GS1 HUG

Global Healthcare User Group
GS1 HUG™ ~ Berlin ~ January 2007
Communication & Coordination Support Team

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GS1 Germany

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New Design Mark:

Communication & Coordination Support Team

Objectives:

Lead and organise internal and external communications of the HUG to establish the HUG as the leading voice in the area of automatic data identification in the Healthcare Industry.

Scope:

- Identify key areas for which we establish recommendations and end-users to address
- Build Communication and Coordination infrastructure

Deliverables:

- Communication strategy
- Brochures
- Press Releases
- Technical Documentation
- Newsletters
- Structured, Informative and user friendly website

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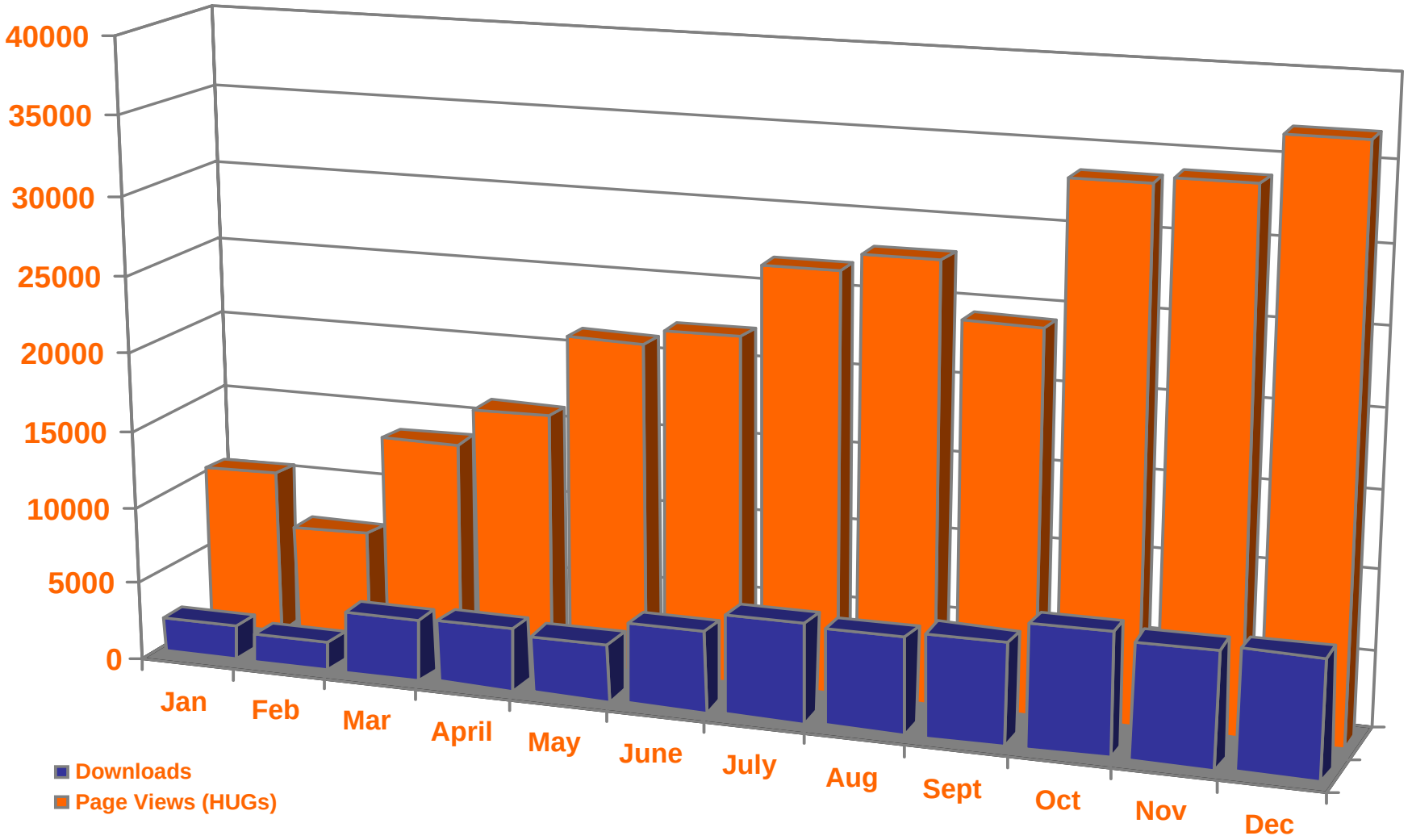
HUG Website:

www.gs1.org/hug/

HUG Website - Page Views (HUGs) & Downloads:



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HUG Top Five Web Page Visits - 2006 Overall (excluding HOME page):

1. **HUG Members List** (www.gs1.org/hug/about/members.html)
2. **HUG Work Teams** (www.gs1.org/hug/about/news.html/hug/work_teams/)
3. **HUG Membership Form** (www.gs1.org/hug/about/news.html/hug/Membership/)
4. **HUG News** (www.gs1.org/hug/about/news.html)
5. **HUG Meetings** (www.gs1.org/hug/meetings/)

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HUG Top Five Downloads - 2006 Overall:

1. **HUG Brochure** (www.gs1.org/docs/patient_safety/hug_brochure.pdf)
2. **HUG Newsletter 2 - Mar 2006** (www.gs1.org/hug/about/news/HUG_Newsletter_2_Mar_2006.pdf)
3. **Press Release: HUG chooses GS1 - Aug 2006**
   (www.gs1.org/docs/media_centre/gs1_pr_220806_Global_HUG_choses_GS1.pdf)
4. **HUG Newsletter 3 - May 2006** (www.gs1.org/hug/about/news/HUG_Newsletter_3_May_2006.pdf)
5. **Minutes from HUG Brussels Meeting - Sep 2005**
   (www.gs1.org/hug/meetings/130905/Minutes_HUG_130905.pdf)

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HUG Press Releases:

Healthcare Industry Works Together to Improve Patient Safety - July 2005

Monday, 18th July 2005

HEALTHCARE INDUSTRY WORKS TOGETHER TO IMPROVE PATIENT SAFETY

Leading global companies from the pharmaceutical and medical device industry have formed a global GS1 Healthcare User Group (HUG). Its objective is to lead the utilisation and development of global standards for the healthcare industry, with the primary focus on automatic product identification to improve patient safety.

Baxter, Boston Scientific, B.Braun, 3M, GSK, Hospira, Johnson & Johnson, Medtronic, Merck, NACDS, Pfizer, Smiths Medical and Tyco have participated in the kick-off-meeting, which took place on 23 May 2005 in Princeton, New Jersey and have committed to participate actively in the group. It is the first time that the healthcare industry is aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide. The work of the HUG will improve the performance of the healthcare supply chain for drugs and medical devices through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices.

The main focus areas for the group are the following:

- Prevention of Medical errors
- Product Authentication
- Tracking and Tracing
- Increase total Supply Chain efficiency

More follows…

Patient Safety is the Focus of the Healthcare Industry and Regulatory Authorities - November 2005

November 2005

PATIENT SAFETY IS THE FOCUS OF THE HEALTHCARE INDUSTRY AND REGULATORY BODIES

Assuring patient safety worldwide was the focus of the second meeting of representatives of the world's leading pharmaceutical and medical device companies and health regulators from the EU and major countries. The participants agreed to drive an industry initiative to develop global barcoding and e-commerce solutions for health care products based on GS1 standards.

Speakers from the European Commission (DG Enterprise and DG Sanco), the European Agency for the Evaluation of Medicinal Products (EMEA), the USA Food and Drug Administration (FDA), the Italian Ministry of Health, the National Patient Safety Agency of the NHS, United Kingdom and the Regional Healthcare Service Area of Andalucía, Spain presented their work and views about patient safety. The participants and speakers appreciated the opportunity to have an open discussion and to exchange information exchange and agreed to carry the work of the HUG forward by working together more closely.

Delegates from 22 leading global pharmaceutical and medical device companies and 10 GS1 Member Organisations discussed the HUG work plan and listened to the requirements of regulatory bodies. The HUG is concentrating particularly on ensuring that appropriate data structures are selected in order to meet common business needs, and to help ensure data standardisation in healthcare. If standardisation is applied globally, systems to improve patient safety will be developed and implemented quicker than if individual countries were to pursue

Global Healthcare User Group Chooses GS1 as Sole System of Standards in Healthcare - August 2006

The global language of business.

BRUSSELS, BELGIUM/LAWRENCEVILLE, NJ, August 2006

Global Healthcare User Group chooses GS1 as sole system of standards in healthcare

The GS1 HUG™ is a voluntary and open group formed by 40 leading pharmaceutical and medical devices companies, wholesalers, hospitals and trade associations from around the world. The HUG's primary objective is to enhance patient safety worldwide through accurate and standardised product identification.

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

After one year of successful operation of the GS1 HUG™, 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. 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

The two co-chairs of the GS1 HUG™ expressed their satisfaction at this achievement. Volker Zeinar, B.Braun, commented, *"The organization of the HUG, the engagement of the members and their willingness to share expertise are the*

www.gs1.org/hug/about/news.html#Press_Releases

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HUG Newsletters:

www.gs1.org/hug/about/news.html#Newsletters

GS1 HUG

The global Healthcare User Group
GS1 HUG™ - Newsletter No. 5

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.

HUG Articles:

Richtiger Patient, richtiges Produkt, richtige Dosierung

Konferenz der GS1 Healthcare User Group

RFID-Einsatz, Unit-Dose und einheitliche Kennzeichnung zur Vermeidung von Fälschungen – das sind die Themen im Fokus dieser Veranstaltung vom 30. Januar bis 1. Februar in Berlin. Inwiefern sind Verantwortliche im Krankenhaus angesprochen? Michael Reiter fragte Michaela Hähn, Senior-Projektmanagerin, Business Solutions & Consult bei GS1.

M & K: *An welche Zielgruppen wenden Sie sich?*

M. Hähn: Die Konferenz der GS1 Healthcare User Group (GS1 HUG) richtet sich an alle Partner entlang der Versorgungskette, die dazu beitragen, dass der richtige Patient das richtige Produkt zur richtigen Zeit in der richtigen Dosierung oder Anwendung erhält. Also an Industrieunternehmen und Krankenhäuser gleichermaßen, aber auch an Logistiker, die oftmals die Schnittstelle zwischen Industrie und Krankenhaus bilden. Eine weitere bedeutende Rolle spielen selbstverständlich auch Behörden, Ministerien und Verbände, die sich aktiv in die Arbeit der HUG einbringen können, um das gemeinsame Ziel der Steigerung der Patientensicherheit zu erreichen. Wichtig ist ein gemeinsames Verständnis über die Prozesse im Gesundheitswesen und die Anforderungen, die seitens der verschiedenen Interessengruppen bestehen – und das weltweit.

Zwar wurde die HUG von führenden Herstellern von Arzneimitteln und Medizinprodukten wie 3M, Baxter, B. Braun, GSK, Johnson & Johnson, Medtronic, Merck, Novartis, Pfizer, Smiths Medical und Tyco unter dem Dach von GS1 (ehemals EAN International) ins Leben gerufen, aber die klar definierte Aufgabe – nämlich die Übernahme einer führenden Rolle im Gesundheitswesen bei der effektiven Nutzung und Entwicklung globaler Standards auf Basis von EAN, um die Patientensicherheit durch automatische Produktidentifikation zu verbessern – kann nur durch intensive Zusammenarbeit aller Partner im Gesundheitswesen erfüllt werden.

Inzwischen zählen neben Industrieunternehmen auch Krankenhäuser, Behörden und Verbände zu den Mitgliedern, die die Notwendigkeit von einheitlichen Standards und damit auch die Möglichkeiten des GS1-Systems erkannt haben.

Welche herausragenden Sprecher kommen zum Kongress?

M. Hähn: Das dreitägige Programm (sh. HUG-Website) bietet verschiedene Schwerpunkte. Wie bereits erwähnt, ist es wichtig, dass die Anforderungen aller Beteiligten vorgestellt und auch diskutiert werden. So wird u.a. Dr. Michael Hartmann, Uniklinik Jena, über seinen Ansatz zum Einsatz von RFID im Krankenhaus informieren – ein Thema, das im letzten Jahr enorm an Bedeutung gewonnen hat. Über die Möglichkeiten der Unit-Dose-Kennzeichnung sprechen Vertreter des Universitätsklinikums Genf sowie von Krankenhäusern aus Brügge und Tilburg.

Michaela Hähn, Senior-Projektmanagerin, Business Solutions & Consult bei GS1

Auch die Comparatio, die Vereinigung der Universitätskliniken von Norddeutschland, werden mit einem Beitrag vertreten sein. Darüber hinaus wird Lothar Jenne, Mitinhaber der Arzneimittelgroßhandlung Max Jenne und Vorsitzender des Technical Committee des Europäischen Verbandes des Pharmagroßhandels (GIRP) die Herausforderungen der einheitlichen Kennzeichnung von Pharmazeutika sowie Lösungsansätze auf Basis der GS1-Standards präsentieren.

Da es sich um eine global aufgestellte User Group und Konferenz handelt, wird auch die Situation in wichtigen Gesundheitsmärkten aufgezeigt: So erläutern die spanischen Behörden ihre Richtlinien für die Kennzeichnung von Medizinprodukten. Ebenso wird die neue chinesische Verordnung vorgestellt, ebenfalls für Medizinprodukte.

Das Programm ist so zusammengestellt, dass die Teilnehmer nicht nur einen detaillierten Einblick in die Praxisanforderungen aus Industrie- und Krankenhaussicht erhalten, sondern auch über die Entwicklungen in einzelnen Märkten weltweit informiert werden.

Welche Technologie-Themen bestimmen die Veranstaltung?

M. Hähn: Wie erwähnt, hat es sich die HUG zum Ziel gesetzt, die Patientensicherheit mit Hilfe der automatischen Produktidentifikation zu erhöhen. Damit steht natürlich das Thema Barcoding im Vordergrund, aber auch Zukunftstechnologien wie RFID fließen mit ein. Bei den Barcode-Systemen rückt verstärkt der EAN Data Matrix ins Rampenlicht, da mit diesem platzsparenden 2D-Code auch sehr kleine Produkte gekennzeichnet werden können. Damit bietet er die besten Voraussetzungen, um auf Patientenabgabeeinheiten wie z.B. einzelne Blister aufgebracht zu werden. So kann eine automatisierte Medikationskontrolle durch Scanning am Krankenbett erfolgen.

Die RFID-Technologie wird insbesondere vor dem Hintergrund der Fälschungssicherheit bzw. Produktauthentifizierung diskutiert. Die GS1-Standardisierungsaktivitäten laufen weltweit unter dem Begriff Elektronischer Product Code – EPC (Elektronischer Produkt-Code). Dieser wird analog wie die EAN-Artikelnummer zur eindeutigen, serialisierten Identifikation von Produkten genutzt und dient als Schlüssel, um Informationen zu einem Produkt und dessen „Geschichte", also den Herkunftsnachweis aus dem Internet der Dinge abzurufen.

Da es jedoch letztendlich darum geht, die Versorgungskette zu optimieren, reicht die Fokussierung auf die genannten Technologien nicht aus. Wichtig ist auch, wie Informationen zwischen den Geschäftspartnern ausgetauscht werden oder wie Produkte klassifiziert werden können. Und da liegt der Vorteil des GS1-Systems: Es funktioniert nach dem Baukastenprinzip und hält für die drei grundlegenden Themengebiete Identifikation, Datenträger und Datenaustausch die entsprechenden Standards bereit. Sie sind kompatibel und können von den Anwendern flexibel nach den jeweiligen Praxisanforderungen eingesetzt werden – rund um den Globus.

Der Zielsetzung der HUG entsprechend werden im Laufe der drei Konferenztage alle Themengebiete thematisiert.

Wo sehen Sie die Relevanz für Alltag und Zukunft von Krankenhäusern?

M. Hähn: Die Krankenhäuser stehen unter einem enormen Kostendruck, und wie sich die bevorstehende Gesundheitsreform auf die Situation auswirkt, bleibt abzuwarten. Krankenhäuser müssen nach Mitteln und Wegen suchen, um bei steigender Versorgungsqualität kosteneffizienter zu arbeiten. Und das sind genau die Aufgaben, die sich die HUG zum Ziel gesetzt hat. Der Vorteil für die Krankenhäuser liegt neben einer interessanten Vortragsreihe darin, dass sich hier namhafte Unternehmen, die durchaus eine wesentliche Rolle im Gesundheitswesen spielen, zusammengefunden haben und gemeinsam daran arbeiten, ihre Zielsetzung zu erfüllen. Mit dieser bisher einmaligen Initiative bietet sich den Krankenhäusern die Chance, sich aktiv einzubringen, mit Herstellern ihre Anforderungen zu diskutieren und gemeinsam Lösungen für ein besseres und sicheres Gesundheitswesen zu erarbeiten. Der Einsatz von Auto-ID bei Pharmazeutika und Medizinprodukten stellt einen entscheidenden Schritt zur Reduzierung von Arzneimittelfälschungen und damit zur Steigerung der Patientensicherheit dar. Medizinische Produkte können vor, während und nach der Anwendung (rück-)verfolgt und ohne großen Aufwand in elektronischen Patientenakten dokumentiert werden. Solche Szenarien sind keine Zukunftsvisionen mehr, sondern durchaus Realität. Sie setzen jedoch die entsprechenden Standards voraus. Die große Zahl an Herstellern und Krankenhäusern, die sich bis dato in der HUG engagieren, haben es erkannt: Es müssen alle an einem Strang ziehen, um die Überlebensfähigkeit der Krankenhäuser in dem größtmöglichen Maß sicherzustellen – zum Wohle des Patienten!

Detaillierte Ankündigung:
www.pro-4-pro.com, Eingabe „GS1".

▶ www.gs1.org/hug

Management & Krankenhaus 01/2007, S. 16, GIT VERLAG GmbH & Co. KG, Darmstadt www.gitverlag.com www.PRO-4-PRO.com

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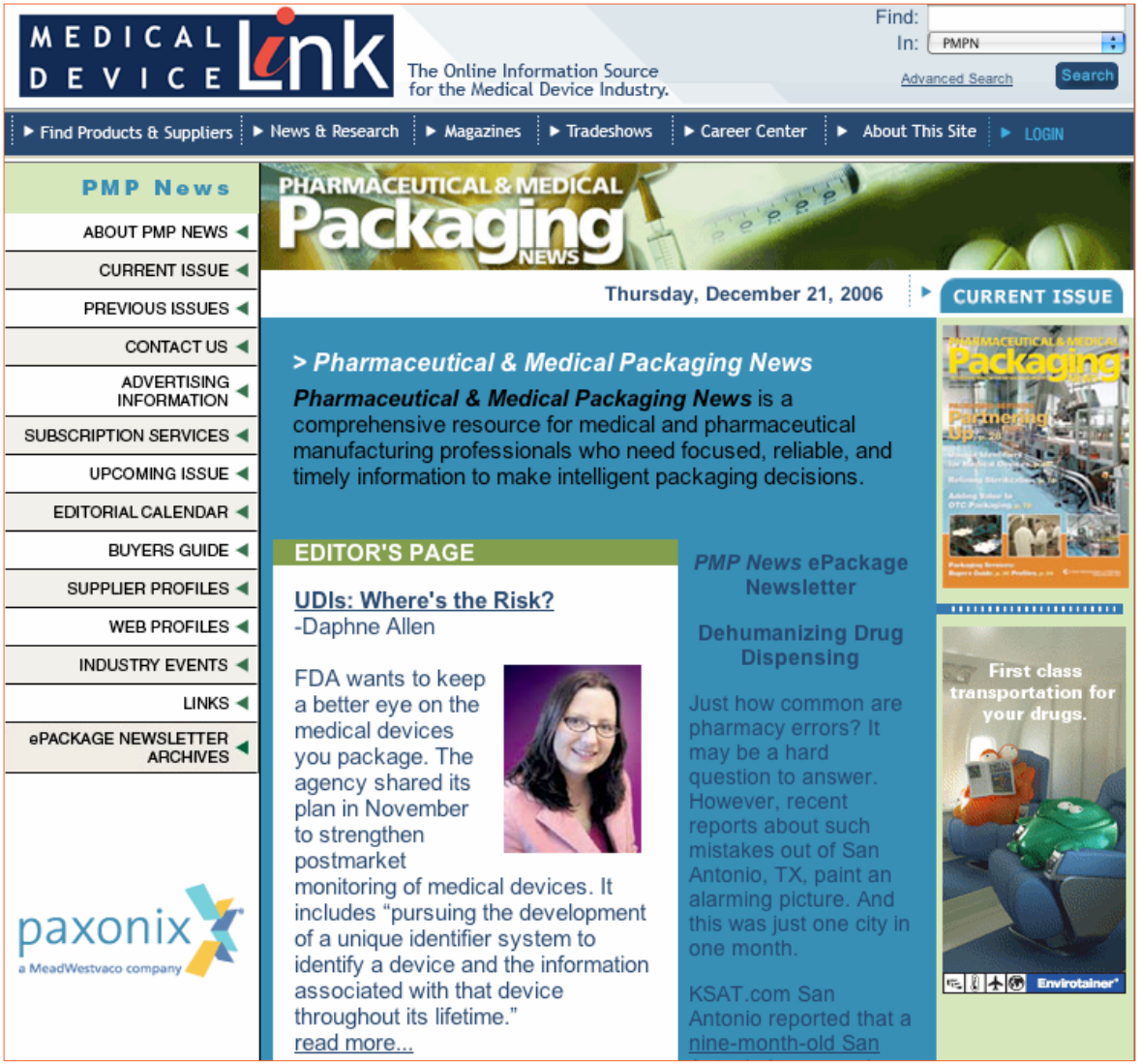
HUG Articles:



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HUG Articles:

MEDICAL DEVICE Link — The Online Information Source for the Medical Device Industry.

Print this Page

Originally Published PMPN December 2006

EDITORIAL

UDIs: Where's the Risk?

FDA wants to keep a better eye on the medical devices you package. The agency shared its plan in November to strengthen postmarket monitoring of medical devices. It includes "pursuing the development of a unique identifier system to identify a device and the information associated with that device throughout its lifetime."

The idea of mandatory unique device identification (UDI) hasn't been widely popular. "AdvaMed is working with FDA to identify a standardized data structure and content for a unique device identifier system," says AdvaMed president and CEO Stephen J. Ubl. "However, we continue to believe that such a system should be voluntary, except in cases where there is a well-documented patient safety issue that could be best addressed through use of a UDI."

Basing UDI requirements on risk certainly has its merits. "Differentiating them according international accepted risk classes (Classes I– III) could be a suitable method of resolution," argues Volker Zeinar of B.Braun. Zeinar shares his perspective in this issue's roundtable.

Risk concerns Joe Pleasant, chief information officer for Premier Inc. Every month, hospitals served by Premier Inc. get several recalls for medical devices that can only be tracked through manual chart reviews. For "every patient . . . [there] is a period of time that we don't know that we can track that back," he explained. Pleasant spoke during FDA's CDRH public meeting on UDI.

And tracking recalls after procedures isn't the only challenge. "A significant risk to patient care and safety is the possibility of implanting an outdated device or using an outdated device," he said.

Differentiation by risk class would keep it simple. The greater the risk a device presents (and, most likely, the more it costs), the stronger the case for justifying the cost of UDI.

But more than class risk may be involved. "One large health system was recently adversely affected by three very public Class I recalls," Pleasant said. "We have some documentation around what they went through . . . having to spend time trying to track those patients down."

Perhaps the usual risk presented by a particular device cannot always be directly correlated to the risk of not finding that device in the event of a recall. When I was an editor for PMP News' sister publication MD&DI in 1994, sponges and other cotton-based devices were found to be contaminated by Pyronema domesticum. Imagine the difficulty of tracking those sorts of low-risk, ubiquitous products whose contamination could have presented more than a low risk. ("Although Pyronema is not recognized as a human pathogen and no infections were reported, this episode raised some serious concerns about current sterilization practices and potentially resistant microorganisms," wrote Joyce Hansen, Trabue Bryans, and other authors in a September 1997 MD&DI column.) Who's to say that low-risk Class I devices will remain low-risk devices in the event of a recall?

Pleasant says that UDIs would help. "In terms of adverse-event reporting, accurate and reliable device tracking would enable all of us in the supply chain in healthcare to be able to better track potential device defects and be able to take a look at those adverse effects on our patients," he argued.

Basing UDI rules on device class risk is a sound approach. But other risks must be still considered. And inaction presents even more risk.

Daphne Allen
Editor

www.devicelink.com/pmpn/archive/06/12/001.html

Communication & Coordination Support Team

HUG Articles:

Medical Packaging Roundtable

Unique Identifiers for Medical Devices

Should bar codes—or other means of automatically identifying medical devices—be required?

The GS1 global Healthcare User Group (GS1 HUG; www.gs1.org/hug) is a voluntary and open group formed by 40 leading pharmaceutical and medical device companies, wholesalers, hospitals, and trade associations from around the world. They have come together to develop automatic identification standards specific to the needs of the healthcare industry. Given FDA's recent exploration of unique medical device identification, *PMP News* sought the perspectives of industry leaders involved in GS1 HUG. Volker Zeinar, a freelancer for B. Braun who is handling the coordination of auto-ID affairs and is HUG cochair, and Peter Tomicki, global project manager for Baxter and HUG leadership team member, offer their insights below.

Why is (or why isn't) unique medical device identification necessary?

Zeinar: Unique device identification could no doubt improve patient safety. Nevertheless, all-inclusive statements are not very helpful. Medical devices are extremely diverse in size, materials, processing, use, and criticality. There is a huge range of products (e.g., cannulas, syringes, IV sets, catheters, adaptors, lines, stopcocks, needles, pumps, filters, motor accessories, cardiovascular systems, gloves, bandages, clothing, surgical instruments, implants, cement, sutures, tissue staplers, utilities like wheelchairs or beds) with different characteristics (e.g., sterile or nonsterile, single or multiple use, very high or very low value, always in contact with a patient or never in direct contact with a patient, large or very small). Differentiating them according to international accepted risk classes (Classes I–III) could be a suitable method of resolution.

Tomicki: For patient safety, unique medical device identification may not be necessary in all circumstances for all products, but cases can be made for the value it adds in certain circumstances. Unique medical device identification will be helpful in some areas. These include track-and-trace functions, adverse-event reporting, supply-chain and reimbursement-efficiency gains, references to databases of product attributes, and additional details not able to be carried by a data carrier, allowing reductions in keystrokes leading to error when handling product, and others.

Are the current systems being used for medical device identification appropriate for unique identification?

Tomicki: Appropriate systems are in use today. However, the key is the harmonization and-or global standardization of these approaches. 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.

Zeinar: GS1 offers tools for numbering systems, data carriers, etc., that are variable and powerful enough to identify medical devices. The GTIN, in combination with various application identifiers, is sufficient to fulfill the requirements.

All product-related characteristics (e.g., size, color, route of administration, etc.) should never be part of the identification system. Instead, this

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What technologies are viable?

Tomicki: Printing and direct part-marking technologies currently offer the most pervasive and standardized technologies for implementation of these types of products and packaging, including standard bar codes or symbologies. RFID is possible for some applications and is being investigated for many others.

Zeinar: For marking of packaging, linear bar codes and two-dimensional codes would work, using all print technologies, especially laser technology. For marking directly on the product, Data Matrix can be applied through laser etching, laser bonding, micropercussion, or ink jet. RFID tags could also be applied directly to the product.

Should the pharmaceutical industry serve as a model?

Tomicki: There are likely many overlaps in possible applications and business cases for various stakeholders. It will therefore be important to have

patient safety, unique identification may not be cumstances for all products, made for the value it adds in circumstances.

pharmaceutical and device industry participation in the discussions to develop global standards that may affect all healthcare products. The pharmaceutical industry certainly has a jump on the device industry when it comes to implementation, and brings much experience to the table.

Zeinar: I don't think so, because we don't have a global standard available. For pharmaceuticals, there is a wide range of country-specific models (bar code types, numbering systems, packaging levels to be marked, Italian Bollino sequential-marking rules, etc.).

Should the identification systems and standards developing for both be the same?

Zeinar: In healthcare, the most important data are product ID, expiry date, and batch number. A selected group of products each additionally needs a serial number. Many manufacturers produce products of both categories, and medical institutions (hospitals, pharmacies, and doctors) handle a mix of these products.

To manage different systems (IT, master data, etc.) in parallel would cause higher costs. Therefore it makes sense to develop a common standard, independent from the category. *Standard* means to use the same numbering system and data structure. It doesn't mean to have the same information machine readable at the item level for all products.

What challenges do medical device manufacturers face?

Tomicki: Variety and practical technical solutions are the two most significant challenges. The standardization of machine-readable data encoded on the wide array of device products in healthcare is not a simple task. There are also the additional technical considerations of where and how to apply machine-readable data onto products and/or packaging. The question of which data should be answered, and then the technical solutions to carry that data, should be sought.

Zeinar: Different requirements from different markets (regions, trade channels, authorities, and customers) are challenging.

Often the surface of the packaging material is critical. Absorbency of materials, color, transparency, shine, smoothness, etc., influence bar code printing and legibility. Requirements for sterile packaging and bar code legibility may contradict each other. In some cases,

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nization, and all of its member organizations around the world, to draw stakeholders to participate at the table and to communicate further the progress and results of the standards development work.

Zeinar: We now have regular HUG conferences in the Americas (or the United States) and Europe and in the future, the Asia Pacific region. We are establishing HUG-LITs (local-interest teams). GS1 member organizations, currently more than 100, are forwarding the HUG messages and solutions in their domestic markets.

What do you predict will happen in the next two years? Five years? Ten years?

Zeinar: In two years, there will be global standards developed by the HUG and approved by GS1. In five years, a significant number of products will carry unique identification at the unit-of-use level (2D codes, linear codes). Hospitals will be more prepared to use the information in terms of their hardware and IT systems. In ten years, a significant number of products will carry RFID tags. The costs of tags will decrease significantly. RFID technology will offer new opportunities to improve processes. An increasing number of hospitals will be ready to use this technology.

Anything else?

Zeinar: Machine-readable product identification is an appropriate tool to improve patient safety and decrease costs in healthcare systems. But before we can get these benefits, all supply-chain stakeholders must make investments and process changes. To put bar codes or RFID tags on products is only one task. Using this information during daily business processes, such as in bedside scanning at hospitals or in the OR, is another challenge. ■

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HUG Articles:

04P_Roundtable_048_052.qxd 4P Pg 48

Pharmaceutical Packaging Roundtable

Striving Toward a Global Code

To stop counterfeiting and to control medical errors around the world, auto-ID standards need harmonizing.

Automatic identification technologies involving bar codes and RFID are being looked at as powerful weapons in the fight against counterfeiting, diversion, and medical errors. FDA in particular has mandated bar codes for drugs supplied to hospitals and is pursuing RFID to develop an electronic drug pedigree.

But given the global nature of the pharmaceutical industry as well as the worldwide threats of counterfeiting and diversion, FDA's work may not be enough. Global standards shared throughout the healthcare industry may be the key to identifying and authenticating products.

The GS1 Healthcare User Group (HUG; www.gs1.org/hug) is a voluntary group of specialists who have come together to develop automatic identification standards specific to the needs of the healthcare industry. In this exclusive roundtable discussion with *PMP News* editor Daphne Allen, several of the GS1 HUG leadership team members and work team leaders discuss the group and its hopes to unify automatic identification standards throughout the world.

Participants include Steve Hess, senior director of packaging technology for Merck; Rich Hollander, senior director of packaging services for Pfizer; Ulrike Kreysa, group manager, healthcare solutions, GS1 Solutions, GS1 Global Office; Peter Tomicki, global packaging project manager for Baxter; and Mark Walchak, senior manager, global package technology and testing, for Pfizer.

Can you explain a little bit about GS1 HUG and what are some of the current tasks at hand?

Hollander: The GS1 HUG was formed about a year ago to help bring together the medical device and pharmaceutical product communities to understand how to best apply automatic identification tools to address issues involving patient safety. When we talk about patient safety, we are talking about everything from prevention of dispensing errors to serialization to enable the authentication, tracking, and tracing of high-risk products subject to counterfeiting. In the past year, we have met three times formally—once each in Brussels, Princeton, NJ, and Rome. During that time we have worked to understand the specific requirements for patient safety around the world. Not just from a user perspective—that is the product manufacturer—but also from the rest of the supply chain.

Are you taking the framework that was already established by the Uniform Code Council Inc. (UCC) and EAN International and developing it into global standards?

Kreysa: EAN International and UCC came together 1½ years ago and formed the new organization GS1, which is a really global organization. Before, there were different member organizations around the world in more than 100 countries, all with different names. The biggest ones were UCC and some member organizations in Europe and Japan. They all have decided to form one global organization called GS1.

Hess: One thing that attracted me to this organization was the approach of trying to leverage the entire portfolio of GS1 technologies. The HUG was not focused solely on using a single technology to solve all problems. Also, there are lots of other initiatives that are very U.S.-centric, but I was attracted to the HUG's global approach. I think that is just so powerful.

Does this mean that there will be one harmonized approach to bar coding or electronic product coding for healthcare products?

Walchak: One of the things that we are trying to do is to have a standardized system for assigning numbers that will be used from a unit-dose aspirin all the way up to an MRI machine. It would cover any OTC or prescription drug and all medical devices. We will have a standardized system that can be used universally.

Tomicki: The scope of the HUG is really across all industries within healthcare—devices, pharmaceuticals, biologics, vaccines, and all the subindustries within those. I think it is across all of healthcare and it is in concert with the GS1, which is across all other industries as well. It makes sense to align healthcare as one industry as best as we can so that it is not

Pharmaceutical Packaging Roundtable

GTINs within our own systems and according to the healthcare industry GTIN allocation rules. This would enable global GTIN standards and infrastructure to take care of them, minimizing regional exceptions.

Walchak: There are different countries that have different ways of assigning the numbers that are to be used for healthcare items. In the ideal world, the way they assign those numbers would fit into the GTIN system. Some of them do not, and we will have two different numbers, one that will be country specific to meet their regulatory requirements and one that is a GTIN. But I think that most countries will be aligned.

Are there any particular healthcare products that will be a challenge to get into this system?

Walchak: One of the biggest issues we face is the medical device area. There is such a broad range of items, and we have a committee that is trying to come up with a system.

Tomicki: The GTIN allocation for devices is going to be one of the most significant challenges. There are many different permutations and possibilities or scenarios for assigning rules for how to assign GTINs to those types of products. That working group will generate rules that make sense and that are manageable within our infrastructure.

Walchak: Examples of some of the issues we face are for the same product—you might have different languages, voltages, or software. A key question arising in GTIN allocation in the medical device area is whether you assign GTINs based on form/fit/function or based on the commercial unit.

What data structure may evolve for the medical device field?

Walchak: EAN13 codes and UPCs that exist for most items can be converted into a GTIN.

What are some of the GS1 HUG work teams?

Hess: I can touch base on the Vaccines Work Group. Vaccine containers are pretty small, so space is an issue. In addition, while FDA has issued a compliance guide that describes its intent to exercise enforcement discretion for Rx and OTC drugs to pilot RFID, we do not yet have that same clearance for biological and protein-based products. FDA is asking for data on RFID's possible effects on biologicals and proteins. Again, HUG's approach involves looking at the full portfolio of GS1 technologies and trying to identify the right technology for each product area, not trying to force-fit a unique technology across the board. At this point we are identifying what our problem areas are. We are trying to also identify as much as possible where we can harmonize with pharmaceuticals, because that is really what we want to do. But there are going to be some unique requirements for vaccines, such as the size and the cold-chain requirements.

Tomicki: The biologics and vaccines group was created because it is a high-need area for auto-ID in healthcare. There are certain countries like Canada that are moving really quickly toward trying to get either mandates or guidances in place to effectively manage biologicals and vaccines in their regions or countries. We want to create one harmonized approach for all of healthcare if we can, including devices, pharma, biologics, vaccines, and all subcomponents or subindustries. Now, in certain cases, there may be some unique features of that particular subindustry that warrant some special attention, and that is what we are looking at with vaccines and biologics. We want to see where there are commonalities and differences and

aging Roundtable

l medical errors?

lollander: The HUG was formed develop global standards in the thcare industry when it comes to matic identification and act as the ing voice for the healthcare indus- As such, we needed to have a rea- for doing it. Ultimately, for those e focus areas we want to use the k groups to help us define the ropriate data elements such as the N or the electronic product code C), the appropriate data structure, ification identifiers, and ultimately appropriate data carrier. Should it a Code 128 linear bar code? uld be it a 2-D Data Matrix? uld it be the RFID tags themselves EPC for non-line-of-sight applica- s? These aforementioned work- ups are focused on defining these nitions.

lany of the standards required ady exist, but there are a multitude hoose from. Multinational compa- are struggling to keep up with vidual market needs that keep g put out there in the form of reg- ions that are divergent from one ther to address the same business , be it dispensing errors, diversion, nticounterfeiting. Individual mar- , such as the United States, Italy, n, Portugal, Spain, Greece, Bel- n, and now France, are all defining r own automatic identification roach. Most of them are at least g GS1 standards, but they are g them differently, and that is part he problem.

reysa: It is not easy to define a al standard for all healthcare ducts. In the last 11 months, HUG gone quite a long way to getting right members involved. We are king on getting more attention n regulatory bodies; this cannot be ugh. We are now really working l to get standards and guidelines ten and agreed on.

think that the group's existence is ady holding up the release of other regulatory requirements from different countries or different bodies. We have achieved this, even if we have not yet released standards. But our work on it makes others think.

A lot of ministries of health are already participating. At our last meeting in Rome we were welcomed by the Italian Ministry of Health and others. The WHO participated, and it plans to include the HUG in reviews of its documents on fighting counterfeits.

Hollander: We communicate quite regularly with FDA. FDA actually came to our meeting in Brussels, presented its business requirements, including some of its work toward serialization via RFID and/or bar codes. They will attend our June meeting in Minneapolis. In addition, one of our guiding principles is to continue to stay closely aligned with the EPCglobal Healthcare and Life Sciences (HLS) business action group (BAG). The trichairs from the HLS BAG attend our HUG meetings regularly, and the HUG leadership attends HLS BAG meetings regularly.

We are looking at establishing global standards for the healthcare industry. Your readership is largely composed of users, supply-chain participants, or manufacturers that produce equipment and software for the healthcare industry. We would very much welcome people who are interested in actively working in the HUG to help establish these standards. We need people to join our work teams and commit to doing work to help establish these standards. We will invite in third-party vendors as appropriate once we understand the standards needed to support existing business issues.

Tomicki: To identify stakeholders, we are looking specifically at global manufacturers, but we are also welcoming all manufacturers, channel partners, and end-users. We are trying to identify all of the stakeholders in the channel who would like to play a role and welcome them to the HUG. ■

HUG Articles - Previous Publications:

Technology update: Barcoding

Benefits of barcoding in the pharmaceutical industry

The use of barcodes on drugs and medical devices will be an important step to improve patient safety and will allow the tracking of medicinal products before, during and after a medical procedure

One of the main concerns in healthcare today is patient safety. In 2000, the Institute of Medicine (IOM) published its report *To Err is Human*[1] and an increasing number of publications are reporting on medical errors, which happen across the world.[2-4] Automatic identification technology (barcoding) is one of the tools that is acknowledged in reducing such errors.[5] It is contributing to improving efficiency and increasing accuracy of data entry into automated systems. The possibility of capturing data via barcode scanners, in conjunction with computerised databases, enables healthcare professionals to verify whether the right drug was used at the right time for the right patient in the right dose on the right route ("five patient rights"). Barcoding has the potential to be not only cost-effective but to save lives while producing a strong return on investment.

Medical errors and usage of barcodes

A barcode is a graphic representation of data that is machine-readable. Barcodes are a fast, easy and accurate way of capturing and entering data. They do not contain descriptive data, but are just a reference number to a computer file with the relevant data.

In a hospital, barcodes can be used to improve processes in the following areas:

- Patient registration and admission for:
  - Patient forms.
  - Patient labels and wristbands.
  - Patient records.
  - Patient accounting and billing.
- Patient safety, clinical care delivery and patient tracking by using barcodes for:
  - Pharmaceuticals down to unit dose level.
  - Medical devices down to unit of use level.
  - Identification of hospital staff and patients.
  - Order requisitions, test/results and patient charts/medical records.
- Product, supply and material management for:
  - Inventory control/tracking.
  - Materials tracking and logistics.
  - Tracking of reusable/refurbished equipment and supplies.
  - Reverse supply chain (eg, product recalls and warnings).

Taking into account the significant benefits of automatic product identification, the Department of Health and Human Services in the USA has issued a final rule requiring electronically readable barcodes on the packaging of hospital administered pharmaceutical products, biologicals and blood products. This will be introduced in April 2006.[6]

Already, in 40 countries worldwide, mandates for automatic product identification exist today – others are in the phase of developing regulations for barcoding of healthcare products, acknowledging the advantages for patient safety.[7-8] While studies conducted in Veteran Affairs hospitals (USA) in the 1990s showed that the use of barcodes reduced medication administration error rates by up to 86%, only a small number of hospitals have recently started to use this technology to improve patient safety. Current estimates indicate that only 2–6% of hospitals in the USA are using barcodes to reduce medication administration errors.[9] It is expected that the number of hospitals will increase significantly in the near future, with more products carrying a barcode and more publications reporting the benefits of barcodes.[10-12]

Global standards for pharmaceuticals and medical devices

The healthcare industry has recently recognised the need for global standards in healthcare and in May 2005, leading global companies from the pharmaceutical and medical device industries formed the global GS1 Healthcare User Group (GS1 HUG™).[13] Its mission is to lead the healthcare industry to the effective utilisation and development of global standards, with the primary focus on automatic identification to improve patient safety. The group currently has 34 members from manufacturers, hospitals, regulatory bodies and associations who are committed to working towards a global solution to enhance automatic

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GS1 Global Office
Brussels
Belgium

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WHAT WE NEED IS...

A global auto ID standard can help solve counterfeit issues

by Rich Hollander
Senior Director, Packaging Services, Global Manufacturing, Pfizer Inc.

There are pressing issues in health care today for which automatic identification—linear or two-dimensional bar codes or radio frequency identification (RFID)—is part of the solution. Specifically, I'm talking about dispensing errors, counterfeiting and diversion or fraud.

The Food and Drug Administration believes that part of the solution to counterfeiting, diversion and fraud is to serialize every package, capture that data as the package moves through the supply chain and authenticate the package at each step. The FDA also believes the use of RFID technology is the most promising technology to enable this to happen. I believe serialization is a very strong solution. Previously, it was difficult to deploy in mass and too many proprietary solutions were available to set any standards.

But when the pharmaceutical industry started hearing about the electronic product code back in 2001, we said, "Oh, now there might be something." The EPC could be that unique serial number as it, and the supporting infrastructure, is being developed with open standards.

Global commonalities

Dispensing errors, counterfeiting and diversion are business issues facing not only U.S. drug manufacturers. There is a need for a clear understanding of these common issues globally. The European Commission and other individual markets are starting to promulgate regulations, forcing standards in the area of automatic identification. They're all trying to solve the same business issues with different approaches though. That's a problem. It's not efficient. Our global sourcing strategies become difficult to implement if we have to cater to different market needs for this.

To start the process for global standards development, GS1 (previously the Uniform Code Council and EAN International) recently established a global Healthcare User Group.

The idea here is that HUG will help align the health care industry to the effective use of global standards for automatic identification. These standards largely exist today; we just need to direct parties on how to effectively use them to address these issues. Where standards still need to be developed, HUG will initiate accordingly with the appropriate group within GS1.

Through an organization like HUG, we can develop technical solutions that will work for everyone.

Generally, the right technical solution will also minimize cost, be scalable at the global level, and have optimal impact on the business issue. By harmonizing around global standards, we can implement solutions faster than if each market would individually mandate their own.

Visit www.gs1.org/hug to learn more about the GS1 HUG™ and to find out how you can participate and benefit. FDP

"They're all trying to solve the same business issues with different approaches, though. That's a problem. It's not efficient."

With Pfizer since 1990, Rich Hollander has responsibility for all areas of global package design and development for Pfizer's Animal Health, Consumer Healthcare and Human Health businesses. Hollander is an active leader on various committees, work groups and task groups aimed at addressing issues within pharmaceutical packaging. He currently serves as co-chair and communications chair for the GS1 Healthcare User Group (www.gs1.org/hug).

BAR CODING OF MEDICAL DEVICES

By Ulrike Kreysa

The term 'medical device' is used for a wide range of products, from a syringe to a heart valve to an infusion pump. Medical devices, like pharmaceuticals, are essential in the treatment of patients and play an important role in the healthcare system. The medical device industry is a fast growing one, with the most important markets being the US, Japan and Germany[1]. A high percentage of healthcare costs are generated by medical devices, and through the rapid progress in technical innovation, the global market figure for 2006 is expected to exceed US$260 billion[2].

Global medical device market is expected to exceed US$260 billion in 2006

At the same time, a number of the issues affecting medical devices are similar to the ones affecting the pharmaceutical industry:

Counterfeiting

There are few official numbers about the counterfeiting of medical devices but for pharmaceutical products the US Food and Drug Administration (FDA) estimates that 10% of them worldwide are falsified[3]. Medical device manufacturers are also reporting counterfeiting of their products, which causes effects on the safety of device users and patients, as well as effects on the manufacturers themselves (e.g. by loss of sale and loss of reputation when counterfeit products fail that have been branded with their company's trademark). A safe and secure supply chain is needed which prevents counterfeiting of products and enables proper traceability of medical devices from the manufacturer to the patient. This will prevent illegal re-processing and re-packaging of products as well as the infiltration of falsified and unsafe products. Through the tracking and tracing of the items, effective alerts and product recalls will be possible.

Counterfeiting of products can be prevented with a safe & secure supply chain

Medical errors

In 2000, the Institute of Medicine (IOM) published its report *To Err is Human*[4] about the causes of medical errors and how one can prevent them. Automatic identification technology (bar coding) was one of the tools the IOM recommended to help prevent medical errors. As a consequence, in February 2004, the US Department of Health and Human Services issued a final rule requiring electronically-readable bar codes on the packaging of hospital administered pharmaceutical products, biologicals and blood products to be applied by April 2006[5]. To date, no such rule has been released for medical devices, despite pressure from the largest American hospital chains such as Premier and the American Hospital Association[6]. However, the FDA has organised an official meeting to discuss unique device identification, where stakeholders were given the opportunity to express their opinion[7].

From April 2006, all US pharmaceutical product packaging must have an electronically-readable bar code

HUG Others:

Time Best Inventions of 2006: Hug Shirt

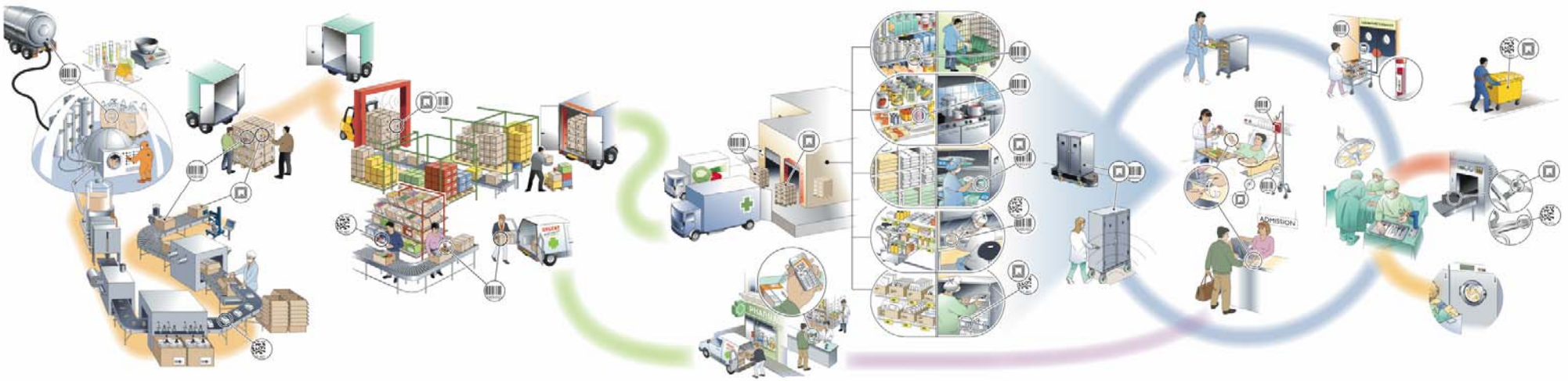
The Hug Shirt has been nominated as one of the Best Inventions of 2006 by Time Magazine!!!

Finally you can see the new Hug Shirt that was presented at Wired NextFest in New York last month. The new design features a very comfortable mix of smart textiles, cotton and micro-fiber that make it very soft and pleasant to wear. And yes! Is completely washable! More images of the new Hug Shirt will be available soon on the Hug Shirt webpage.

Time Best Inventions 2006

This entry was posted on Tuesday, November 7th, 2006 at 4:24 pm and is filed under CuteCircuit News. You can follow any responses to this entry through the RSS 2.0 feed. You can leave a response, or trackback from your own site.

HUG Technical Material:

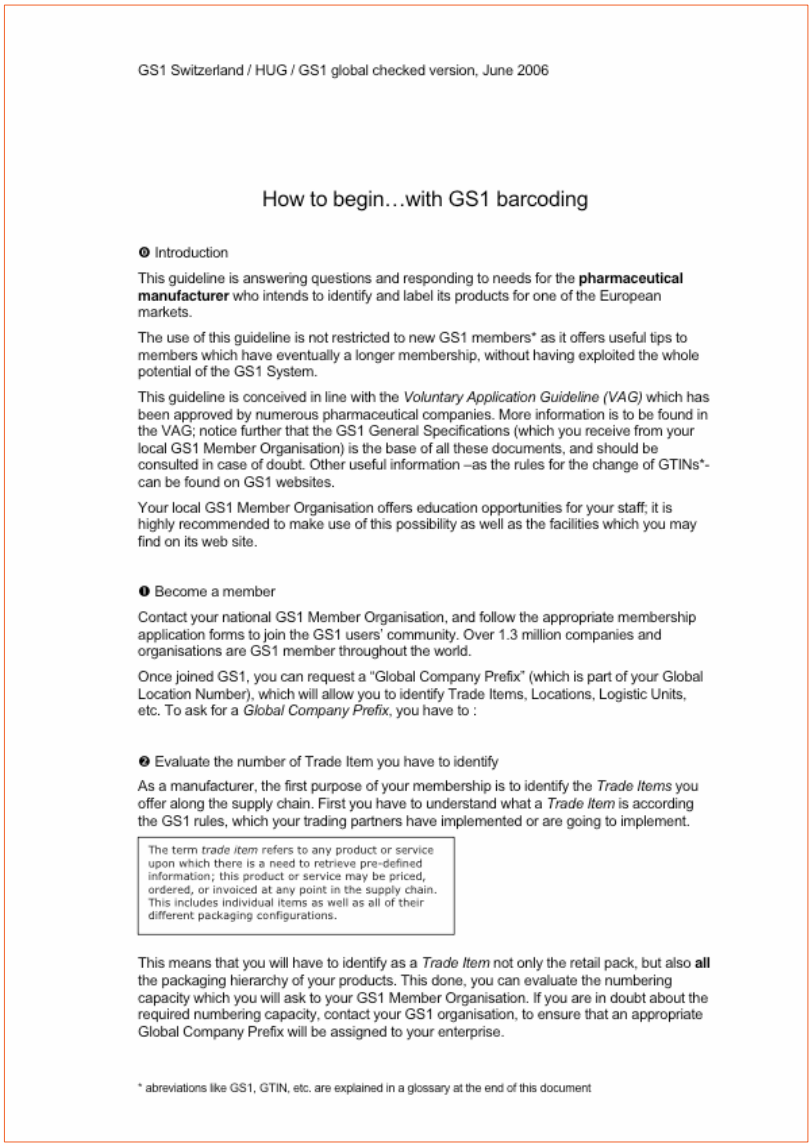


Communication & Coordination Support Team

HUG Technical Material:

Thank you for correcting the translation.

Now I understand better what I intended to say!



GS1 Switzerland / HUG / GS1 global checked version, June 2006

How to begin…with GS1 barcoding

❶ Introduction

This guideline is answering questions and responding to needs for the **pharmaceutical manufacturer** who intends to identify and label its products for one of the European markets.

The use of this guideline is not restricted to new GS1 members* as it offers useful tips to members which have eventually a longer membership, without having exploited the whole potential of the GS1 System.

This guideline is conceived in line with the *Voluntary Application Guideline (VAG)* which has been approved by numerous pharmaceutical companies. More information is to be found in the VAG; notice further that the GS1 General Specifications (which you receive from your local GS1 Member Organisation) is the base of all these documents, and should be consulted in case of doubt. Other useful information –as the rules for the change of GTINs*- can be found on GS1 websites.

Your local GS1 Member Organisation offers education opportunities for your staff; it is highly recommended to make use of this possibility as well as the facilities which you may find on its web site.

❶ Become a member

Contact your national GS1 Member Organisation, and follow the appropriate membership application forms to join the GS1 users' community. Over 1.3 million companies and organisations are GS1 member throughout the world.

Once joined GS1, you can request a "Global Company Prefix" (which is part of your Global Location Number), which will allow you to identify Trade Items, Locations, Logistic Units, etc. To ask for a *Global Company Prefix*, you have to :

❷ Evaluate the number of Trade Item you have to identify

As a manufacturer, the first purpose of your membership is to identify the *Trade Items* you offer along the supply chain. First you have to understand what a *Trade Item* is according the GS1 rules, which your trading partners have implemented or are going to implement.

> The term *trade item* refers to any product or service upon which there is a need to retrieve pre-defined information; this product or service may be priced, ordered, or invoiced at any point in the supply chain. This includes individual items as well as all of their different packaging configurations.

This means that you will have to identify as a *Trade Item* not only the retail pack, but also **all** the packaging hierarchy of your products. This done, you can evaluate the numbering capacity which you will ask to your GS1 Member Organisation. If you are in doubt about the required numbering capacity, contact your GS1 organisation, to ensure that an appropriate Global Company Prefix will be assigned to your enterprise.

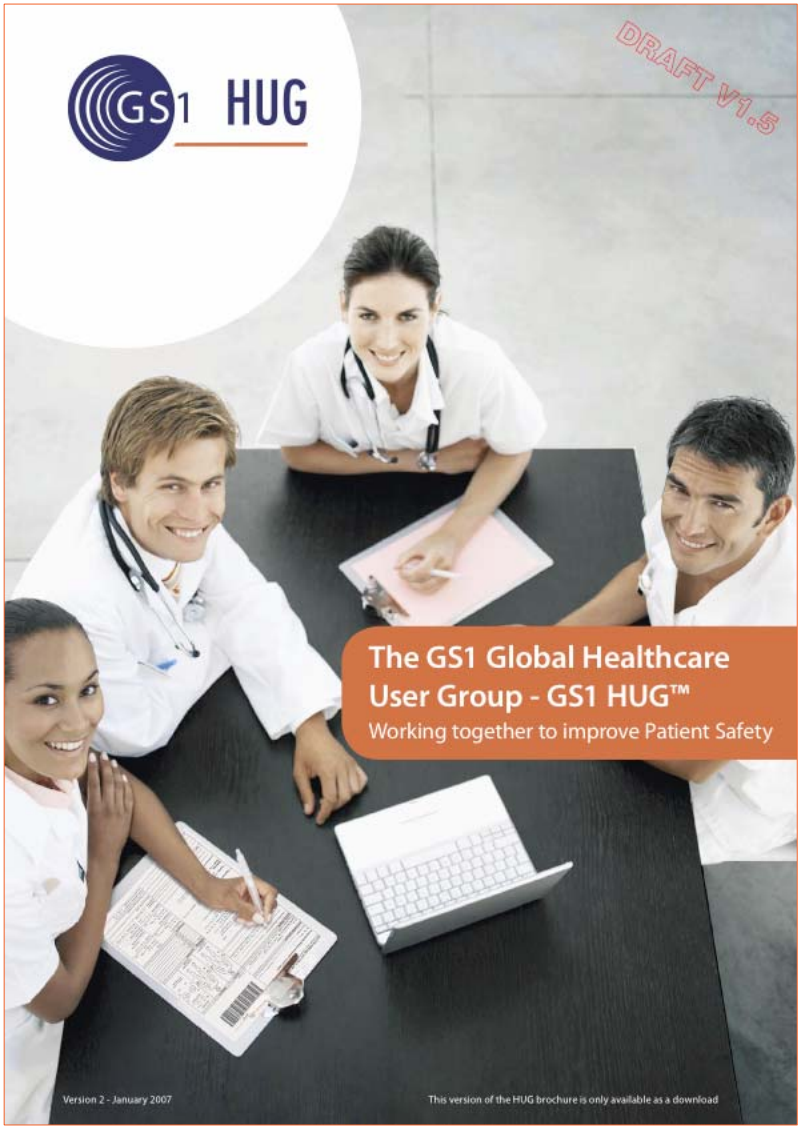
* abreviations like GS1, GTIN, etc. are explained in a glossary at the end of this document

Communication & Coordination Support Team

HUG Technical Material:

Communication & Coordination Support Team

HUG Brochure Update:



Communication & Coordination Support Team

HUG Brochure Update:

DRAFT V1.5

What is the GS1 HUG™?

Leading global companies from the pharmaceutical and medical device industry have formed the GS1 global Healthcare User Group (GS1 HUG™). It is the first time that the healthcare industry is aligning around a global solution to enhance automatic product identification for the benefit of patients worldwide.

The work of the HUG will help to improve the efficiency of the healthcare supply chain for pharmaceuticals and medical devices through the collaborative development and endorsement of recommended voluntary GS1 standards and best practices.

Mission and Vision

The **mission** of the GS1 HUG™ is to lead the healthcare industry to the effective utilisation and development of global standards with the primary focus on automatic identification to improve patient safety.

The **vision** of the GS1 HUG™ is to become the single source for regulatory agencies and trade organizations (manufacturer, wholesaler, distributor, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

"I'm delighted that GS1 standards will be used to improve the safety of patients world-wide while simultaneously increasing the transparency and efficiency in the healthcare supply chain. GS1 standards are already used in many countries worldwide and for many different products and services in the healthcare sector, but with the industry leadership of the GS1 Global Healthcare User Group (GS1 HUG™) we will see wide implementation and improvement globally."
Miguel Lopera, President & CEO of GS1.

Communication & Coordination Support Team

HUG Brochure Update:

DRAFT V1.5

HUG Leadership Team

The **HUG Leadership Team** is responsible for the activities of the **HUG**. It comprises a minimum of 7 and a maximum of 12 full members. The seats are split by region; 5 North America, 5 Europe and 2 Asia/Japan region. The Leadership Team selects two Co-Chairs. Qualifications to serve as a Co-Chair include prior experience in the GS1 HUG™ Leadership Team. The Co-Chairs provide representation from all healthcare sectors and an attempt will be made to keep a geographical balance. The Leadership Team holds regularly scheduled teleconferences to monitor progress, discuss issues and meet in person in connection with the HUG conferences, which are held in various geographical locations. Further face-to-face meetings are organised as required.

HUG Work Teams

The HUG Leadership Team initiates **Work Teams** to work on clearly define global requirements, with expertise provided by HUG members and, where necessary, support from GS1. Each Work Team works to a defined scope, objectives and deliverables. Since the formation of the HUG in May 2005, a number of Work Teams have already completed projects or the teams have been merged with other teams to work on enlarged requirements (e.g. Instruments & Implants Marking, Standards Development, GTIN Allocation Rules, Standards Implementation, Regulatory Affairs and Vaccines & Biologics). Work Teams will continue to evolve, depending upon changing or new requirements.

HUG Support Teams

Within the HUG Leadership Team are two **Support Teams** - **Membership** and **Communication & Coordination.** These teams are lead by; **Volker Zeinar, B.Braun** & **Rich Hollander, Pfizer** and both supported by **Jim Willmott, Smiths Medical**.

The objective of the **Membership Support Team** is to organise HUG enlargement to progressively include all stakeholders.

The objective of the **Communication & Coordination Support Team** is to lead and organise internal and external communications of the HUG and establish the HUG as the leading voice in the area of automatic data identification in the healthcare industry. This includes; Press Releases, Articles for Publication, Newsletters, Formal Communications, Structure & Content of the HUG website and support for the Work Teams and Local Interest Teams (HUGLITs). The Support Team works very closely with the HUG Leadership Team and the GS1 Global Office, Marketing Department.

Communication & Coordination Support Team

HUG Brochure Update:

DRAFT V1.5

HUG Work Teams:

- **Business Case**

Scope: International (global) coverage of all patients, regulatory bodies, supply chain participants. It includes healthcare providers as well as first and third party payers.

Objectives: Develop a compelling business case to demonstrate the benefits of using a GS1 global standard for automatic identification in healthcare. The case will be applicable to linear bar codes, 2D codes, and RFID. The case will be based on direct, first hand data gathered from the international environment.

Deliverables: A full report of the findings for printing and Internet publication. From the report, an executive summary will be prepared for top management and electronic presentation material for regulators and general audiences. The executive summary will include details of benefits that are important to high level management.

Leaders: Ed Dzwill - Johnson & Johnson

Dr. Hugh Lockhart - MSU School of Packaging

- **Public Policy**

Scope: International. To include all GS1 service offerings: bar coding, RFID, numbering systems (SGTIN, EPC, GLN, GSRN, etc.), and data synchronization.

Objectives: Identify regulatory, technical, commercial, and process barriers to implementing GS1 standards in the global healthcare sector. Develop strategies to overcome barriers and speed adoption.

Deliverables: Maintain database of regulatory agencies and auto identification policies. Maintain database of GS1 HUG™ members' adoption status. Identify three (3) target markets and strategies to drive adoption. Develop publication "Global Guidelines for Automatic Product Identification of Pharmaceuticals and Medical Devices".

Leaders: Jackie Rae Elkin - Medtronic

Tom Werthwine - Johnson & Johnson

Communication & Coordination Support Team

HUG Brochure Update:

DRAFT V1.5

HUG Work Teams:

- **Auto-ID Data**

Scope: 1) From the moment a product is "finished" in manufacturing through to the end of patient treatment. 2) Adverse events, related to data capture. 3) Animal health products will be in the scope for gathering requirements only. 4) Food services will not be included other than therapeutic nutritional products. 5) Equipment used to transport patients is out of the scope, other than those classified as medical devices. 6) Facility assets used by a patient such as tables, lights, etc. is out of the scope.

Objectives: To improve patient safety by standardising the data content for healthcare applications of automatic identification data capture systems. The work team will generate the business and data requirements required for all products within the scope of the HUG.

Deliverables: Report defining the business and data requirements will be delivered to the HUG Leadership Team for HUG vote. This document will be used by the Serialisation, Carrier and AIDC Application Standards Work Teams for incorporation into the final AIDC Application Standard.

Leaders: Mark Walchak - Pfizer

Mark Hoyle - Tyco Healthcare

- **Serialisation**

Scope: Define serialisation schema for healthcare products, with product traceability for patient safety as highest priority (how and where to use mass serialisation for traceability).

Objectives:

Deliverables:

Leaders: Steve Hess - Merck

Pierre Stoquart - GSK

- **Data Carrier**

Scope:

Objectives: Identify the data carriers for healthcare product packaging and direct marking. Establish standards for carrier printing/marking/encoding, scanning/verifying/decoding and quality (where and when to use which bar code type like EAN-13, GS1-128, RSS, Data Matrix or RFID tags).

Deliverables:

Leaders:

Communication & Coordination Support Team

HUG Brochure Update:

Working groups

GS1 Global Healthcare User Group (HUG)

The mission of the global Healthcare User Group (HUG) is to lead the healthcare industry to the effective utilisation and development of global standards with the primary focus on automatic identification to improve patient safety.

The vision is of this group is to become the single source for regulatory agencies and trade organisations (manufacturer, wholesaler, hospital and pharmacy) to seek input and direction for global standards in the healthcare industry.

On the 22nd of August 2006, after one year of successful operation, the members of the Global Healthcare User Group officially announced that they will use GS1 standards exclusively as the basis for automatic product identification.

Click here for more information about the HUG.

GS1 Australasian Healthcare User Group Local Interest Team (HUGLIT)

In order to ensure the requirements of Australian and New Zealand Healthcare organisations are taken into account by the HUG, the GS1 Australasian HUGLIT has been formed. This group will serve two main functions:

- Provide Australian and New Zealand input into the work of the HUG
- Work on Australian and New Zealand specific Healthcare issues and bring these to the attention of the global HUG for incorporation into this group's work plan

Meetings

- 25th October 2006 – (Inaugural Meeting) Melbourne, Australia
- 14th December 2006 – Sydney, Australia

To register your interest to participate in the GS1 Australasian HUGLIT, contact Tania Snioch at GS1 Australia, via telephone to **+61 3 9558 9551** or click here to email.

DRAFT V1.6

HUG Local/Regional Teams:

In addition to the HUG Work Teams, sometimes it becomes a requirement to create **HUG Local/Regional Teams**. The teams work on clearly define local or regional requirements, with expertise provided by HUG Work Teams, the local/regional GS1 member organisation and local HUG members. Each local/regional team works to a defined scope and deliverables. These deliverables could be to resolve a local requirement, implement a global requirement or turn a local requirement into a global standard. The teams are there to reduce global diversity and reduce potential complications for manufacturers or the supply chain. Currently the following local/regional teams are in operation and up-to-date information can be obtained from the HUG (Work Teams) or Member Organisation's website.

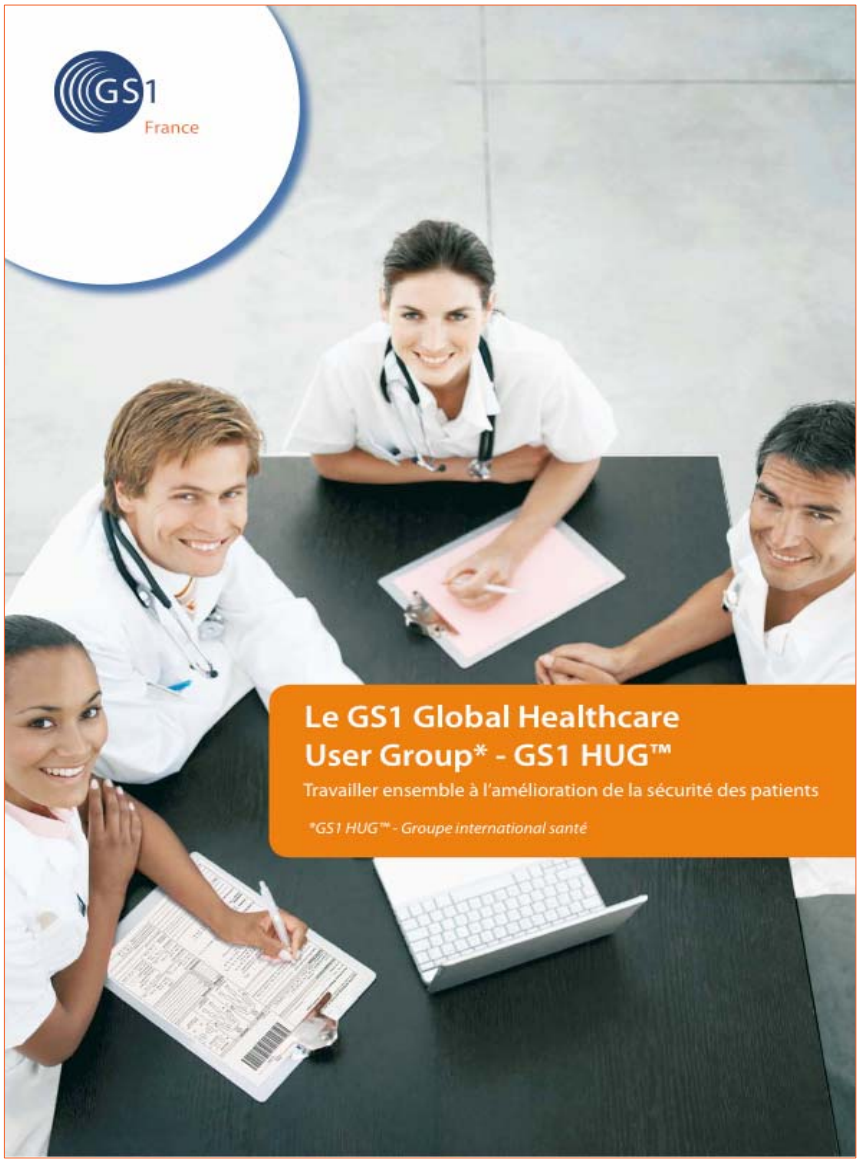
- **Australasia**
  GS1 Australia (www.gs1au.org/home.asp)
  GS1 New Zealand (www.gs1nz.org/)

- **Chile**
  GS1 Chile (www.gs1chile.org/default.asp)

- **Switzerland**
  GS1 Switzerland (www.gs1.ch/)

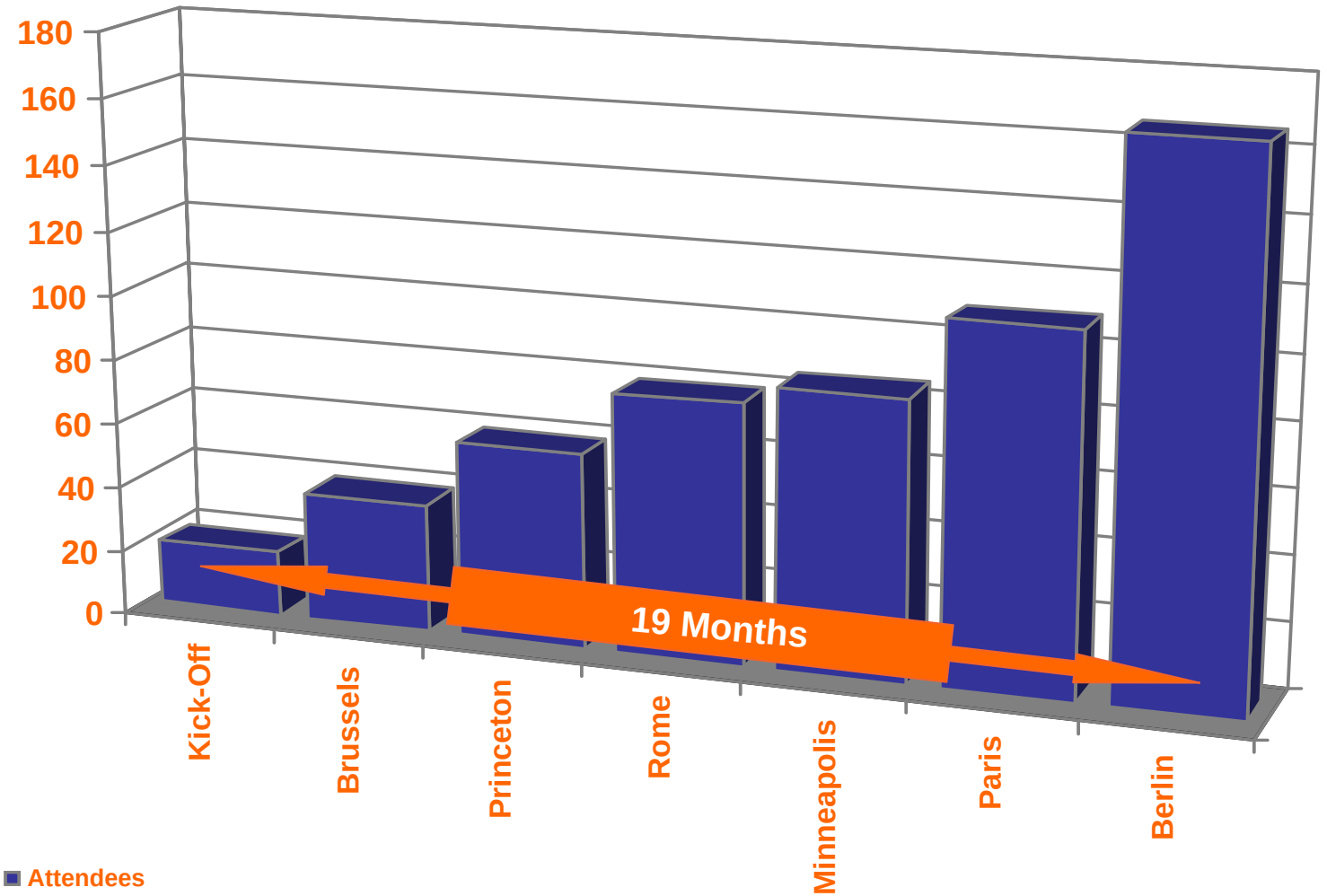
Communication & Coordination Support Team

HUG Brochure Français:



Now available in:
French/Français

HUG Conference Attendees:



Any questions for ‘anyone’ in the Communication & Coordination Support Team?

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