The global Healthcare User Group
GS1 HUG™ - Newsletter No. 4

Welcome to the fourth edition of the GS1 HUG™ Newsletter! This newsletter aims to inform you regularly about our activities and progress in the global Healthcare User Group, GS1 HUG™.
We look forward to receiving your comments, feedback and questions, possibly for inclusion in future newsletters.
More information can be found on our website www.gs1.org/hug/.

The global Healthcare User Group (GS1 HUG™) has chosen GS1 as the sole system of standards in healthcare

After one year of successful operation the HUG officially announced on 26 July 2006 that it will use GS1 standards exclusively as the basis for its automatic product identification developments (Bar Codes and Radio Frequency Identification Product Tags). Over the course of the next 18 months the HUG members will continue to further promote the existing GS1 standards for their application and implementation, in the healthcare sector.
Accurate product identification is crucial to patient safety in three key aspects:

- Avoiding medication errors by ensuring that the right drug is delivered to the right patient
- Preventing the use of counterfeit drugs and medical devices
- Allowing the traceability of medical products

"The HUG was formed to develop global standards in the healthcare industry when it comes to automatic identification and act as the leading voice for the healthcare industry. Many of the standards required already exist, but there is a multitude to choose from. The HUG is developing global healthcare application standards relying on the GS1 system."

Rich Hollander, Co-Chair, Pfizer

While the primary focus is on developing global standards for automatic product identification, the HUG will also be working on other topics e.g. serialisation, medical catalogues, data synchronisation, classification and e-commerce, to make the healthcare systems safer and more efficient worldwide. A more detailed roadmap will be presented and discussed at the next HUG conference in Paris, France (20 to 22 September 2006).

Fourth meeting of global Healthcare User Group (GS1 HUG™) in Minneapolis, Minnesota, USA

The GS1 global Healthcare User Group, GS1 HUG™ met from 13 to 15 June 2006 for the fourth time, further evaluating and discussing global healthcare business requirements to improve patient safety.

During the three days a number of different topics were presented and discussed, ranging from the prevention of medical errors in hospitals in Italy, USA and Japan, the importance of classification and data synchronisation, the latest FDA counterfeiting report and the progress made at EPCglobal.

In the Work Teams, current work was progressed and new topics were discussed intensively – all this with the common goal to develop global standards for automatic product identification.

The meeting was hosted by Medtronic at their World Headquarters in Minneapolis, USA and their VP, Dr. Susan Alpert, welcomed the participants and wished them a successful conference.

Michel van der Heijden, GS1 CFO with responsibility for new sectors and **Rich Hollander, HUG Co-Chair** from Pfizer introduced GS1 and the GS1 global Healthcare User Group to the 60 participants from global manufacturers, wholesalers, hospitals, associations, regulatory bodies, GS1 member organisations and GS1 Global Office.

GS1 BarCodes: *"A beep can save lives"*

Scott Gray, GS1 BarCodes Business Manager discussed the long history of the "beeps", how they are part of everybody's daily life and have proven reliability over many years. He is convinced that bar codes will contribute to make patients' lives safer across the world.

The HUG Work Team leaders from **Smiths Medical, Medtronic, Johnson & Johnson Medical Devices and Pharmaceuticals, Baxter, GSK, Merck, B.Braun, Pfizer** and **Tyco Healthcare,** provided an update about the work going on in their teams, since the last conference, and invited those not yet engaged in the teams to help contribute to their efforts.

Risk Management, Traceability and Measuring Productivity with POAS

Prof. Masanori Akiyama from the **Tokyo Medical University** and teaching professor at the **MIT** in Boston, showed the impressive results of introducing the "Point of Act System" (POAS) in his hospital. A reduction of error rates to nearly zero and improved logistics and efficiencies in the business processes justify the investment in such a system. POAS synchronizes and interacts with each department's system in the hospital including, finance, accounting, pharmacy, imaging and allows continuous and up-to-date information exchange.
Bar codes on drugs and the bar code ID tags worn by all patients are checked before administration. If a mix-up occurs, the computer terminal beeps to immediately warn of the error. So the five patient rights are guaranteed at any administration of a medication or procedure to a patient.
At the same time traceabilty is ensured, because each pack of the same drug can be identified with the product code, the system can immediately find patients who took a specific medicine, if a drug is found to be harmful. On the economic side the system allows for detailed cost analyses per patient and case, and is useful to monitor inventories of drugs. So far over four million US dollars per year have been saved due to increased supply chain efficiencies. But of equal importance is the significant improvement of the quality of care and patient safety.

"The organisation of the HUG, the engagement of the members and their willingness to share expertise are the key success factors. Patient safety is a valuable matter, which has to be protected and improved. The GS1 HUG™ wants to contribute with voluntary global standards."

Volker Zeinar, Co-Chair, B.Braun

Stop Counterfeit Drugs – FDA Report

The participants eagerly awaited the presentation of **Ilisa Bernstein** from the **US Food and Drug Administration (FDA)** following the publication of

the latest FDA Counterfeit Drug Task Force Report, only a few days before. She confirmed that the FDA would no longer delay the effective date of the Prescription Drug Marketing Act (PDMA) implementation beyond December 1, 2006. But the Compliance Policy Guide (CPG) will focus the pedigree-related efforts on those drugs that are most counterfeited.
FDA still believes that RFID is the most promising technology for that, but they will not mandate the use of RFID. The FDA wants to secure the supply chain through track and tracing and mass serialization. Thereby the serial number can be carried in RFID tags as well as in bar codes. Additionally, other anti-counterfeiting technologies like overt, covert and forensic methods can further secure the supply chain, in their opinion.

Vertical Integration in the Health Value Chain

Dr. Alberto Sanna from the **Scientific Institute and University Hospital San Raffaele** talked

about the approach to improve patient safety in their hospital in Italy. He has lead two major projects there: In DRIVE the focus is on a smart and safer healthcare system through e-prescribing and control of the administration of medication. Each prescription will first be checked in the system through a pharmacist. Then product and patient identification will be checked, through automatic product identification, and compared with the prescription before the medication is given to the patient. As in the Japanese hospital, significant improvements in patient safety could be measured, accompanied by a reduction of the operational costs through supply chain efficiency. Traceability was realized through including the serial number in the product data in the IT system and out-of-date drugs could be reduced by including the expiration date in the data base. As a next step Dr. Sanna is now looking at the usage of RFID tags.
In addition to the DRIVE project, which is realizing benefits in the hospital, the PIPS project aims to improve the patient self-care in the daily environment – one example is the monitoring of risk patients.

Global Data Synchronisation Network (GDSN)

Peter Alvarez from **GS1 GDSN** introduced the concept of the Global Data Synchronisation

Network (GS1 GDSN™) to the audience. GDSN is an automated, standards-based global environment that enables secure and continuous data synchronisation, allowing all partners to have consistent item data in their systems, at the same time. It connects trading partners via their selected data pools (SINFOS, 1SYNC and others), and through to the GS1 Global Registry™ and enables them to exchange data in standardized formats. The key information exchanged is item (GTIN[1]), location (GLN)[2] and classification (GPC)[3]. GDSN is thereby laying the foundation for electronic commerce, where the partners rely on accurate data. This leads in parallel to cost savings though more efficient

[1] GTIN = Global Trade Item Number
[2] GLN = Global Location Number
[3] GPC = Global Product Classification

business process in logistic, accounting and inventory management.

For the first time the whole of the second day was devoted to the **Work Teams.** The teams; Vaccines & Biologicals, Instruments & Implants, GTIN Allocation Rules, Standards Implementation/Regulatory Affairs, Standards Development and Business Case, progressed their work in smaller teams, with increased delegate participation.

The leaders of the work teams reported their progress to the plenary on the next day. The summarizing slides can be found on the GS1 HUG™ website
http://www.gs1.org/hug/meetings/130606/

Premier Inc. and the Coalition for Healthcare electronic Standards (CheS) – an Update on Standards

Premier is the largest healthcare alliance in the USA with 1,500 hospitals. Their **CIO Joe Pleasant** explained their view of an integrated supply chain and coordination for purchasing.
The Coalition for electronic Healthcare Standards (CheS) is a group composed of large American Group Purchasing Organisations (GPO), the Department of Defence and Veteran Affairs as well as other members of the healthcare industry. Their objective is to accelerate the adoption, implementation and active usage of industry-wide data standards for improving the efficiencies throughout the healthcare supply chain. At the moment they focus on four initiatives:

- Provider and Supplier Identification through GLN[4]
- Product Classification/Taxonomy through UNSPSC[5]
- Universal Product Identification and
- Product Synchronisation (PDU)

Common background to all these initiatives is the need for clean, shared and standardized data for the trading partners, which contribute to the improvement of patient safety and supply chain efficiency.

EPCglobal – the HLS BAG[6] – State of Pedigree and EPC/RFID[7]

Mike Rose, VP RFID/EPC Global Value Chain at Johnson & Johnson and **Ron Bone, Senior VP of Distribution Support at McKesson Pharmaceutical** – both tri-chairs of the HLS BAG - gave an update on the status and work of their group.

The membership in EPCglobal is constantly growing across the different continents and good progress has been made with regards to frequency allocation by the regulatory bodies worldwide.
With the upcoming ePedigree regulation in some states in the USA the HLS BAG has concentrated in their efforts on progressing the according standards to meet the time lines. The last call for comments to the working document, regarding ePedigree, has been recently published.

Mike and Ron also informed about the first meeting of the new Medical Device Work Group and that new groups for Industry Adoption and Track and Trace have been chartered. They expressed that there are plenty of opportunities for the HLS BAG and the GS1 HUG™ to work more closely together on specific work items e.g. serialisation and public policy.

[4] GLN = Global Location Number
[5] UNSPSC = United Nations Standard Products and Services Code
[6] HLS BAG = Healthcare & Life Sciences Business Action Group
[7] EPC = Electronic Product Code

Lessons learned with Bar Coding and eMAR

Tom Cooley, Assistant Director Pharmacy Services of the **Brigham and Women's Hospital in Boston, USA** presented the results of their bar coding project, which lead to a significant improvement of patient safety in their 720 bed hospital.
They introduced an Electronic Medication Administration Record (eMAR) system and a patient bar coding system in the last years and the results are very convincing – ***the overall dispensing error reduction rate was 85%!***

The system allows online-checks by the pharmacy of the prescription itself and can detect possible interactions, wrong doses and allergies, as it links also to drug information and real-time laboratory data. It provides a check to ensure the correct medications are given to the correct patients. The hospital has decided to use Data Matrix to bar code all their drugs, because it can hold additional information such as lot number, expiration date and NDC number in a readable, but small format, while being very accurate. To make use of all the advantages, through this additional information, the hospital has accepted the higher costs of the necessary image scanners. Most manufacturers today don't mark their products with the data matrix symbology, as the FDA bar code rule does not accept it. The bar code repackage centre in the hospital prepares almost 1.4 million doses per year, which shows the significance of this work. Whenever possible the pharmacy uses the bar code of the package, applied by the manufacturer.

To make the project successful a lot of information and training was necessary for the hospital staff, the best motivation being the recognised reduction of errors and involvement in the decision and implementation processes. Although the ultimate goal is to protect patients, these measures also save on the bottom line, since the average adverse event costs an estimated (US) $4,700 in extra hospital days and ancillary services — excluding the cost of litigation.

Automation and Traceability Pilot in Public Health System in Chile

Eduardo Rodriguez Pinot from **GS1 Chile**

presented the early results of the activities of GS1 Chile in cooperation with their Ministry of Health, manufacturers, hospitals and a public security agency, as well as plans for the next steps. The **Auge-Plan** has the goal to achieve process efficiency, cost control and automation in hospitals.
After 12 months, major progress can be reported. The implementation of GS1-128 bar codes has increased significantly and with the first experiences with a track and trace model, down to the patient bed, progress has been identified.
The project also showed important improvements in the logistic processes, by reduction in time and manpower needed. The number of products which had expired could be reduced significantly and accordingly the related costs.
The regulatory authorities now want, in the second phase, to introduce bar coding of unit-doses with the objective of reduction of dispensing errors while enabling, at the same time, cost analyses per case. The Chilean Ministry is also initiating a national unique medical catalogue, which will be hosted by GS1 Chile.
GS1 Chile invites more manufacturers to join their local Healthcare User Group to define common and agreed solutions.

Implementation of Bar Code Labelling of Ethical Drugs in Japan

The Japanese government is planning a new rule for the implantation of bar code labelling of ethical drugs. **Yasuo Kurosawa** of **GS1 Japan** informed the audience about the details.

The Japanese Ministry of Health intends to mandate bar coding with RSS/Composite symbology on the unit-of-use level for ethical drugs (drugs which are used in hospitals). GTIN, expiry date, lot number and quantity are the required data. The structure of the GTIN in Japan will also change in the future – there will be a transition period determined when the regulation is finalized in July 2006.

The vaccines and biologicals work team had already intensively discussed this topic the day before and had used the occasion to send, in the name of the HUG Leadership Team, a letter to the Ministry of Health in alignment with the colleagues of GS1 Japan and Prof. Akiyama. The letter can be read at:
http://www.gs1.org/hug/meetings/130606/HUG_Letter_MHLW_Japan%202006-03-24.pdf

Advanced Medical Technology Association (AdvaMed)

The Advanced Medical Technology Association AdvaMed represents more than 1,300 member companies and covers 90% of the domestic USA market, thereby a high percentage are small suppliers **Jeffrey Secunda, Associate VP of the Technology & Regulatory Affairs Auto-ID Working Group at AdvaMed** presented their work. The association is lobbying the Congress and represents the industry before legislative committees and regulatory agencies, but also works on international policy collaboration. AdvaMed is involved in a number of standards organisation, for example ISO and IEC. The primary goal of AdvaMed is to ensure an appropriate premarket and postmarket regulatory environment on local and global level. The 2006 political focus is on "Unique Identifiers".

A special Auto-ID working group, chaired by members of the HUG LT[8], supports the development of Auto-ID technology and standards that address specific patient and public health safety problems. Medical devices have a great diversity of size, material, processing, use and criticality; this has to be considered in developing global standards for product identification. While AdvaMed supports the development of consensus standards for different modes and applications of Auto-ID, it also demands that an adoption plan must be included in any solution.

[8] Leadership Team

GS1 Australia

GS1 New Zealand

Next HUGLIT will be launched in Australia/New Zealand

GS1 Australia and GS1 New Zealand will launch a HUG Local Interest Team (HUGLIT) in the Asia-Pacific area, in the last week of October. Rich Hollander, HUG Co-Chair, will represent the HUG at the first meeting in Melbourne and update the participants on the mission and vision of the global Healthcare User Group, the strategy and work plan.

The participants of this kick-off meeting will come from all stakeholders in the supply chain, hospitals, wholesalers, manufacturers, associations and regulatory bodies. The HUGLIT will work closely with the HUG, providing local and specific requirements and input. They will contribute and participating in the work on developing and reviewing global application standards to improve patient safety worldwide!
The HUGLITs promote global standards on local/regional level including regulatory bodies and local associations. They support local implementation and create case studies to demonstrate the benefits.

5th HUG Conference in Paris, France

The 5th **GS1 HUG™** conference will be hosted by **Tyco Healthcare** at their Elancourt Centre of Excellence near **Paris, France** and takes place from **20** to **22 September 2006**.

Conference details, agenda and registration can be found on the GS1 HUG™ website:
http://www.gs1.org/hug/meetings/200906/

http://www.gs1.org/hug/meetings/200906/Agenda_HUG_200906_draft.pdf

The **Global Standards Management Process** or **GSMP**, is the pre-eminent worldwide collaborative forum where GS1 standards are built and maintained. For the first time, healthcare will play an important role in this forum as the first HUG change request will have been introduced into the process. Therefore we would like to ask you to become familiar with the GSMP procedures and community at the:

GSMP World Wide (Fall) Event 2006 in Philadelphia

The GSMP Fall conference will be held from **23** to **27 October 2006** in **Philadelphia, Pennsylvania, USA.**

Detailed information for the meeting, including event and hotel registrations, is available at http://www.gs1.org/philadelphia2006/

The sessions dedicated to healthcare, at the GSMP event, will be held on Monday 23 and Tuesday 24 October.

6th HUG Conference in Berlin, Germany (2007)

The 6th HUG conference will take place from **30 January** to **1 February 2007** in **Berlin, Germany**, hosted by **B.Braun** in the Aesculap-Akademie.

For more information on the GS1 HUG™, please visit the website http://www.gs1.org/hug/ or contact Ulrike Kreysa at ulrike.kreysa@gs1.org

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