

Welcome to the fifth 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.

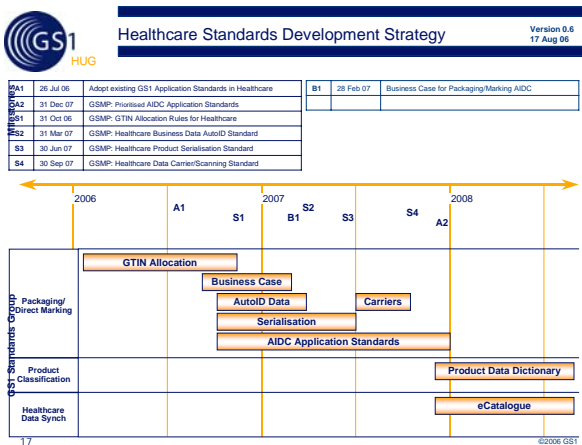
More information can be found on our website <http://www.gs1.org/hug/>

The global Health Care User Group (GS1 HUG™) - New Governance and Roadmap

After more than a year of existence the GS1 HUG™ has now published their new **governance charter** and the approved **roadmap** for the next 18 months.

All stakeholders in the supply chain; suppliers, wholesalers, distributors, hospitals, pharmacies, associations, academic institutions and regulatory bodies can be either voting or non-voting members of the HUG. Solution providers can at the moment only participate upon invitation, they will be fully included at a later stage. The full governance charter can be found at <http://www.gs1.org/hug/about/charter.html> and the application for membership can be made online at <http://www.gs1.org/hug/Membership/>

The **HUG roadmap** describes the deliverables for the next 18 months and the HUG has restructured their Work Teams accordingly.



For some of the former Work Teams; like Vaccines & Biologics and Instruments & Implants, they have now joined the new Work Teams; **Auto-**

ID Data and **Serialisation**, which kicked off in Paris. Details of the roadmap can be found at <http://www.gs1.org/hug/about/roadmap.html>.

Fifth conference of global Healthcare User Group (GS1 HUG™) in Elancourt near Paris, France.

The GS1 global Healthcare User Group, GS1 HUG™ met from 20 to 22 June 2006 for the fifth time to gather further input and business requirements while discussing global healthcare business requirements to improve patient safety.



For the conference, which was hosted by Tyco Healthcare at their Centre of Excellence in Elancourt near Paris, over 100 participants from 17 countries came, from around the world, to France. They experienced a conference programme full of interesting presentations, to the topic of improving patient safety, but also good opportunities for networking.

An important part of the conference was the Work Team meetings, in which important progress was made.



Michael Linney, VP at Tyco Healthcare, welcomed the participants and underlined the strong interest of Tyco Healthcare in the HUG group and their strong support to the HUG work.

Pierre Georget, CEO of GS1 France, explained the mission, vision and organisational structure of GS1. Healthcare is a core sector for GS1 and Pierre confirmed the strong engagement of the whole GS1 organisation in this sector for improving patient safety worldwide.



Rich Hollander, HUG Co-Chair from Pfizer gave then an overview of the mission, vision, focus area's and organisation of the GS1 global Healthcare User Group, to the participants from global manufacturers, wholesalers, hospitals, associations, regulatory bodies, GS1 member organisations and GS1 Global Office. **Peter Tomicki, Baxter** explained in detail the new roadmap and **Michel van der Heijden, GS1 CFO**, and responsible for **new sectors**, presented the new governance in the name of the HUG Leadership Team.



The HUG Work Team leaders from **Smiths Medical, Baxter, Johnson & Johnson Pharmaceuticals, Merck, Pfizer, Tyco** and **B.Braun** provided an update about the results and status of their Work Teams.

French Hospital Initiative



Pascal Mariotti informed that the e-procurement hospital initiative in France has grown significantly and has been linked to a new purchase group representing 51 hospitals. They realised that to be efficient, they need a common system of

references and standards for their co-operation. The board of the group and the university hospital managers have confirmed the choice of GS1 standards for codification, for classification they decided for ATC, Cladimed and UNSPSC/GPC. The strategy of the whole group is to systematically use GS1 Standards, in every hospital, for every new project with tracking, traceability, processes, organization and logistic, on the same basis as the projects of the hospital of Dijon.

Unique Device Identification – FDA and UDI

Jay Crowley from the **US Food and Drug Administration (FDA)** presented their recent initiative regarding unique device identification (UDI) for medical devices. The objective is to reduce device-related medical errors and improve compatibility and interoperability issues such as MRI compatibility. Other advantages could include better identification of specific devices in adverse event reports, more effective device recalls, improved supply chain efficiency and the capturing of medical device use information in Electronic Medical Record Systems. In a federal register notice, FDA proposed that, at the "unit of use", a unique identifier should combine these device elements and attributes:

- Manufacturer, make, and model;
- Unique attributes (e.g., size, length, quantity, software version); and
- Serial number, identifying lot number, manufacturing or expiration date.



Other questions are the choice of the best suitable technology and the minimum data set. The FDA is looking at global harmonization and would prefer not to put a US-focused solution forward.

GS1 HUG™ UDI - Recommendations

Tom Werthwine from **Johnson & Johnson** welcomed the FDA initiative in the name of the HUG. He pointed out that the GS1 system is a globally recognized system and the FDA should contribute to harmonizing medical device identification systems around the world. The main UDI data requirements can be fulfilled by the corresponding GS1 Applications Identifiers, the product attribute size should be better held in a database. Tom expressed the opinion, that the data carrier should not be specified by the FDA, but every GS1 data carrier should be acceptable.



EFPIA – Supply Chain Integrity



Graham Smith, Chairman of the **EFPIA**¹ Distribution Group, explained the EFPIA position that a harmonised EU coding system could offer a more secure, effective and efficient supply chain. The supply chain in Europe today is fragmented and complex. Concerns regarding integrity are counterfeiting, issues arising from parallel trade and batch recall capability. Therefore an increased control of the transactions in the supply chain is needed. The EFPIA recommendation is the adoption of a 2D (Data Matrix) bar code across Europe to enable authentication of products in the pharmacy and increase transparency and security of products for the patients.

¹ EFPIA = European Federation of Pharmaceutical Industries and Associations

EUCOMED – The European Medical Technology Industry Association



Mike Kreuzer, Chairman of the eBusiness Task Force (ETF), presented the recent developments at **EUCOMED**. In a recent review the group has compared their mission and vision with those of the HUG and found that the groups are complementary and not competitive. There are overlaps and possible synergies and therefore an official collaboration is in place. ETF has official representatives working in the HUG and the HUG is participating in the ETF activities. The ETF group has launched a research project, with their member base, to find out the actual status and trends with regards to the usage of automatic product identification. The results will be presented at the next HUG conference in Berlin.

Hospital of Rouen - Blood derivate (CFC) supply chain in the hospital



Bernard Dieu, Chief pharmacist at the **CHU Rouen**, a hospital with 2,500 beds, reported about a study made on process enhancements in the blood derivate supply chain. The hospital manages already its sterilisation supply chain with the GS1 system. The study compared the processes before and after their reengineering with source market products, eProcurement, global and hospital wide stock management, ePrescribing and Bedside Scanning. Whilst eProcurement is in deployment, other tools are planned for the very next years. The GS1 system

supports all these processes, with GTINs (products), SSCC (deliveries), GLNs (locations), GSRN (patient episode). The study demonstrated strong benefits in terms of error reduction, stock management and time spent. The study allows further expanding the calculated benefits in other product areas, as implants, narcotics, etc.

Asept InMed - Wholesaler experience in France



Jean-Luc Maurat reported about the introduction of traceability, total control over the goods at any point in time, down to the customer at the French wholesaler, Asept InMed. Thereby reliability and the efficiency of traceability depend on the quality of data acquisition all along the logistic process and the rapidity of data treatment/analysis in order to act as soon as a defective device is detected. At their goods receipt all product data is fast, easily and accurately captured in a GS1-128 standard and then consistently followed through all warehouse processes. Asept InMed achieved, within two years, a growth in turnover of 20% per year, a significant improvement of customer service ratio and productivity and could, at the same time, introduce a permanent inventory.

Animal Health Products - Identification Standard



The **International Federation of Animal Health (IFAH)** has already developed their worldwide standard for product identification and traceability. **Jean-Claude Muller, Merial**, reported that to fulfil

some existing EU regulations, and to prevent further regulation, the industry agreed to implement the GS1 symbology Data Matrix with the GS1-128 syntax including GTIN, batch number and expiry date. The implementation in Europe is planned from 2005 to 2007. Regular communications and review of the progress has lead to satisfaction of the regulatory bodies and customers. The solution has proven to be reliable, robust and flexible.

Day 2 of the conference was totally dedicated to the HUG Work Teams. The **GTIN Allocation Rules** Work Team discussed the issues and questions which had been collected from the broad user community and incorporated them where applicable.

"I believe that Global Trade Item Numbers (GTINs) following GS1 HUG Allocation Rules offer the strongest approach to global harmonization and are pervasive in healthcare today."

Peter Tomicki, Baxter

The **Business Case** Work Team reported on further progress and collected input and ideas from the audience.

Finally, two new Work Teams kicked-off – **Auto-ID Data** and **Serialisation** – with Serialisation being a joint team with the HLS BAG group. The work results of the Auto-ID team will be valuable input in the new combined team.

EPCglobal Overview



Chris Adcock, president of EPCglobal, gave a broad overview regarding the whole EPCglobal community. The core purpose is global leadership in developing and promoting multi-industry, user driven standards for collaborative commerce utilising the EPC². The EPC board is multi-

² EPC = Electronic Product Code

sectorial, the membership growing fast, with now over 1000 members across 36 countries. In the JAG³ participants from different sectors work together on common topics. So far 7 global standards have been approved – the standard for Gen2 tags is one of them. Gen2 can operate on a global level and has also been recognized by ISO⁴. While the spectrum allocation has made good progress world wide, the work for item level tagging is now progressing in UHF⁵ and HF⁶ Work Teams.

EPCglobal Healthcare and Life Sciences



Ron Bone, Senior VP of Distribution Support at McKesson Pharmaceutical and Tri-Chair of the HLS BAG⁷ updated the participants on the status of the work being done.

The BAG was formed in 2004 and the US members represent 38 of the 40 largest manufacturers, the 3 largest distributors and

major retailers. They are focusing on addressing critical needs to meet regulatory requirements, for example pedigree management and serialization. The major active Work Teams are Serialisation, which has now amalgamated into a common Work Team with the HUG, item level tagging, pedigree, industry adoption and track & trace. EPC pilots are underway and the learning's are contributing to the standard development process. Ron presented one of the pilot projects "Track". It is bringing together trading partners to test and learn how RFID technology can be applied to advance the supply chain with regards to product safety and item serialization. Manufacturers, wholesalers, associations, the FDA, EPCglobal and solution provider are involved in this project and share their learning's with regards to the critical questions of data sharing, track & trace, tag data, frequency, read ranges and necessary changes in business processes.

³ JAG= Joint Action Group

⁴ ISO = International Organisation for Standardisation

⁵ UHF = Ultra High Frequency

⁶ HF = High Frequency

⁷ HLS BAG = Health Life Science Business Action Group

MBA Research Dissertation about RFID



Janice Kite, Johnson & Johnson discussed the hypothesis of her MBA⁸ dissertation: "Medical Device manufacturer applied / embedded RFID has benefits to Patient Safety over existing Auto-ID technologies, e.g. Bar Codes". Janice had in the last months done intensive literature

research, conducted interviews with stakeholders and launched a questionnaire to a wider group. In the literature zero tangible evidence was found that tagging medical devices improves patient safety. In the interviews, RFID tags were seen by the stake holders as advantageous in the supply chain and there mostly for the groups of assets because of their high value. As main barriers: technology/physics, implementation costs, privacy and lack of global standards were named. Although there are pilots in progress, no evidence of success is yet available. As a result, at present, the hypothesis has not been definitively proven or disproved.

GS1 Spain: Projects for the Healthcare sector



Jose Javier Sanchez, GS1 Spain gave an overview about the healthcare activities in Spain, where the sector is decentralised: There are 17 different Healthcare Service Areas, which determine the local requirements.

The central Ministry of Health has recently released a new regulation, which shall

enable traceability of pharmaceuticals. An AIDC system must be implemented for all pharmaceutical products in July '07, which shall permit serialization and include information for track & trace (product code, batch number and expiry date). The goal is to have a fast and economic implementation.

⁸ MBA = Master of Business Administration

The Andalusia Healthcare Service (SAS) has a project to improve the logistic & purchase processes, patient safety and enable track & trace. They request labelling of all products with GS1-128 – the deadline for that has just been extended to January 2007. Also in Catalonia is a project for the traceability of vaccines is in the focus of the authorities. Other projects in Spain concentrate on the traceability of prostheses, EDI implementation and creation of a medical catalogue. A healthcare committee composed of; regulatory authorities, manufacturers, wholesalers and providers is providing direction to GS1 Spain.

GDSN and classification – an overview



Sally Herbert, president of GDSN (Global Data Synchronisation Network) introduced the concept of GDSN.

Data synchronisation is the electronic transfer of standardized item and location information and the continuous harmonization of that data over time. Thereby standardized information of the trade items (GTIN)

including attributes controlled by the brand owner/data source (e.g. net content, dimensions, weights) and location information (GLN) including locations involved (e.g. headquarter, billing, ship to) are shared between trading partners. The main components of GDSN are a single registry (GS1 Global Registry), certified data pools and the trading partners. The benefits of GDSN are clean and accurate data and, as a consequence, reduced out-of-stock events and invoice-errors.

GS1 is responsible for two classification systems; one of them is the United Nations Standard Product and Services Code (UNSPSC), the other the Global Product Classification (GPC). Both are complementary, while one is broader the other one goes more into the depth of product classification. GS1 is working on an integration plan for both.

Sally underlined that for GDSN healthcare is still a new sector, so far they have worked mainly in the retail sector. She offered intensive discussions to evaluate opportunities and the right processes for healthcare involvement in GDSN.

Diversity of Classification Systems

Maurice Ventura from the French association **Cladimed**⁹ gave an overview of the existing classification systems. As the medical device sector is lacking a real classification, Cladimed has developed one with five levels. The devices are divided into different groups, according to the organ or system on which they act, their main use and their validated indications. All modifications are agreed by a scientific committee and are submitted to manufacturers and users for comments or objections. The e-procurement platform of the French University Hospitals has chosen this classification and it is already actively used by a number of hospitals in France. In the future it is planned to link it also to GMDN¹⁰.

The Work Team Leaders reported the results of their sessions back to the plenary; the summarizing slides can be found at <http://www.gs1.org/hug/meetings/200906/#agenda> on the GS1 HUG™ website.

GS1 Industry and Sector Strategy

Michel van der Heijden, GS1 Global Office provided some insight into the GS1 strategy and latest developments. Next to retail, healthcare is now the second core industry with the according priorities. In an integration project, the three different GS1 groups currently working in this sector: HUG, EHI (European Healthcare Initiative) and HLS BAG will come to ONE strategic roadmap.

The global Healthcare User Group (GS1 HUG™) and Initiatives of Regulatory Bodies around the World.

The need for more traceability and safety, motivates more and more regulatory bodies, around the world, to consider further possible regulations in the healthcare industry, to improve patient safety. The GS1 HUG™ is providing feedback and comments to such initiatives while developing standards for automatic product identification.

The comments and recommendations of the HUG, to different regulatory bodies, can be found in the working area for members on the HUG website.

⁹ Cladimed = Association for the Classification of Medical Devices and other health products

¹⁰ GMDN = Global Medical Device Nomenclature

Kick-off meeting of HUGLIT Australasia

The GS1 global Healthcare User Group Local Interest Team (HUGLIT), **Australasia**, was successfully launched on 25 October 2006, further expanding the HUG pool of knowledge. Keynote speakers included the **New Zealand Ministry of Health**, the **Australian National eHealth Transition Authority (NETHA)**, Rich Hollander as **Co-Chair of the GS1 HUG™**, **GS1 Australia** and **GS1 New Zealand**.

"The Australasian HUGLIT will give Australia and New Zealand's work global exposure. I can't think of any market around the world that doesn't have a lot to learn about what GS1 and the Healthcare sector is doing here."

Rich Hollander, Pfizer

The local HUGLIT's will work closely with the global group, providing local requirements and input and reviewing and participating in the work on developing global application standards to improve patient safety worldwide!

For more details of the event including presentations please see http://www.gs1au.org/services/member_industry_support/industry_sectors/healthcare/mis_huglit_25_1006.asp

To find out about more about the work of the HUGLIT's please see at http://www.gs1.org/hug/work_teams/huglit.html

Next HUGLIT to be launched in February 2007

GS1 Serbia & Montenegro intends to launch a HUGLIT working team with a kick-off meeting on the 22nd and 23rd February in Belgrad. **GS1 Bosnia & Herzegovina** and **GS1 Macedonia** have agreed to join in this work effort. Please notify your local companies or distributors of this event.

Next HUG Conference in Berlin, Germany



The next **GS1 HUG™** conference will be hosted by **B.Braun** at their Aesculap Akademie in Berlin, Germany and takes place from **30 January to 1 February 2007**. The **Work Teams Auto ID Data and Serialisation** will already meet on the afternoon of the 29th January.



Conference details, agenda and registration can be found on the GS1 HUG™ website: <http://www.gs1.org/hug/meetings/300107/>

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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