

Programme

25th Global GS1 Healthcare Conference

1 - 3 April 2014 Seoul, South Korea





GS1 Celebrating 40 years, shaping a new future together

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Acknowledgements

This conference is hosted by:



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Tuesday 1 April 2014

Plenary on Unique Device Identification

General lunch or Working lunch (*)

Implementation reality

Think Tank (**)

Wednesday 2 April 2014

Plenary on Traceability

General lunch

Implementation reality

Networking event

Thursday 3 April 2014

Plenary on Hospital implementation

Closing plenary -Patient safety worldwide

Site visits (*)

(*) Upon registration

(**) On invitation only





Welcome

Global standards across the world

It is our pleasure to invite you to our **Global GS1 Healthcare Conference** in Seoul, South Korea for an exciting and enriching week. This edition is particularly special as it is our **25th Global Healthcare Conference!**

It all started in 2005 when healthcare industry leaders agreed to kick off a truly global initiative with the objective to develop global healthcare standards to improve patient safety and supply chain efficiency. Over the last years, GS1 Healthcare has built a solid foundation for global standards available to the healthcare sector and has continuously driven implementation of globally harmonised standards-based solutions for a more secure and efficient healthcare supply chain.

This conference promises a truly stimulating and diverse programme, with many international experts presenting the latest regulatory and industry developments in healthcare on UDI (Unique Device Identification), traceability and hospital implementations.

The three-day programme is packed with informative speaker sessions, implementation reality sessions and Public Policy sessions.

In addition to the wide variety of presentations, the conference will also provide you the possibility to network and benchmark with other stakeholders from around the world, please make good use of this opportunity.

At the end of the conference you will have the chance to **visit one of the local stakeholders' sites**, which have implemented GS1 standards in healthcare: Hanmi Pharm. Co., Ltd, TaeJeon Pharm Wholesale or Seoul National University Bundang Hospital.

Special thanks to **GS1 Korea** for hosting this conference, to **Hanmi**, **Coesia**, **Domino** and **KRPIA** (Korean Research-based Pharmaceutical Industry Association) for sponsoring the week.

Thank you for participating to the Global GS1 Healthcare Conference in Seoul. We hope you will have interesting, challenging and enlightening few days.

Ulnihe Klypa Ulrike Kreysa

Vice President Healthcare GS1 Global Office



Tuesday, 1 April 2014

From 7:30	Registration and welcome coffee		
8:00 – 9:30	PRIMER SESSION: Introduction to GS1 Healthcare – global standards across the world A starter session on GS1 standards in AIDC (Automatic Identification and Data Capture), eCommerce, GDSN (Global Data Synchronisation Network), Public Policy, Traceability. GRAND BALLROOM B&C Lower Lobby		
9:30 – 10:00	Welcome coffee	FOYER Lower Lobby	
10:00 – 12:15	OPENING PLENARY SESSION – Unique Device Id UDI aims at establishing a single device identification consistent, unambiguous, standardised and globall The U.S. FDA published its regulation in September time, similar regulations are being developed in oth The opening session of the conference provides an overview of the status around the world.	on system that is y harmonised. 2013, and at the same	
10:00 – 10:20	Welcome to Conference Ulrike Kreysa, Vice President Healthcare, GS1 Glob Kyung Jong Kim, President GS1 Korea	al Office	
10:20 – 10:30	Welcome and Introduction Korean Ministry of Health & Welfare		
10:30 – 11:10	The UDI Rule - Details of the new U.S. FDA rule Jay Crowley, VP UDI Practice, USDM, formerly US Fo Administration (FDA)	ood & Drug	
11:10 - 11:30	Mr. Yang Lianchun, Director of Division, CFDA, Chi	na	
11:30 – 11:55	The Australian supply chain reform agenda - No Mark Brommeyer, Supply Chain Manager, NEHTA,		
11:55 – 12:15	Harmonisation steps in medical device controls Joanna Koh, Chair, Technical Committee, Asian Harr		
12:15 – 14:00	or Working Lunch Public Policy – Medical Devices requirements and initiatives related to medical devi – normally a closed group - is open for this session focused on Pharmaceuticals takes place in the implementation reality session in the afternoon.).	ices around the world	

IMPLEMENTATION REALITY – Round 1

Three concurrent breakout sessions on how to implement UDI and the regulatory requirements and developments for pharmaceutical products across the world. 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.

Medical Devices: How to identify/mark my medical device products
 Chaired by Jackie Elkin (Medtronic)
 Panelists: Dennis Black (BD), Jithendra
 GRAND BALLROOM C

14:00 - 15:30

2 · Medical Devices: How to get ready to provide the requested data to the FDA Global UDI Database (GUDID)

Chaired by Mike Wallace (Abbott).

Panelists: Dan Wilkinson (1WorldSync), Rob Webb

(Cook Australia), Margot Drees (GHX), Mark Wasmuth (GMDN)

Nair (Cook Medical), Tom Werthwine (J&J).

GRAND BALLROOM B Lower Lobby

Lower Lobby

3 · Pharmaceuticals: Public Policy Session

Medical Devices, takes place earlier this day.)

Regulatory requirements and initiatives related to pharmaceuticals around the world – normally a closed group, it is open for this session

(a Public Policy working lunch, focused on CORAL ROOM

3rd Floor

15:30 - 16:00

Coffee break and MO poster session

FOYER Lower Lobby

IMPLEMENTATION REALITY - Round 2

Participants can select a second topic from the implementation reality session:

1 • Medical Devices: How to identify/mark my medical device products

Chaired by Jackie Elkin (Medtronic)

Papelists: Dennis Black (RD), lithondra Nair

GRAND BALLROOM C

16:00 - 17:30

Panelists: **Dennis Black** (BD), **Jithendra Nair** (Cook Medical), **Tom Werthwine** (J&J).

Lower Lobby

2 · Medical Devices: How to get ready to provide the requested data to the FDA Global UDI Database (GUDID)

Chaired by Mike Wallace (Abbott)

GRAND BALLROOM B

Lower Lobby

Panelists: **Dan Wilkinson** (1WorldSync), **Rob Webb** (Cook Australia),

Margot Drees (GHX), Mark Wasmuth (GMDN)

17:30 – 19:30 International Government Healthcare Supply Chain ThinkTank
ON INVITATION ONLY

Open to international government healthcare organisation

Discussions will be held under the Chatham House Rule

TOPAZ 3rd Floor



Wednesday, 2 April 2014

8:30 - 9:00	Welcome coffee and Poster Session		
9:00 – 12:10	PLENARY SESSION – Traceability Traceability is today in the focus of many regulator regulations, and activities are evolving. This session and authentication, counterfeiting and the need to the patient.	n discusses traceability	
9:00 – 9:20	U.S. federal regulation on track & trace Connie Jung, Pharmacologist, U.S. FDA		
9:20 – 9:35	APEC track & trace systems working group Connie Jung, Pharmacologist, U.S. FDA (on beha Regulatory Counsel, U.S. FDA)	f of Mark Paxton,	
9:35 – 10:00	Traceability for pharmaceuticals Prof. Saleh A. Bawazir, Vice President for Drug Affairs, Saudi Food and Drug Authority		
10:00 – 10:30	The European Stakeholder Model Grant Courtney, European Federation of Pharma Associations (EFPIA)	ceutical Industies and	
10:30 – 10:50	The eTact system Francois-Xavier Lery, EDQM, Council of Europe		
10:50 – 11:20	Coffee break and MO poster session	FOYER Lower Lobby	
11:20 – 11:45	Goun Lee, Deputy Director Division Office of Hea Ministry of Health & Welfare	lthcare Policy, Korean	
11:45 – 12:10	Traceability implementation use case in Korea Jonghoon Lim, Executive Director, Hanmi Pharm		
12:10 - 13:30	General Lunch	ORANGERIE 3 rd Floor	





IMPLEMENTATION REALITY - Round 1

Two concurrent breakout sessions on how to implement traceability regulations and best-practice 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-bystep procedures and detailed discussions.

Participants can chose from two sessions:

1. How to enable/implement traceability:

- Traceability and the GS1 the standards as base for it
- The different models for traceability across the world
- What does serialisation mean for a manufacturer
- Traceability everybody needs to be involved the wholesaler view
- Traceability pilot in the U.S. experiences and learnings
- Conclusions

Moderator: Grant Courtney (GSK)

Panelists: Peggy Staver (Pfizer), Lloyd Mager

(AbbVie), **Scott Mooney** (McKesson), **Christian Riediger** (Baver)

2. The Hong Kong Hospital Authorities and GS1 Hong Kong:

How to start implementation of standards in hospitals? How a large hospital group implements GS1 standards.

Q&A opportunity for other providers on the various GRAND BALLROOM B approaches and their challenges.

Lower Lobby

FOYER Lower Lobby

GRAND BALLROOM C

Lower Lobby

15:00 - 15:30 Coffee break and MO poster session

Participants select a second topic from the breakout sessions:

1 · How to enable/implement traceability

IMPLEMENTATION REALITY - Round 2

Moderator: Grant Courtney (GSK)

Panelists: **Heather Zenk** (AmeriSource Bergen). Margot Drees (GHX), Christian Riediger (Bayer)

GRAND BALLROOM C Lower Lobby

Lower Lobby

2. The Hong Kong Hospital Authorities and GS1 Hong Kong:

How to start implementation of standards in hospitals? How a large hospital group implements GS1 standards.

Q&A opportunity for other providers on the various GRAND BALLROOM B approaches and their challenges.

Networking event

Meeting at 18:00 at main lobby. Buses leave at 18:30 Don't forget your badge, you will need it to board the cruise.

13:30 - 15:00

15:30 - 17:00

18:30

Thursday, 3 April 2014

Titul Sudy,	3 April 2014		
8:30 - 9:00	Welcome coffee FOYER Lower Lobby		
09:00 – 10:15	PLENARY SESSION – Hospital implementation A session for both suppliers and providers, to learn about hospital implementations from around the world GRAND BALLROOM B&C Lower Lobby		
9:00 – 9:30	ICT Use Case for Patient Safety: SNUBH's Experience Dr. Kee-Hyuck Lee, Center for Medical Informatics, Seoul National University Bundang Hospital		
9:30 – 10:00	Level-below-the-each Prof. Su-Yu Chien, Director of the department of pharmacy, Changhua Christian Hospital, Taiwan		
10:00 – 10:15	Better Procurement, Better Value, Better Care – the NHS mandate for GS1 Chris Doyle, Healthcare Marketing Manager, GS1 UK		
10:15 – 10:45	Coffee break and Poster Session		
10:45 – 12:30	CLOSING PLENARY – Patient safety worldwide GRAND BALLROOM B&C Lower Lobby		
10:45 – 11:00	Healthcare Provider Advisory Council (HPAC) Awards • Recognition Award • Best Implementation Case Study Award		
11:00 – 11:30	Transforming the supply chain Ms S C Chiang, Senior Pharmacist, The Hong Kong Hospital Authority		
11:30 – 12:10	Roundtable with hospitals: How can standards support hospitals to improve patient's care		
12:10 – 12:20	The next global GS1 Healthcare conference in Scandinavia – invitation Lars Kyed, CEO, GS1 Denmark		
12:20 – 12:30	Closing remarks – GS1 Healthcare Tri-chairs		
From 12:35	Site Visits to: • Hanmi Pharm. Co., Ltd (manufacturer) • TaeJeon Pharm Wholesale Co., Ltd. (wholesaler) • Seoul National University BUNDANG Hospital (university hospital) Meeting Point hotel lobby from 12:30 Buses leave at 13:00 sharp The lunch boxes will be on board the bus for all the participants		



General Information

Conference venue

The Millenium Seoul Hilton Hotel 50, Sowol-Ro, Jung-Gu, Seoul, 100-802 South Korea





Internet access

Complimentary wireless internet access in the meeting rooms. For all the other areas of the hotel, internet will be charged KRW 22.000 (Approx. EUR 14,00) per 24 hours.

Dress code

Conference: business

Networking event: smart casual. Don't forget your badge, you will

need it to board the cruise

Meeting rooms

Plenary sessions: Grand Ballroom B & C (lower lobby)

Implementation reality: Grand Ballroom B, Grand Ballroom C and

Coral Room (lower lobby & 3rd floor)

PP working lunch: Grand Ballroom A (lower lobby) MO poster session: Registration Foyer (lower lobby)

Lunch: Orangerie (3rd Floor)

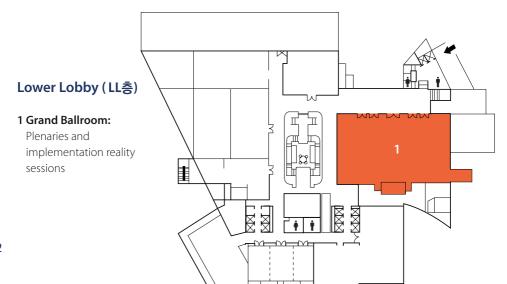








Floor plan



3rd floor (3층)

2 Orangerie:

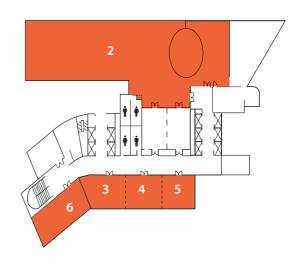
General lunch

3, 4, 5 Coral:

Public Policy implementation reality session, LT and HIG meetings

6 Topaz:

ThinkTank









Contact

Conference enquiries:

Agathe Daskalidès: +32 479.06.93.35 Kevin Lee: +82 10 428.402.15

Poster session

During the coffee and lunch breaks, we invite you to read out different case studies available on big poster boards in the Grand Ballroom Foyer. You will gain insight on recent and innovative cases implemented in several countries: Argentina, Australia, Ireland, and globally.

Networking dinner

At the conclusion of Wednesday's meetings, enjoy some networking time with your fellow attendees. **Don't forget your badge. You will need it to board the boat.**

Schedule:

18:00	Meeting point at hotel lobby
18:30	Hotel departure by bus
19:10	Board cruise boat + cocktail
20:00	Dinner with jazz band playing
21:30	Dock and disembark boat
22:15	Scheduled arrival time back at hote

Address:

290 Yeouido-dong, Yeongdeungpo-gu, Seoul

Sponsored by:









Explore Seoul

Seoul is the capital and largest metropolis of Korea. Home to over 10 million citizens, it is one of the largest cities in the world. Seoul is roughly divided into northern and southern halves by the Han river and is surrounded by vast mountains. This fast-paced and high tech city embraces both tradition and modernity, making it a very unique city.



Weather in April in Seoul

Seoul has a continental climate with dry winters and hot summers. April marks the start of the transition from the cold, dry winter to the summer rainy season with daily highs increasing from 13°C to 20°C over the course of the month, and daily low temperatures ranging from 2°C to 9°C.

Places to visit and things to do in Seoul

Gyeongbok Palace

This former seat of power is probably Korea's most famous royal palace. It was built in the late 1300s, and has been destroyed and reconstructed numerous times. It served as the main palace of the Joseon Dynasty.

1-1 Sejongno, Jongno-gu, Seoul



Insadong

Nowhere exudes more local and traditional charm than Insadong. With its wooden tea houses, boutique galleries and street vendors selling traditional snacks, a stroll through Insadong is mandatory for all visitors

Insa-dong, Jongno-gu, Seoul



N Seoul Tower

N Seoul Tower was built as Korea's first integrated transmission tower. Since opening to the public in 1980, it has become a much-loved Seoul landmark. It's mountain surroundings on Namsan (Mt.) have made it a popular place to unwind for locals and tourists alike. 1-3 Yongsandong 2(i)-ga, Yongsan-gu, Seoul





Changdeok palace

It is also known as Donggwol, the Eastern Palace, because of its location to the east of Gyeongbok palace. Compared to other palaces, it is well-preserved and still has many of its original features. In 1997, it was added to the UNESCO World Heritage List. 2-71 Waryong-dong, Jongno-gu, Seoul



Myeong-dong

Myeong-dong is Seoul's shopping mecca and is a must-see for tourists. For shoppers there is a mixture of street stalls and retail outlets selling everything from high fashion to casual attire as well as many Korean cosmetics stores offering high-quality products at competitive prices. 31-1, Myeong-dong 2(i)-ga, Jung-gu, Seoul

Cheonggye Stream

you want to break free from the hectic city, take a strowl along this 5.8-km (3.6-mile) stream, located more than 15 ft. (4.6 m) below street level. It's very serene with small waterfalls, and nearly two dozen overhead bridges.

Cheonggyecheon-ro, Dongdaemun-gu, Seoul, Korea



Places to eat

Hotel restaurants

- Cilantro: Buffet counter with the finest rotisserie, sizzling steaks and succulent seafood, or choose Mediterranean meals from the à la carte menu. Piano entertainment from 6pm to 9pm every night. Open Monday-Sunday 6:00 am - 10:30 pm
- Genji: Savor a Japanese meal in intimate teppanyaki sections or enjoy views across the expansive Millennium Seoul Hilton hotel gardens. This restaurant is decorated in warm tones and wood with a light and airy ambience. Open Monday-Sunday 11:30 am - 10:00 pm
- Il Ponte: Savour authentic Italian cuisine in contemporary surroundings that ooze continental chic. Open Monday- Saturday 11:30 am - 10:30 pm
- Orangerie: Choose from the noodle bar or sushi counter at this informal restaurant which also served an array of international cuisine. Open Monday-Sunday 11:30 am - 10:00 pm



- Seasons: Chandeliers adorn the ceiling at this light and contemporary restaurant. Pick from the à la carte French menu for a formal meal accompanied with a French house wine. Open Monday-Sunday 11:30 am - 10:30 pm
- Taipan: Taste classic Cantonese cuisine in elegant surroundings. Contrasting black and gold upholstery compliments the chandeliers and Oriental wall hangings. Open Monday – Sunday 11:30 am - 10:30 pm

Close by the hotel

- JinJinbara: Located less than 300m from the hotel, JinJinbara is a representative Korean cuisine brand, which is largely based on Korean royal court cuisine and serves 17 to 22 different coursetype meals. Lunch: 11:30~15:00 / Dinner: 17:30~22:00. 12 Dongja-dong, Yongsan-qu, Seoul - http://www.jinjinbara.com/
- Korea House: Korea House was built in the typical style of an upper-class house from the Joseon Dynasty and offers international visitors an excellent introduction to traditional Korean culture and lifestyle. There is also the chance to sample a Hanjeongsik (Korean table d'hôte) offering a selection of rare royal cuisine of the highest quality. Lunch: 12:00~14:00 / Dinner: 17:00~18:30, 19:00~20:30. 80-2, pildong 2 (i)-ga, Jung-gu, Seoul - www.koreahouse.or.kr
- Myeongdong Gyoja: The restaurant is a noodle restaurant located near Myeongdong Cathedral that has been in business for about 40 years. The restaurant is known for their knife-cut, handmade kalguksu noodles, which is its main menu item. Monday-Sun 10:30-21:30. 25-2 Myeongdong 2(i)-ga, Jung-gu, Seoul - http://www.mdkj.co.kr/en/
- · Naos Nova: Located 270m from hotel, this modern French cuisine with Asian ingredients will treat your pallet. Experience a truly unique experience: the architecture, ambience, nosh and almost endless wine list make it the place to be after the sun sets on the city. Open from noon -1 am. 448-120 Huam-dong Youngsan-gu Seoul - www.naosnova.com

Cafes & Bars at the hotel

- Palm Court: Located in main lobby. Relax with a cup of coffee or tea as natural light floods in through the floor-to-ceiling windows at this lounge. Indulge with a favorite pastry, or enjoy a drink and light bite. Mon-Sun 8:00-11:30.
- Oak Room: Order a cool drink from the elegant English-style bar overlooking the scenic hotel gardens. Mon-Fri 11:30 - 2:00, Sat-Sun 17:00 - 2:00; wine buffet 18:00 - 20:30; bar 15:00 - 02:00





Useful information

Time zone: Seoul is located in the KST (Korea Standard Time) - GMT+9

Electricity: The standard electricity supply is 220-volts AC/60 cycles. Although Korea uses both the 110 and 220-volts systems, the use of 220-volts system is more widespread and common. The Hilton Millenium's supply is 220V.

Telephone: Country access code for Korea is: +82, Area code of Seoul: 02

Language: Korean

Currency: The currency of Korea is wons (KRW). 1000 KRW ± \$0.93 ± 0.68€

Notes come in 50.000 – 10.000 – 5.000 -1.000 and coins come in 5 cents – 100 cents – 500 cents and 10 wons. The most common means of payment is cash. Most stores and restaurants also accept credit cards (Visa, Mastercard, American Express…)

Tipping: Tipping is not required nor expected in Korea. But most major hotels add a compulsory 10% service charge to bills. This is on top of the 10% VAT (which is usually included in prices at most stores in Korea, but not in some high-end restaurants).

Smoking: Smoking is less and less tolerated in Seoul. Smoking is currently forbidden in parks, plazas within a 50-meter radius of schools (Seoul), all main shops and restaurants/cafés, and most public buildings.

Internet: Korea is the most wired country in the world. The city offers many free public wifi zones (The government's aim is to offer 10,000 free public wifi zones by 2015). For more information, connect to: http://speed.nia.or.kr/publicWifiFree/publicWifiFree.asp

Basic Korean Phrases:

Hello	.안녕하세요	an·nyeong·ha·se·yo
Thank you	.감사합니다	. gam·sa·hab·ni·da
I'm Sorry	.죄송합니다	choé·song·hab·ni·da
Excuse me	.실례합니다	. shil·le·hab·ni·da
Yes./No	.네./아니요	ne/ a·ni·yo
How much is it?	.얼마예요?	. ol·ma·ye·yo
It's okay	.괜찮아요	gwaen·chan·ah·yo
I don't know	.몰라요	mol·la·yo
I'm lost	.길 잃었어요	gil·yi·russ·o·yo
My name is	.제 이름은 입니다	. che yi·reun·eun im·ni·c



Conference speakers



Prof. Saleh A. Bawazir, Saudi Food and Drug Administration
Prof. Saleh A. Bawazir, Vice President for Drug Affairs
Saudi Food and Drug Authority, obtained his PhD from the University
of Wales Cardiff, U.K. and works as professor of clinical pharmacy in the
College of Pharmacy, King Saud University Riyadh, Saudi Arabia and
as Vice President for Saudi Food and Drug Authority (SFDA) for drugs.
Beside his work in the college of Pharmacy, Prof. Bawazir worked as
an advisor to the Ministery of Health, the Executive Office for Health
Ministers in the GCC States, Riyadh, Saudi Arabia.



Dennis Black, BD, United States

Dennis is currently Director, e-Business for BD. With more than 20 years of healthcare industry experience, Dennis has responsibilities related to achieving the "Perfect Order", leading operational effectiveness initiatives, and other e-Business processes. Dennis is on the GS1 Healthcare U.S. Leadership Team and the GS1 Healthcare Global Leadership Team. He participates in work groups within SMI, AdvaMed and MDSCC and other organisations that are focused on improving the healthcare supply chain. Dennis is involved in a number of pilot and implementation activities to enable BD and healthcare providers to achieve operational efficiencies.



Mark Brommeyer, National E-Health Transition Authority (Nehta), Australia

Mark leads the Supply Chain Reform Programme at NEHTA, incorporating the National Product Catalogue (NPC), the eProcurement solution and purchasing reform. Having spent 30 years in the health sector, he has provided consultancy, project and change management services in public and private health sectors in Australia, New Zealand, Malaysia, China, England and Wales.

Mark is a Registered Nurse and has obtained a Bachelor of Applied Science in Nursing, a Graduate Diploma in Adult Learning and a Master's of Educational Administration (Open Learning).









Miss Chiang started her engagement in the pharmacy informatics by being the pioneer to develop the first Dispensing and Labelling System that was subsequently used in all the pharmacies in the public sector. Ms Chiang was also the first to introduce dispensing automation technologies into the pharmacies in the early 1990s. Ms Chiang obtained her Bachelor of Pharmacy from the University of Bradford, England and obtained her Master Degree in Health Administration from the University of New South Wales, Australia.



Su-Yu Chien, Changhua Christian Hospital, Taiwan

Ms Chien has been Director of the department of Pharmacy at the Changhua Christian Hospital in Taiwan since 1985. In parallel, she is also a clinical professor at the school of pharmacy at Kaohsiung Medical University, President of the Taiwan Healthcare Automation Association, Honorary President of the Taiwan Society of Health-System Pharmacists, and Investigator for the Joint Commission on Hospital Accreditation at the Department of Health.

Ms Chien holds a BS in Pharmacy from the Kaohsiung Medical University in Taiwan and a MS in Pharmacy Administration from the University of Illinois, U.S.



Grant Courtney, GlaxoSmithKline, U.K.

Grant Courtney, Supply Chain Integrity Strategy Lead at GlaxoSmithKline, is recognised for his extensive experience in product security, coding & serialisation, product development and supply chain solutions in the pharmaceutical industry, having spent the past 19 years working in these areas.

Grant has been an active member of EFPIA for several years advising on both manufacturing and supply chain related issues; most recently as a member of the Serialisation and Coding Steering Team. In addition, Grant is a member of the GS1 Global Healthcare Leadership Team, establishing standards for product coding and serialisation. Grant obtained a Business degree at the University of Hertfordshire Business School.







Jay Crowley, USDM, U.S.

Jay Crowley is currently Vice President, UDI Practice at USDM, a leading global professional services firm focused exclusively on providing business process, technology and compliance solutions for the regulated life science industry. Prior to joining the firm in January 2014, Crowley was Senior Advisor for Patient Safety, in FDA's Center for Devices and Radiological Health. He held a variety of positions over his nearly 27 years at FDA. Jay had primary responsibility for the development and implementation of FDA's Unique Device Identification System requirements of the 2007 FDA Amendments Act and 2012 FDA Safety and Innovation Act.



Margot Drees, Executive Director Global Strategy, GHX

As Executive Director, Global Strategy at GHX, Margot Drees leads strategy for an organisation that brings together healthcare providers, manufacturers, distributors and group purchasing organizations in a collaborative and connected community to improve efficiencies, visibility and accuracy in the healthcare supply chain. In her current role, Margot is additionally responsible for development of an industry model in support of track and trace and epedigree. Drees joined GHX in 2005 with more than 15 years of experience in product management and marketing for healthcare and hightech companies, including the Micromedex division of Thomson Healthcare Publishing. She received a BA in International Affairs from the University of Colorado, Boulder and an MS in Communication from the University of Denver.



Jackie Rae Elkin, Medtronic, U.S.

Jackie has been working in the medical device sector for more than 27 years and currently holds the position of Global Process Owner of Standard Product Identification for Medtronic, Inc. Global Regulatory Affairs.

Jackie has co-chaired the AdvaMed Auto-Identification Committee since 2006, providing guidance on product identification standards related to the FDA's Unique Device Identification (UDI) legislation. She has also provided advisory role in many other initiatives involving UDI legislation in both the United States and around the world, including the International Medical Device Regulators Forum (IMDRF).

Jackie is one of the founding members of GS1 Global Healthcare and has maintained a leadership role in the organisation since its inception in 2005. Jackie also chairs the GS1 Global Healthcare Public Policy work group for the medical device sector.







Dr. Lee Kee-Hyuck, Seoul National University Bundang, South Korea

Dr. Lee is a professor of the Department of Family Medicine and Medical information center in Seoul National University Bundang Hospital (SNUBH). He completed his residency at the Department of Family Medicine of Seoul National University Hospital, and his fellowship at the Department of Family Medicine of SNUBH. He has previously received an MBA degree in Medical Management from Kyunghee University. His areas of expertise include medical informatics and technology, and he has played a major role in developing the novel hospital information system that is currently used in SNUBH. He also strives to promote good health through his sessions in the outpatient clinics of the Department of Family Medicine.



Joanna Koh, Asian Harmonisation Working Party, SingaporeAs Director of the Compliance Branch for the Health Product

Regulation Group (HPRG), at the Health Science Authority (HSA), Singapore, Mrs. Joanna Koh is in charge of the set up and the operations of the branch.

Joanna is also co-chair of the Medical Device Working Group, ASEAN Consultative Committee for Standards and Quality (ACCSQ-MDPWG) as well as a member of the International Medical Device Regulators Forum (IMDRF) UDI Workgroup and the Global Medical Device Nomenclature (GMDN) Policy Advisory Group (PAG). Prior to her current position, Joanna was the General Manager of NHC Health Resources, a subsidiary of NTUC Healthcare Co-operation, a retail chain pharmacy group.



François-Xavier Lery, EDQM, France

Dr Francois-Xavier Lery is responsible for anti-counterfeiting projects such as eTACT (EDQM anti-counterfeiting traceability service for medicines). Since June 2012 he has been Head of Section for Pharmaceutical Care, Consumer Health Protection and Anti-Counterfeiting within the Department for Biological Standardisation, OMCL (Official Control Laboratories Of Medicines) Network and HealthCare (DBO). He joined EDQM in 2001 as a scientific officer dealing with Certificates of suitability. Prior to joining EDQM, he has worked at the French Health Products Safety Agency as a pharmaceutical assessor for chemical products (1999-2000). Dr Lery obtained his degree in Pharmacy and his PhD from the University of Paris.







Yang Lianchun, Chinese Food & Drug Administration, China Mr. Yang Lianchun, Director of Division II of the Department of Medical Device Registration, China Food and Drug Administration, is also the chair of STG – Nomenclature - (Special Task Group) of AHWP (Asian Harmonisation Working Party). He also served as an Associate Chief Pharmacist at the General Hospital of Air Force, and as Chief Pharmacist at the Certification Center for Drugs of the former State Food and Drug Administration of China. He obtained his Master's degree of Science in West China University of Medical Science in 1990.



Jonghoon Lim, Hanmi Pharmaceutical Co. Ltd, South Korea Jonghoon Lim is an executive director of Hanmi Pharmaceuticals and responsible for the information-processing operation and serialisation compliance in the company. He is managing information technology and integrated systems to increase information usability. He is also involved in applying GS1 global standard for the compliance with serialisation in the company. He started his professional career at Hanmi Medicare, an affiliate of Hanmi Pharmaceuticals, after receiving bachelor's degree in the US. After several years, he received MBA degree in USC Marshall School of Business and came back to Korea to resume his career at Hanmi Pharmaceuticals.



Jithendra Nair, Cook Medical, Australia

Jithendra Nair is Director of Information Technology at Cook Medical for the Asia Pacific region.

He is responsible for the strategic direction and implementation of IT services in the APAC region to complement Cook's customer needs to reduce healthcare costs by implementing efficient processes and working in partnership with internal and external stakeholders. Jithendra is a Post Graduate in Computer Science and holds an MBA from Griffith University, Gold Coast, Australia and is a Professional Member of the Australian Computer Society





John Michael (Mike) Wallace, Abbott, U.S.

As Director, Global Standards & Serialisation, Mr. Wallace's role is to implement the adoption of GS1 global product and customer identification standards and an enterprise approach to serialisation for Abbott. This will allow the corporation to cost effectively meet the growing and evolving customer and regulatory requirements. Mr. Wallace represents Abbott on the GS1 Global Healthcare Leadership Team and is currently serving as a tri-chair. For the past ten years, he has consulted with a cross section of groups across Abbott and the supply chain for healthcare and consumer packaged goods to prepare to implement these emerging standards and technologies. Mr. Wallace holds a BA in biochemistry and a MS in chemical engineering from the University of Virginia.



Mark Wasmuth, GMDN, UK

Mark is a Chartered Engineer and Member of IET. Has been at the GMDN Agency since the start of 2010 and is now the CEO. This follows 15 years at the British Standards Institution responsible for Technical Help to Exporters and then International Projects. Before that he was a Senior Engineer with Instron Materials Testing and Molins PLC.



Robert Webb, Cook Medical, Australia

Rob Webb is the director of healthcare business solutions for Asia Pacific at Cook Medical. Responsibilities include working with healthcare systems, distribution channel partners, group purchasing organisations and hospital supply chain executives to identify new ways to streamline and enhance the supply chain process and reduce health care costs. His tenure with Cook spans nine years, beginning as a business development manager in Australia. He was also Cook Medical Korea's general manager.

Rob has extensive experience in the medical sales and marketing industry, and served as a senior manager in a variety of areas for Glaxo SmithKline. Rob received his MBA from Southern Cross University in New South Wales, and is a Fellow of the Australian Institute of Management.









Tom Werthwine, Johnson & Johnson, U.S.

Tom Werthwine has been employed by Johnson & Johnson for 33 years. The majority of his time has been focused on the development, marketing, and supply chain delivery of medical devices to acute care settings. Tom has been a member of the GS1 Global Healthcare leadership team since its inception. He has also co-chaired the ADVAMED working group on Unique Device Identification and is a member of the MEDTECH UDI and Supply Chain Task Force. Tom also serves as a member of the GMDN Agency Policy Advisory Group.



Dan Wilkinson, 1WorldSync, U.S.

As Chief Commercial Officer, Dan is responsible for ensuring that 1WorldSync's clients derive maximum value from its services and solutions. Dan brings over 20 years of strategic business development and general management experience to 1WorldSync. He was previously senior vice president, Marketing & Commercial Operations at 1SYNC, 1WorldSync's predecessor. He has a deep knowledge of product data management and supply chain processes, and served as vice president, GS1 US Foodservice, before moving over to 1SYNC. Dan began his career at General Dynamics in 1986, and honed his strategic sales and management talents with senior positions at companies like Nortel Networks and Juniper Networks. Dan holds a BS in Marketing from Villanova University.





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