GS1 Healthcare

GS1 Healthcare Newsletter

No. 10 – March 2008

GS1 Healthcare holds successful conference in Granada, Spain

The SAS (Andalusian Health Service) hosted the 9th GS1 Healthcare Conference in the Andalusian School of Public Health in Granada, Spain. Juan Carlos Castro, General Manager SAS opened the conference: *"It has been four years since the Andalusian Healthcare Service decided to adopt the GS1 Identification System throughout the supply chain in order to guarantee traceability, patient safety and efficiency in logistics management. Healthcare organisations ask suppliers and providers for a high commitment to safety and efficiency, especially when they are financed by public funds. We are sure that these decisions have drawn a successful path towards a safer and more efficient supply chain. We also realise the importance of this kind of meetings to help this purpose and we welcome everyone to Granada."*

The conference in Granada was also a milestone for GS1 Healthcare: the Leadership Teams of GS1 EPCglobal HLS Industry Action Group and GS1 global Healthcare User Group (GS1 HUG) formally approved the GS1 Healthcare Governance Charter and funding model.

GS1 Healthcare – working worldwide towards global standards in the Healthcare supply chain

GS1 Healthcare is working, both at a global and local level, with international and national organisations towards the development and adoption of global standards throughout the Healthcare supply chain. For example, GS1 Healthcare was represented at a recent meeting of the WHO IMPACT Technology work team in Singapore. Authorities of Hong Kong, Italy, Spanish regions (Andalusia and Galicia) and Turkey shared their ongoing projects at the conference in Granada. Japan will soon issue revised bar code guidelines for medical devices, recommending the continued use of GS1 Standards but with some changes to align with global standards.

DATES FOR YOUR DIARY:

Our next GS1 Healthcare Conference
- 17 to 19 June 2008, Toronto, Canada

GOVERNMENT AND REGULATORY ACTIVITIES

GHTF: towards global unique device identification (UDI)

One of the recently suggested objectives of the Global Harmonisation Task Force (GHTF) is to work towards a global approach for UDI.

The regulatory bodies from Australia, Canada, Germany, Panama, Mexico, Shanghai and the USA, as well as the European Commission and the Pan-American Health Organization met at the end of January in Washington DC (USA). Sharon Frank (European Commission) reported about this meeting in Granada. The participants discussed a number of issues including, for example, a common definition of what triggers a new UDI (refurbishing, reprocessing etc). It was also considered that medical devices are a very large and diverse product group, a reason to make any regulation on UDI technology agnostic: different technologies can be suitable depending on the type and class of the medical device, intended use and the end-user.

Anti-counterfeiting: making an impact

The World Health Organization (WHO) launched IMPACT (International Medical Products Anti-Counterfeiting Taskforce) in response to the growing public health threat of counterfeited drugs and medical devices. IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medical products around the globe. GS1 Healthcare is proud to be part of the IMPACT Technology work group.

At a recent IMPACT conference in Singapore, GS1 Healthcare was invited to talk to the topic "Global Standards". Maria Palazzolo, CEO of GS1 Australia, presented the work of GS1 Healthcare with regards to the development of global standards for unique identification and traceability, which will make the supply chain much safer and will make it more difficult for counterfeiters. Participants appreciated in particular the local reach of GS1 through the GS1 Member Organisations across the world. Cooperation at a local level will be encouraged to advance global standards that will enable systems to combat and prevent counterfeiting.

www.who.int/impact

Hospital Authority Hong Kong

The Hospital Authority of Hong Kong manages all public hospitals in Hong Kong, totalling almost 28,000 beds. One of its focus areas is procurement and materials management. *"Our vision is to establish a seamless supply chain operation with maximal risk management"*, said Raymond Wong, Chief Manager Business Support Services, Hospital Authority. To improve purchasing control and efficiency, the Hospital Authority is considering best practices in the electronic exchange of supply chain data and the use of universal data standards such as GS1.

The implementation of bar codes on medical products in their hospitals resulted in some remarkable improvements. Patient safety has been improved through traceability down to the patient consumption level and freeing up nurses' time for better patient care. It also increased the efficiency of supply chain management, for example, the stock level of surgical items for the operating rooms was reduced by 30%. 2-D bar codes on patients' wristbands are already used for certain applications (including blood sampling), and its use will be extended in the future (for example for patient identification in operating rooms and the administration of chemotherapy drugs).

The implementation of bar codes on medical products in their hospitals resulted in some remarkable improvements.

RFID pilots have recently been started in two hospitals: assets (e.g. infusion pumps and ultrasound scanners) will be tracked using RFID solutions. The objectives are to analyse cost-benefits and to assess reading performance and end-user acceptance.

www.ha.org.hk

Drug tracking system in Italy

The Italian Ministry of Health introduced the "Bollino" identification system for all medicines in 2001/2002. This system is built on the AIC code (the authorisation number issued by the Italian Drug Agency) and a serial number (progressive identification code of the single package). A central database was established in 2004 to record all movements of each drug package in the distribution chain.

"To quickly obtain initial results and to mitigate the system impact on the involved players, a phased approach was adopted." said Claudia Biffoli, Ministry of Health, Italy. During a first phase that started in June 2005, limited information was gathered for about 1.6 billion movements. The Ministry of Health is currently assessing the situation with all relevant stakeholders to come to a full implementation of the tracking system. This will then include information such as serial number, lot number, expiry date and tracking of inward and outward movement. GS1 DataMatrix is being considered as the appropriate symbology. A working group is also considering a GS1 Identification Key as an alternative to using the National AIC code in the bar code. A Global Identifier (GTIN – Global Trade Item Number) would be in line with International Standards and use, and also provides a dynamic approach to managing multiple product identification codes for each AIC. The GTINs can be linked to AIC in a cross-reference table.

"In the coming months, the working group will clarify the open issues and will work towards a final tracking system addressed to all the players involved", concluded Claudia Biffoli.

The Ministry of Health is currently assessing the situation with all relevant stakeholders to come to a full implementation of the tracking system.

Purchasing and logistics in the Andalusian Health Service

GS1 Identifiers are fundamental in the business model of SAS (Andalusian Health Service). *"More than 150,000 references have been registered in the SAS product database since it became operational in 2003. Products need to be identified using GS1 codes"*, said Jesus Gavira, SAS. *"Also the e-commerce platform that will be implemented will identify products based on GS1 codes."*

The hospital logistics processes will start using bar codes (linear or 2-D) to enable traceability up to the patient and to increase supply chain efficiency. A logistics management system, SIGLO, will manage the different stages in the logistics chain.

Purchasing and logistics in the Galician Health Service

SERGAS (Galician Health Service) started a project 'towards an intelligent supply chain' in 2000. *"We wanted to achieve a supply chain with the minimum of paper handling. Two important tools in this project were the use of GS1 Standards for product identification and the use of Electronic Document Interchange"* said María José García Sexto, SERGAS. A review of the situation in 2006 showed that logistics was not the main priority at hospitals and that suppliers were not sufficiently involved in the implementation of standards.

"SERGAS will continue to use GS1 Standards as a tool to improve the Healthcare supply chain, and will ask suppliers to be more involved and try to increase the automation level in the supply chain", concluded María José García Sexto.

Turkish databank for pharmaceuticals and medical devices

The goal of the NDB, the Turkish databank for drugs and medical devices, is to create a common system to share data electronically between all relevant parties. All product data entries are submitted via the Internet by accredited users and then inspected and approved by the Turkish Ministry of Health. *"More than 2,400 companies are currently accredited, totalling approximately 590,000 registered medical devices, of which about 588,000 are inspected and approved"*, said Doruk Göksin from the TITUBB Project in Turkey. This represents a significant increase versus the previous update given at the GS1 Healthcare conference in October 2007.

The NDB is now also connected to the database of the Public Procurement Authority. Hospitals announce their tenders in this database and will also publish and upload the successful offer. These tender results will automatically be transferred to the NDB and, after calculating the item tender price, to the Social Insurance Association.

Korea expands the use of GS1 Standards in Healthcare

Korea's MOHW (Ministry of Health & Welfare) officially announced new regulations expanding the use of GS1 standards in Healthcare. Previously all drugs, except specific types of small drugs, were required to carry an EAN-13 bar code.

The new regulation includes the following requirements:

- all drugs, except specific types of small drugs, must have a GS1 bar code with a GTIN structure (effective January 15, 2008)
- all drugs, regardless of their size, must have a GS1 bar code encoded with a GTIN structure (effective January 1, 2010)
- all specified drugs (effective January 1, 2012) and ethical drugs (effective January 1, 2013) must have a GS1 DataMatrix or a GS1-128 linear bar code which also contains the expiry date and batch number

This significant achievement has been made through collaboration between MOHW, HIRA (Healthcare Insurance Review Agency) and GS1 Korea, as well as GS1 Healthcare.

The authorities expect that the expanded use of GS1 standards will increase patient safety and greatly improve supply chain efficiency.

ASSOCIATIONS AND STANDARDS ORGANISATIONS

Traceability of *in vitro* diagnostic products (IVD)

"The key value of a Unique Device Identification (UDI) system for IVD's should be to support traceability from the manufacturer to the patient and thus improve patient safety" said Andy Rutter, chairman of the UDI Task Force of EDMA (European Diagnostic Manufacturers Association). *"Benefits of such a system include reducing medical errors, improving the identification of devices in adverse events, facilitating field service corrective actions and the identification of counterfeit devices. It will also facilitate a more efficient management of purchasing and distribution."*

EDMA recognises that various regulatory authorities have been considering the possibility of regulatory requirements for UDI and emphasises that global harmonisation of such regulations is essential. Identification keys and data carriers should be standardised and EDMA considers GS1 Healthcare to provide a unique forum and opportunity to achieve this. Furthermore, EDMA advocates a stepwise approach based on the level or risk and an implementation of UDI at the level of finished products (and not on components).

www.edma-ivd.be

Generic medicines and automatic identification

"Global coding is a great enabler in the development of global business." according to René Kappers, chairman of the anti-counterfeiting HPA Group of EGA (European Generic medicines Association), *"Automatic identification is the important enabler for greater dynamics while increasing accuracy in the supply chain. Global coding and automatic identification strikes right in the strategic heart of the generics pharmaceutical industry: cost reduction!"*

The generics medicines industry is not only a cost driven industry with fierce competition, but also an increasingly international industry, with many true global companies that were not active internationally ten years ago.

www.egagenerics.com

Global coding and automatic identification strikes right in the strategic heart of the generics pharmaceutical industry: cost reduction!

COCIR, EDMA and Eucomed and the need for global standards

In a meeting with the European Commission, three industry associations: COCIR (the voice of the European Radiological, Electromedical and Healthcare IT Industry), Eucomed (the Voice of the Medical Technology Industry in Europe) and EDMA (European Diagnostic Manufacturers Association) advocated the need for global standards for unique device identification. They recommended that EU Member States should refrain from local regulations, which are not aligned with the global approach. The focus should also be on patient safety, which should make Healthcare providers fully engaged.

The following must also be considered when it comes to UDI:
- A risk-based approach is essential
- Flexibility is essential – some products can (currently) not be marked
- Device identifiers need to be assigned by the manufacturers
- Ownership of product data must with the manufacturer
- Solutions need to be technology agnostic

www.cocir.org, www.eucomed.org, www.edma-ivd.be

Bar coding guidelines for medical devices in Japan

The Ministry of Health in Japan (MHLW) will soon release revised bar code guidelines for medical devices. *"The revised draft guidelines are now fully harmonised with GS1 Standards. The use of GTIN's is recommended"* according to Shuichi Harayama, Chairman of the IT Committee of the JFMDA (Japanese Federation of Medical Devices Associations), *"The JFMDA continues to promote advanced IT infrastructure in Japan which is harmonised with GS1 Standards in partnership with GS1 Japan and the global GS1 community."*

The JFMDA started to promote standardisation in 1999 by issuing guidelines for standardised bar codes on medical devices together with the MHLW. A survey in 2006 indicated that more than 70% of medical devices in Japan were bar coded. More than 500,000 items are registered in MEDIS-DC, a Japanese language public data base, and about 85 million orders per year are processed through MD-Net, an ordering network of the Japanese medical device industry.

International Hospital Federation Reference Book

The 2007/2008 Reference Book of the International Hospital Federation (IHF) features a special report on "Global Standards and patient safety" including the following articles:
- The New Zealand Medication Safety Project (by Elizabeth Plant and Dr. Bruce Anderson)
- The UK Department of Health 'Coding for Success' (by Dr. Helen Lovell)
- Implementing barcode technology strategies to improve patient care at Brigham & Women's Hospital, Boston, US (by Thomas W. Cooley)
- The traceability project at Dijon University Hospital, France (by François Bisch)
- Enabling safer patient care: Automatic Identification Standards for pharmaceuticals and medical devices (by Ulrike Kreysa & Jan Denecker)
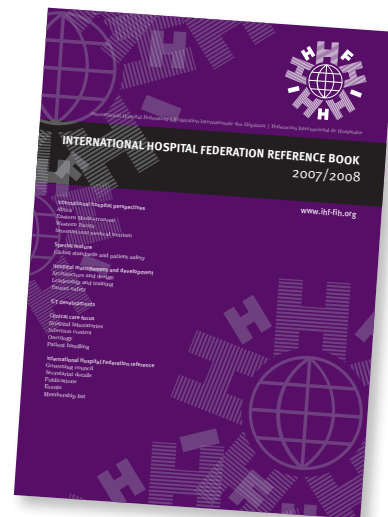
The complete Reference Book is available at www.ihf-fih.org/jsp/index.jsp?lnk=313
For the special report only, please refer to www.gs1.org/sectors/healthcare/docs/IHF_GS1_section.pdf

Support for GS1 Standards in Healthcare at HIMSS 2008

The benefits of adoption of GS1 Standards in Healthcare were the highlight at the Supply Chain Technology Symposium at HIMSS 2008 in Orlando (USA), presented in collaboration with AHRMM (Association for Healthcare Resource & Materials Management of the American Hospital Association). Jay Kirkpatrick, President-Elect of AHRMM and CEO of HCA Nashville Supply Chain Services, explained how AHRMM is partnering with Coalition for Healthcare eStandards (CHeS), the US Department of Defense (DoD) and GS1 Healthcare US, to inform and advise the Healthcare industry on the specific standards and how they will affect everyday transactions in Healthcare.

In the January/February 2008 issue of the AHRMM newsletter (Supply Chain Strategies & Solutions), Frank Fernandez (Baptist Healthcare, Miami, USA) states: "*Hospitals needs to get ready for the change that is coming, and there are many things you can do now to more quickly reap the benefits of synchronised, standardised data.*"

Ensuring compatibility between GS1 and ISBT 128 Standards

In September 2007, GS1 and ICCBBA signed a Memorandum of Understanding to join forces to advance global standards in Healthcare. ICCBBA was established by the International Society for Blood Transfusion in order to manage ISBT 128, a global information standard for blood transfusion.

A group is currently working on the labelling of blood cartons, containers and sets of pouches to ensure compatibility in the IT systems, managing stocks and traceability. Blood containers have ISBT 128 codes, while blood container cartons have GS1 labels. GS1 coding and ISBT 128 coding therefore need to be aligned (size of the lot number, expiry date).

Another activity concerns the delimitation between the two standards when blood products pass through a manufacturing process, to become a standardised trade (branded) product. An international meeting bringing together all stakeholders has been scheduled for June 20, 2008 in Toronto (Canada) to discuss requirements for labelling blood derivatives.

NEWS FROM AROUND THE WORLD

Data synchronisation in the Netherlands

"Thanks to the G-Standard every prescriber, be it a specialist or a general practitioner, every pharmacist, every wholesaler, every health insurer in the Netherlands, uses the same basic information for medical products." said Rick Dekker from KNMP (the Royal Dutch Association for the Advancement of Pharmacy). G-Standard is a source for process data: the G-Standard backbone contains the identifying characteristics of medicinal products, sufficient information for a pharmacist to place an order. The G-Standards also provides KNMP the opportunity to achieve a high level of medication surveillance.
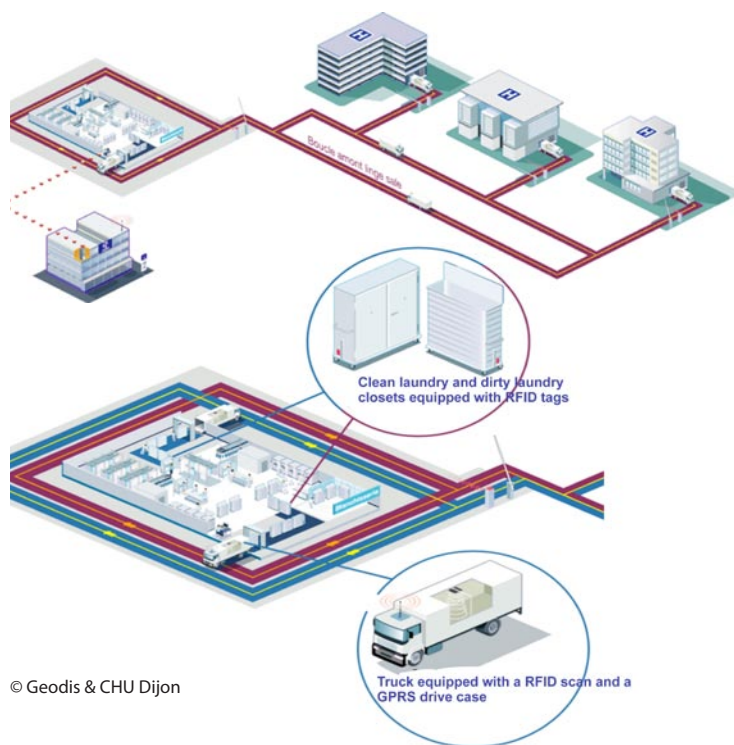
G-Standard is planning to connect to the Data Pool of GS1 Netherlands (GS1 DAS) which is part of the GS1 Global Data Synchronisation Network (GDSN).

GS1 Healthcare Conference at the Andalusian School of Public Health in Granada, Spain

Managing assets with RFID at CHU Dijon

The University hospital CHU Dijon (France) has implemented an RFID solution based on GS1 Standards to track and trace 500 laundry closets in their 15 sites. All laundry closets have RFID tags containing a GRAI (Global Returnable Asset Identifier). The vehicles transporting the laundry closets are equipped with an RFID reader and a GPS system. Also the laundry facilities have an RFID tag with a GLN (Global Location Number). Reading the tags of the closets and locations, combined with the GPS system, provide the position of the vehicle, allowing management of assets in real time: its position, its status, …

© Geodis & CHU Dijon

Clean laundry and dirty laundry closets equipped with RFID tags

Truck equipped with a RFID scan and a GPRS drive case

The Monash Pharmacy Project in Australia

Phase 1 of the Monash Pharmacy Project was an influential demonstration of electronic messaging using the GS1 System of standards in the hospital pharmaceutical supply chain. It successfully proved the application of the GS1 System of identification, bar coding and electronic messaging, in the areas of hospital pharmaceutical ordering, picking, packing, despatch and receipt of goods.

The benefits measured during Phase 1 included, a reduction in stock receipt time of 25% at the hospital pharmacy, a reduction of about 50% in inaccurate orders delivered to the pharmacy and an embracing of the new processes and technologies by staff. Phase 2 of the project furthered the Phase 1 concept, by broadening both the project team and the implementation scope, whilst focussing on ease of implementation and further roll out of the standards. Phase 2 could replicate the beneficial outcomes reported in Phase 1. Furthermore, scanning the Serial Shipping Container Codes (SSCCs) and matching these with the electronic Despatch Advice resulted in a quantitative reduction of 60% to 92% in time taken to receive stock into the Southern Health pharmacy system. Phase 3 is intended to further refine and improve the supply chain efficiency of those organisations involved.

For more information about the Monash Project, please contact Tania Snioch at tsnioch@gs1au.org
www.gs1au.org/industry/healthcare/monash.asp
www.gs1.org/sectors/healthcare/implementation/ecom.html

A quantitative reduction of 60% to 92% in time taken to receive stock into the Southern Health pharmacy system.

Pfizer's Pedigree & RFID Pilots

Pfizer initiated an RFID pilot programme at the end of 2005. The programme aimed at shipping RFID/EPC tagged Viagra, Pfizer's most frequently counterfeited product, and creating an authentication capability. The key objective was to learn more about mass serialisation at item, case and pallet level, about RFID technology and about the business processes requiring its use. All Viagra produced for sale in the USA, now contain an RFID/EPC tag, and have bar codes for back-up. A second RFID pilot with Celebrex was deployed in December 2007 (at case and pallet level).

Pfizer is committed to working with GS1 and GS1 EPCglobal towards a global standards based approach for mass serialisation for greater patient safety.

In another pilot, the first production pedigree was successfully sent to a major wholesaler in the USA in January 2008. A pedigree was provided at a serialised item-level, utilising the EPCglobal Pedigree Messaging Standard. Three more pilots are planned for the next few months.

"Pfizer is committed to working with GS1 and GS1 EPCglobal towards a global standards based approach for mass serialisation for greater patient safety." stated Tim Marsh, Pfizer.

Time savings of 86%

A study conducted with the Herzzentrum Bad Krozingen (Germany), a hospital specialising in the treatment of vascular diseases, has demonstrated significant cost savings after the implementation of GS1 bar codes. Before bar code scanning was introduced, three steps were necessary to register the consumption of material: documentation at the ward/operation room, recording in the materials management department and allocation in controlling. The last two steps could be eliminated with the introduction of bar code scanning. Accurate data was transmitted directly and the documentation took place in real-time. This achieved an 86% time saving through the use of GS1 bar codes! Furthermore, it enabled optimised inventory and accurately calculated DRG's (Diagnosis Related Groups). It also enabled traceability within the hospital as consumption and movement of the goods was automatically registered. The hospital invested €5,600 in hardware and software – payback was already realised in the first year!

Payback was already realised in the first year!

For more information about this study, please contact Michaela Hähn at haehn@gs1-germany.de

ROI of GS1 Standards for SME's in Healthcare

Before adopting GS1 Standards, a company must be able to project and measure their Return on Investment (ROI). A study conducted with a French SME (Small and Medium Sized Enterprises) in the Healthcare sector, has demonstrated that first, the necessary investment is quite moderate and second, it results in cost savings, a more efficient utilisation of capacity and an improvement in customer relations.

The company began implementing the GS1 System of Standards in 2004, by bar coding its products. The applications are in inventory management, traceability and order filling. Order picking, using bar codes instead of manual information reading, resulted in a 5% productivity gain. Using bar codes enabled a precise management of stored lots; inventory operations required fewer corrections and therefore less time. Better identification at every stage of packaging and improved order picking reliability has also practically eliminated disagreements with customers.

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

Turkish delegation of the Ministry of Health and the TITUBB Project in Granada

Visit to the HEFAGRA distribution center in Granada

GS1 HEALTHCARE

GS1 Healthcare formally approved

The GS1 EPCglobal HLS Industry Action Group and the GS1 global Healthcare User Group (GS1 HUG) agreed last year to join forces into one global Healthcare user group: "GS1 Healthcare". Both groups have now formally approved the GS1 Healthcare Governance Charter and funding model.

The Mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

The global standards development roadmaps have also been integrated and updated and there are now 3 main work streams: AIDC Application Standards, Traceability in Healthcare and Data Synchronisation & Product Classification.

Our new website can be found at: www.gs1.org/healthcare

We want this website to be your "go to" place when you are looking for information on GS1 Healthcare. We welcome your feedback and contribution.
Please contact us at healthcare@gs1.org

Mark Hoyle (Covidien) and Tim Marsh (Pfizer) Co-Chairs of GS1 Healthcare

The GS1 Healthcare Leadership Team has elected Mark Hoyle, Covidien and Tim Marsh, Pfizer, as its Co-Chairs. At the conference in Granada, Michel van der Heijden (President Healthcare & New Sectors, GS1 Global Office) thanked the previous co-chairs for their inspirational leadership over the last 2-3 years. For HLS: Ron Bone (McKesson), Ramesh Murthy (CVS) and Mike Rose (J&J) and for HUG: Rich Hollander (Pfizer) and Volker Zeinar (B.Braun).

Tim Marsh, Michel van der Heijden, Ulrike Kreysa and Mark Hoyle

Networking opportunities at the conference in Granada

Work team session at the conference in Granada

Plenary session at the conference in Granada

GS1 Healthcare
at other international events

Representatives of GS1 Healthcare will speak at the following international events in the next few months:

- 25-29 March 2008: 2nd International Patient Safety Congress, Antalya (Turkey)
  www.patientsafetycongress.net
- 16-18 April 2008: RFID Journal LIVE! Las Vegas (USA)
  www.rfidjournalevents.com/live
- 22-25 April 2008: LogiPharma Europe 2008, Geneva (Switzerland)
  www.wbresearch.com/logipharmaeurope/index.html
- 20-23 May 2008: HIMSS AsiaPac08, Hong Kong
  www.himssasiapac.org
- 4-6 June 2008: Global Forum on Pharmaceutical AntiCounterfeiting, Washington DC (USA)
  www.pharma-anticounterfeiting.info
- 1-2 July 2008: Securing the Pharma Supply Chain Conference, Amsterdam (the Netherlands)
  www.vibevents.com
- 1-2 July 2008: 3rd Pharmacological Anti-counterfeiting Conference, London (UK)
- 16-18 July 2008: Informa Medical Device Summer School, Fritzwilliam College,
  University of Cambridge (UK)

UPCOMING GS1 HEALTHCARE CONFERENCES

- **17-19 June 2008: Toronto, Canada**
  (Le Royal Meridien King Edward)
- **November 2008: Tokyo, Japan**
  (exact date and venue to be confirmed)
- **17 to 19 March 2009: Vienna, Austria** (Orthopädisches Spital Speising – Speising Orthopaedic Hospital)