile (cell) phones at the wrapping on their hamburgers and get nutritional information on their screens’ (New York Times, 2 April 2007).

Bar codes and RFID tags can “speak” with mobile phones. One can also envisage many applications in Healthcare, including product information and instructions, authentication, product recalls and daily alerts for medication.

Diane Taillard, Director, Solutions GS1, however points out that the lack of standards is a barrier to further market development: there is no global bar code standard for mobile phones and there are two parallel standards for RFID (EPC and NFC). GS1 is building a Mobile Commerce Community to eliminate these barriers and to facilitate the market development by providing global standards for bar codes, RFID and data access that are compatible with all mobile devices and operators.

To join the GS1 Mobile Commerce Group, please go to: www.gs1.org/mobile

Any other business

Business case for global Auto-ID Standards: patient safety is paramount

The Healthcare supply chain lacks transparency, according to Dr. Laura Bix, Michigan State University. Research has shown that as many as 17 transfers in the process and tracing products through these permutations is often impossible or requires significant efforts. In an environment of parallel trade and differential pricing, such a multi-echelon supply chain that lacks transparency presents great opportunities for those with illicit intentions.

The number of Adverse Drug Events reported to the U.S. FDA has increased significantly in the last 10 years, but incidence rates of medication errors in many care settings, the costs of such errors and the efficacy of prevention strategies are not well-understood.

Auto-ID should be expanded into all elements of Healthcare, from manufacturer to patient, with standardised data requirements and full interoperability throughout the world.

Any other business
GS1 Australia: Working with the Healthcare sector

GS1 Australia continues to actively work with the Australian Healthcare industry on a number of important and ground-breaking initiatives:

- **Streamlining procurement processes**
  The NPC (National Product Catalogue) is the new synchronised and online catalogue being rolled out by NEHTA (the National E-Health Transition Authority) in association with GS1 Australia. It will be hosted on GS1 Australia’s EANnet Data Pool (soon to be GS1net) and is endorsed by all state, territory and federal health departments. After data upload is completed in mid-2007 the NPC is expected to increase data quality and generate savings of around AU$200 million annually. The NPC will replace literally scores of databases currently maintained by individual hospitals around the country to become Australia’s central data source for all items procured by the public Healthcare sector. It also incorporates the ACOM (Australian Catalogue of Medicines) to provide accurate and standardised medical data for prescription and non-prescription medicines, including complementary Healthcare products.

- **Collaborative eCommerce**
  The Monash Project is a pilot of an automated eCommerce supply chain in the hospital pharmaceutical sector involving Abbott, Baxter, Bristol-Myers Squibb, CH2 Health Purchasing Victoria, Orion, Pfizer, Southern Health and Symbion Hospital Services. Following its 2005 success the project team proceeded to a self-funded Phase 2 in 2006. Phase 1 showed faster and more accurate receipt of deliveries, while a pharmaceutical manufacturer demonstrated the process needed to ensure that products were marked with GS1 bar codes at all levels of packaging. Phase 2 deals with further use of EANCOM electronic purchase orders, purchase order acknowledgements and dispatch advice messages.

- **Healthcare Global Standards**
  Today more than 30 organisations are represented in the GS1 Local Healthcare User Group, Australasia, which only began in October 2006. The focus of this group is to enhance patient safety in harmony with Global Standards. As well as providing input into the work of the GS1 Global Healthcare User Group, specific work areas for Australasia include capturing experience from the implementation of data synchronisation and product classification.

Canada Establishes Advisory Committee for the Identification of Vaccines and Biologics

The Automated Identification of Vaccine Products Advisory Committee was established in May 2007 following the successful completion of a pilot project conducted by the Public Agency of Canada that used GS1 Standards for the auto-identification of vaccines and biologics.

The pilot project, which was conducted in a physician’s office and in a medical clinic in Western Canada, provided caregivers with the ability to capture accurate vaccination information, including a vaccine’s Global Trade Item Number (GTIN), lot number and expiry date using a 2D Data Matrix bar code.

The primary objective of this pilot project was to test the feasibility of using bar coding technology to transfer vaccine-specific information from a national database to an electronic client record quickly, accurately and automatically. The desired result was improved immunisation and record keeping through auto-identification technology.

The Automated Identification of Vaccine Products Advisory Committee provides overall guidance, direction, advice and support for the development and implementation of bar codes for vaccines and biologics in Canada. The Committee is also in the midst of developing a plan for contributing to – and ultimately adopting – GS1 global standards for the bar coding of vaccines and biologics. The primary work plan also includes establishing a Canadian Healthcare User Group subcommittee, which will be led by GS1 Canada.

The Automated Identification of Vaccine Products Advisory Committee is comprised of representatives from leading organisations including: the Public Health Agency of Canada, the Canadian Immunization Registry, the Institute for Safe Medication Practices, the Canadian Paediatric Society, Biotech, leading vaccine manufacturers and GS1 Canada.

For more information, please contact Nigel Wood, at nigel.wood@gs1ca.org
The use of Data Matrix mandatory for traceability of pharmaceuticals in France

AFSAPPS (the French Health Products Safety Agency) announced the transposition of the European Directive CE 2004/27: information on the batch numbers and the expiry dates of pharmaceuticals will have to be kept throughout the supply chain. AFSAPPS decided to adapt the national CIP code from 7 to 13 characters, associated with a special prefix in a Data Matrix symbology using the GS1-128 syntax. This must be implemented at the latest on December 31, 2010.

Kick-off - Local Healthcare User Group France

More than fifty key stakeholders from the French Healthcare sector joined the Local Healthcare User Group kick-off meeting on 31 May. Among them, 18 public hospitals that want to be involved in the standardisation process. The purpose of this first meeting was to present the initiative and the accomplishments of the GS1 Global Healthcare User Group. Various working groups will be created in France in association with Cologh (Hospital Logistics Commission in France), CIP (Club Inter Pharmaceutique), and ACL (Logistics Codification Association in France).

For more information, please contact Valérie Marchand at valerie.marchand@gs1fr.org

Kick-off - Local Healthcare User Group Malta

Representatives from the Ministry of Health, St. Luke’s Hospital / Mater Dei Hospital, CSSD (Sterilisation Department within St. Luke’s Hospital), the Union of Pharmacists, Actavis Ltd, Pharmadox Ltd., the Maltese Mentoring Society and other local associations all joined for the kick-off of the Local Healthcare User Group on 10 May.

Actavis Ltd., a manufacturer of generic pharmaceuticals and forming part of the Actavis Group, which operates in over 30 countries, shared their experience in bar coding. They use GS1-128 throughout their internal processes however, externally, they are sometimes required to use other symbologies, as requested by their clients. They recognise the advantages of the GS1 System and believe standardisation would be the best solution.

The President of the Maltese Mentoring Society also talked about his experience in the Healthcare industry and emphasised the importance of tracking in this delicate industry. He talked about mistakes that happened and could have been prevented with proper standardisation and traceability tools. He also stressed the advantages of the GS1 System.

For more information, please contact Katya Saliba at katya.saliba@gs1mt.org

GS1 standards to cut GBE2bn wasted in extra bed days and save lives in England

The government has recommended that GS1 standards should be adopted throughout the NHS and its supporting industry to reap the benefits of auto-identification and data capture technologies. In its policy document ‘Coding for Success’ (see also HUG Newsletter No. 6), the Department of Health says the potential applications for auto-identification and data capture (AIDC) technologies are very wide, from verification of patient identity and recording implant serial numbers in patient records, to tracking and tracing of individual instruments through decontamination and for stock control and supplies management. The Department says this message needs to be heard by clinicians who want to improve safety and quality of care for patients, where AIDC can be a vital tool in verifying patient identity through a bar code or RFID tag on a wristband; by finance directors and others responsible for investment decisions who want to reduce costs and improve efficiency.

By adopting auto-identification and data capture systems, a series of hospitals are now spending less money and saving more lives. For example at the Leeds Teaching Hospitals, Cardiac Catheter Laboratories have already reduced stock levels from GBE1.6 million to GBE700,000. Orders are now placed twice weekly on an electronic system instead of twice daily on a paper system, reducing staff time dramatically and reducing the costs of the purchasing process from up to GBE7.05 per line to GBE 0.39 pence. The Oxford Radcliffe Hospital’s electronic blood transfusion system, for which the reduced time taken for each procedure is estimated, equates to personnel savings of GBE17.44 for each transfusion. For their 30,000 transfusions per year, this amounts to total savings of GBE523,200 per year. One trust deploying a robotic dispensing system saw a reduction in time spent in the dispensary of 34% for pharmacists and 51% for technicians, enabling far more time to be spent on the wards, working directly with patients and ward staff.

For more information, please contact Roger Lamb at roger.lamb@gs1.uk.org
The next Conference will take place from Monday 29 to Wednesday 31 October 2007 at Beaumont House in Old Windsor (near London), UK. Details will soon be available on the website: www.gs.org/healthcare

If you would like to review the location please visit the following website link: www.hayley-conf.co.uk/beaumont_house.asp