Global GS1 Healthcare Conference
San Francisco, 1 – 3 October 2013

GS1 Standards in Action

Participants from around the world join the global GS1 Healthcare conferences to:

- **share** the latest news on industry and regulatory developments in automatic identification, traceability and electronic product catalogues
- **network** and benchmark with other stakeholders from around the world using this unique, neutral and global platform
- **learn** more about existing supply chain data standards

Supply chain excellence through global standards

The global GS1 Healthcare Conference brings together key strategists, actors and influencers to advance the development and adoption of global standards in the healthcare supply chain. Past conferences have proven significant value to be gained for participants from the full range of healthcare related organisations, from (inter-) governmental bodies and regulators, healthcare providers, pharmacists, manufacturers, distributors & wholesalers, logistics providers, industry associations, and the GS1 Member Organisations representing local communities.

Venue

HILTON SAN FRANCISCO FINANCIAL DISTRICT
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About GS1 Healthcare

GS1 Healthcare is a voluntary, global Healthcare User Group leading 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. For more information, visit www.gs1.org/healthcare.

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Final Agenda

Tuesday, 1 October 2013	
8:00	**Registration and welcome coffee**
8:30 – 12:30	**OPENING PLENARY SESSION** **Unique Device Identification (UDI)** *The FDA UDI Rule aims at establishing a single device identification system that is consistent, unambiguous, standardized and globally harmonized. At the same time, similar regulations are being developed in other parts of the world. The opening session of the conference provides an overview of the status quo around the world.* *The UDI regulation will not only be important for all of medical device manufacturers, as everyone will have to fulfil the requirements.*
8:30 – 8:50	**Welcome to conference, Bob Carpenter, GS1 US**
8:50 to 9:50	**Jay Crowley, US Food & Drug Administration (FDA)** *The UDI Rule - Details of the new requirements*
9:50 – 10:10	**Tomohiro Inoue, Japanese Ministry for Health, Welfare and Labour** *An update on the bar code guideline for medical devices in Japan*
10:10 – 10:15	**Laurent Selles, EU Commission / International Medical Device Regulators Forum IMDRF** *Status of UDI guidance at the IMDRF and the EU regulatory developments on UDI*
10:15 – 10:30	**Mark Wasmuth, CEO, GMDN Agency** *GMDN as substantial part of UDI – how to get and apply GMDN codes to Medical Devices*
10:30 – 10:35	**GS1 Member Organisations** *Introducing their poster*
10:35 – 11:00	**Coffee break and Poster Session of the GS1 Member Organisations** *Between 10:30 and 3:30 you have the opportunity to visit the exhibition on special projects, which have been realised by the GS1 Member Organisations and speak directly with the teams about their work and results.*
11:00 – 11:20	**Valentino Bulaon, Business Procurement Services, HealthShare**

	NSW, New South Wales Government, Australia *The experiences of NSW in using a product catalogue for procurement in their hospitals*
11:20 – 11:40	**Joe Pleasant , Premier** *The Benefits of UDI - The perspective of a major US GPO*
11:40 – 12:00	**Ron Bone, McKesson** *The Wholesaler's Point of View on UDI: Implementation, processes and benefits*
12:00 – 12:20	**Tom Werthwine, Johnson & Johnson** *How to implements UDI: Operational challenges of implementing the regulation in a global enterprise*
12:20 – 12:30	**Healthcare Provider Advisory Council (HPAC) Awards** *HPAC recognizes with two awards the best case study and special merits on the involvement and promotion of GS1 Healthcare standards*
12:30 – 12:35	**GS1 Member Organisations** *Introducing their poster*
12:35 – 1:30	**Lunch and Poster Session of the GS1 Member Organisations** *Visit the exhibition on special projects and speak directly with the teams about their work.*
1:30 – 3:00	**IMPLEMENTATION REALITY – Round 1** ***Two concurrent breakout sessions on how to implement UDI. The smaller groups allow for a more involved exchange between participants, speakers and moderators. Technical background, short presentations of case studies, panel discussions, step-by-step procedures and detailed discussions.*** **1. How to identify/mark my medical device products** **2. How to get ready to provide the requested data to the FDA Global UDI Database (GUDID)**
3:00 – 3:30	**Coffee break and Poster Session of the GS1 Member Organisations** *Visit the exhibition on special projects and speak directly with the teams about their work.*
3:30 – 5:00	**IMPLEMENTATION REALITY – Round 2** **Second round of the breakout sessions, switch of topics between**

	the groups: **1. How to identify/mark my medical device products** **2. How to get ready to provide the requested data to the FDA Global UDI Database (GUDID)**
5:00 – 7:00	**International Government Healthcare Supply Chain ThinkTank** *ON INVITATION ONLY* *Open to international government healthcare organization* *Discussions will be held under the Chatham House Rule*
Wednesday, 2 October 2013	
8:15 – 8:45	**Welcome coffee and Poster Session of the GS1 Member Organisations** *Between 8:15 and 5:00 you have the opportunity to visit the exhibition on special projects, which have been realised by the GS1 Member Organisations and speak directly with the teams about their work.*
8:45 – 12:10	**PLENARY SESSION – Traceability** *Traceability is today in the focus of many regulatory bodies and worldwide regulations and activities are evolving. This session discusses traceability and authentication, counterfeiting and the need to get the original product to the patient.*
8:45 – 9:05	**Connie Jung, Pharmacologist, US FDA** *Processes and measures to ensure drug security and integrity on federal level*
9:05 – 9:25	**Virginia Herold, California Board of Pharmacy** *The ePedigree regulation in California – an update on details and timelines*
9:25 – 9:45	**Dr. Hakkı Gürsöz; Vice President - Turkish Medicines and Medical Devices Agency** *How to Make Traceability a Reality* *Turkey already has full traceability in place for all refundable medication. An overview of implementation processes, challenges and milestones and benefits derived throughout the rollout.*
9:45 – 10:05	**Dra. Jésica Carino, ANMAT, Argentina** *The successful implementation of traceability in Argentina – learning's and stats – future plans*
10:05 – 10:20	**GS1 Member Organisations** *Introducing their poster*

10:20 – 10:50	**Coffee break and Poster Session of the GS1 Member Organisations**
10:50 – 11:10	**Benoit Goyens, World Customs Organisation WCO** *Crossing the border - IPM as a tool against counterfeiting* *An introduction to the activities of the global customs authorities*
11:10 – 11:40	**Grant Courtney, European Federation of Pharmaceutical Industries and Associations EFPIA** *ESM - The European Stakeholder model* *Pharmaceutical research manufacturers, wholesalers and pharmacies and parallel importers have developed a model to fulfill the requirements of the EU False Medicine Directive (FMD).*
11:40 – 12:00	**Brian Johnson, Pfizer** *RX360 - Major manufacturers and other stakeholders working together for drug integrity*
12:00 – 12:10	**GS1 Member Organisations** *Introducing their poster*
12:10 – 1:30	**Lunch and Poster Session of the GS1 Member Organisations** **or** **Working Lunches:** 1. **HPAC –** *Experience of hospitals in implementation* 2. **Public Policy** *– Regulatory requirements and initiatives around the world – normally a closed group it is open for this session*
1:30 – 3:00	**IMPLEMENTATION REALITY – Round 1** **Three concurrent breakout sessions on how to implement traceability regulations and best-practise examples from leading US hospital groups on implementation of standards. The smaller groups allow for a more involved exchange between participants, speakers and moderators. Technical background, short presentations of case studies, panel discussions, step-by-step procedures and detailed discussions.** **Participants can attend two of the three sessions.** 1. **How to fulfill the requirements in California? What does this mean for a manufacturer?** 2. **Traceability is central to requirements of regulatory bodies across the world. What are the different developments and**

	models across the world? How to implement, where to start? **3. The Healthcare Transformation Group (HTG) advises: How to start implementation of standards in hospitals? 5 majors US hospital groups on how to implement GS1 standards. Q&A opportunity for other providers on the various approaches and their challenges.**
3:00 – 3:30	**Coffee break and Poster Session of the GS1 Member Organisations**
3:30 – 5:00	**IMPLEMENTATION REALITY – Round 2** **Participants select a second topic from the breakout sessions:** • **How to fulfill the requirements in California?** • **Traceability is central to requirements of regulatory bodies across the world. What are the different developments and models across the world? How to implement, where to start?** • **The Healthcare Transformation Group (HTG) advises: How to start implementation of standards in hospitals?**
5:30	**Networking event: Alcatraz Island and Dinner Cruise** *Originally designated as a long-term detention facility in 1868, Alcatraz Island is a one-of-a-kind experience. Visit of the cell house, where infamous convicts such as Al Capone and George "Machine Gun" Kelly were housed. After the tour, dinner cruise with a stunning panoramic view of the San Francisco skyline.* ***Bring walking and dancing shoes!***

Thursday, 3 October 2013	
8:30 – 9:00	**Welcome coffee and Poster Session of the GS1 Member Organisations** *Between 8:30 and 1:00 you have the opportunity to visit the exhibition on special projects, which have been realised by the GS1 Member Organisations and speak directly with the teams about their work.*
9:00 – 10:00	**PLENARY SESSION – Hospital implementation** *A session for both suppliers and providers, to learn about hospital implementations from around the world*
9:00 – 9:40	**Dr. Joseph P. Drozda, Mercy Health** *UDI outcomes research at a hospital*
9:40 – 10:00	**Heidi Wimmers, Hospital Alemán, Buenos Aires, Argentina** *Traceability in Real Life: implementations in a hospital following regulations in Argentina*
10:00 – 10:20	***Akram Hossain & Mike Wallace, Abbott*** *A case study – using serialisation to improve laboratory operations.*
10:20 – 10:50	**Coffee break and Poster Session of the GS1 Member Organisations**
10:50 – 12:50	**CLOSING PLENARY – Patient safety worldwide**
10:50 – 11:10	**Dr. Erin Kennedy, United States Public Health Service , Centers for Disease Control and Prevention, Immunization Services Division** *Implementation pilot for 2D bar code for vaccine, overview and findings*
11:10 – 11:30	**Brian Lee, Merck, Co-Chair of World Health Organization WHO / Vaccines Presentation and Packaging Advisory Group VPPAG Bar code subgroup** *Barcoding for efficient handling in the vaccine supply chain in Tanzania – warehouse and inventory management, introduction of traceability*

11:30 – 12:30	**Keynote: Mark Neuenschwander** *On Bedside Scanning - An informative, funny, insightful, scary and entertaining attempt to change your mind about things – also on bedside scanning.*
12:30 – 12:35	**The next global GS1 Healthcare conference in Korea - invitation**
12:35 – 12:50	**Closing remarks – GS1 Healthcare Tri-chairs**
12:50	**Closing lunch**