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MEDIA RELEASE

GS1 Singapore Organises Inaugural Healthcare Forum on Patient Safety and Healthcare Quality

2 September 2014 – The need to raise the bar on healthcare quality has never become more critical than in recent times. According to a report by McKinsey & Company, the estimated annual incidence of 50-100 million medication errors has led to 10-35 million preventable adverse drug effects and USD \$18-115 billion in associated potential healthcare costs globally. Healthcare professionals are thus focusing their attention on using global standards in the industry to provide better solutions to reduce medical risks in a cost-effective manner.

The discussion on Unique Device Identifier (UDI) was one of the highlights at the GS1 Healthcare Forum held at Singapore Manufacturing Federation (SMF), organised by GS1 Singapore, which is a Centre of Excellence under SMF and the key resource centre in Singapore for helping companies to implement UDI.

GS1 Singapore leads the implementation of UDI

With GS1 United States being one of the accredited agencies by the United States Food and Drug Administration (USFDA) to issue UDIs to most medical devices distributed in the USA, GS1 Singapore believes that a single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

Hence, the GS1 Healthcare Forum was aimed at providing a good platform for participants to acquire understanding on the importance of global standards. During the forum, participants also gained knowledge on UDI and understood how its use can improve patient safety and healthcare business processes.

The forum featured a strong line-up of speakers and panellists on relevant topics. Ms. Ulrike Kreysa, Vice President, Healthcare, GS1 Global Office in Brussels, was the Keynote Speaker. She gave a detailed presentation on UDI, its benefits and its implications for stakeholders. She also shared with the participants the experience so far in the UDI implementation. Through her presentation, participants learnt about the advantages of achieving a global UDI system for global traceability and post market surveillance.

"UDI will transform the world of Medical Devices significantly and improve patient safety beyond borders as well as increase the efficiency and safety of the Healthcare supply chain. It is vital that all countries worldwide introduce a harmonized identification system for medical devices and allow interoperability of their related UDI databases. I am confident that Singapore will follow the global recommendations of the International Device Regulatory Forum and derive the benefits from the implementation of UDI for their patients," she said.

With the recent debate on spiraling healthcare costs, this forum was a timely event during which discussions were held on how implementation of UDI could help to reduce medical risks as a cost-effective solution.

"Healthcare costs are rising and are expected to grow faster than national income in most countries, including Singapore in the foreseeable future. Stemming this growth has become a major policy priority and healthcare suppliers and providers alike, are exploring ways to control costs. One area of better controlling healthcare costs is in efficiently managing the healthcare supply chain. Better visibility of inventory across nodes of the supply chain and transparency on inventory expiry dates will reduce inventory and obsolescence cost. Integrating data and using global standards across the healthcare supply chain will help reduce transaction and processing costs. It will also reduce manual data capture, double checking, and relabeling while increasing the accuracy of these processes," concluded Mr. Liew Wai Leong, Chief Executive Officer of GS1 Singapore.

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About Singapore Manufacturing Federation (SMF)

Established since 1932, SMF represents the interests of the Singapore manufacturing community, driving its competitiveness and sustainable growth through serving industry-specific needs. Supported by 10 industry groups and six Centres of Excellence, including GS1 Singapore, SMF enhances the competitiveness of the industry by encouraging capacity development and capability building, and innovation-led productivity. It provides opportunities for companies to collaborate, network and to grow and expand both locally and internationally. Current membership stands at more than 3,000 corporate members ranging from SMEs to MNCs. For more information, please visit <u>www.smfederation.org.sg</u>

About GS1 Singapore

GS1 Singapore Limited is part of the international, neutral, not-for-profit GS1 organisation based in Brussels, Belgium, with 111 member organisations worldwide. GS1 Singapore was established in 1987 to implement and administer the global multi-industry GS1 standards-based system of automatic identification and communication for products, services, assets and locations.

GS1 Singapore facilitates collaboration amongst trading partners, organisations and technology providers, in order to solve business challenges that leverage standards and to ensure visibility along the entire supply chain.

GS1 develops the most widely used supply chain standards system in the world serving close to two million companies doing business across 150 countries in multiple sectors and industries.

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Annex A

UDI: Transforming the Healthcare Industry

Unique Device Identifier, or UDI, is a new revolutionary development in the healthcare industry. Under the rule by the United States Food and Drug Administration (USFDA), most medical devices distributed in the USA are required to carry UDI in automatic readable format. Both the USA and Europe have participated with other regional authorities to develop harmonised guidance for global UDI implementation in the International Medical Device Regulatory Forum (IMDRF). By 2018, all medical devices sold in the USA will be required to have a unique identifier. As such, UDI is something that the industry should not overlook as also other regulatory bodies work on UDI regulation.

It is only relatively recently that the potential benefits of UDI have become apparent. Each UDI will contain important information on the device, such as a unique product number and expiry date, so as to improve the quality of information in medical device adverse event reports. This will in turn help suppliers and the authorities to identify product problems more quickly, target recalls and improve patient safety. In addition to more efficient traceability of devices and recalls, UDI specificity also better counteracts counterfeiting and elevates patient safety. As such, UDI could potentially help to reduce medical costs.



Above is a fictitious example of what a unique device identifier (UDI) would look like on a medical device label. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, bar code, and details about the item.

A UDI consists of two parts:

- a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
 - the lot or batch number within which a device was manufactured;
 - the serial number of a specific device;
 - the expiration date of a specific device;
 - the date a specific device was manufactured;
 - the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Benefits of Unique Device Identification

When fully implemented, the UDI system can:

- Allow more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhance analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust post-market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Lead to the development of a medical device identification system that is recognized around the world.

Annex B

Event Day Programme

2 SEPTEMBER 2014 – AM			
08:30	Registration		
09:00	Welcome & Opening Address by Mr. Liew Wai Leong CEO, GS1 Singapore		
09:05	Keynote Presentation - Improving Patient Safety and Healthcare Efficiency by Implementing Unique Device Identification (UDI) <i>Ms. Ulrike Kreysa, Vice President, Healthcare, GS1 Global Office</i>		
09:30	Presentation – Managing Growth and Improving Efficiency across the Healthcare Value Chain <i>Mr. Harsh Babarkar, Director, Regional Operations Development ASEAN & Ethicon</i> <i>Surgical Care Asia Pacific, Johnson & Johnson Medical Asia Pacific</i>		
09:55	Networking Tea Break		
10.15	Presentation – Understanding Unique Device Identification (UDI) <i>Ms. Ulrike Kreysa, Vice President, Healthcare, GS1 Global Office</i>		
10:40	Case Studies Sharing – A Possible Roadmap to Adoption Mr. Teng Chun Chong, Regional Sales Director – APAC, Cortex a subsidiary of CODE		
11:00	Panel Discussion – Transforming the Healthcare Supply Chain to Improve Patient Safety & Increase Productivity Ulrike Kreysa, Vice President, Healthcare, GS1 Global Office Harsh Babarkar, Director, Regional Operations Development ASEAN & Ethicon Surgical Care Asia Pacific, Johnson & Johnson Medical Asia Pacific Teng Chun Chong, Regional Sales Director – APAC, Cortex a subsidiary of CODE Dr. Stuart Koe, Managing Director, ICM Pharma Pte Ltd Mr. Kwan Fook Weng, Member of Biomedical Standards Committee (BMSC), SMF- Standards Development Organisation		
12:15	Networking Lunch – Forum ends at 1.30pm		

Annex C

INFORMATION ON SPEAKERS

Keynote Speaker



Ms. Ulrike Kreysa Vice-President, Healthcare GS1 Global Office Brussels, Belgium

Ulrike Kreysa is responsible for the Healthcare sector at the GS1 Global Office in Brussels and works with her local colleagues in 111 countries across the world to develop and implement GS1 standards in the healthcare industry.

Having started her career as a Pharmacist she manages GS1 Healthcare, the global GS1 user group, formed by the stakeholders in the healthcare supply chain, including pharmaceutical and medical device manufacturer, wholesaler/distributor, group purchasing organizations, hospitals, pharmacies, logistic providers, governmental and regulatory bodies and associations.

Guest Speakers



Mr. Harsh Babarkar, Director, Regional Operations Development ASEAN & Ethicon Surgical Care Asia Pacific, Johnson & Johnson Medical Asia Pacific

Harsh is working as Director for Supply Chain in Johnson & Johnson. He is looking after the supply chain for Singapore market and strategic projects in South East Asia region. He brings with him the experience of various supply chain functions in planning, sourcing, manufacturing, and distribution in FMCG, Engineering, Pharmaceuticals and Healthcare industry.

He has done Masters in Business Administration with specialization in Supply Chain Management and Bachelors in Mechanical Engineering. He is certified in six sigma process excellence black belt.

Prior to joining J&J, he has worked with Saint-Gobain India and Mattel Toys.



Mr. Teng Chun Chong Regional Sales Director – APAC Cortex a subsidiary of CODE

Mr. Teng Chun Chong is the Regional Sales Director of Code Corp, manufacturer of advance barcode reader. For more than 12 years in the IDC industry, he focused on processes and work-flow within the vertical markets such as Retails, Transportation & Logistic Manufacturing & Healthcare.

Panellists

Ms. Ulrike Kreya	Vice President, Healthcare	GS1 Global Office
Mr. Harsh Babarkar	Director, Regional Operations	Johnson & Johnson Medical
	Development ASEAN &	Asia Pacific
	Ethicon Surgical Care Asia	
	Pacific	
Mr. Teng Chun Chong	Regional Sales Director – APAC	Cortex a subsidiary of CODE
Dr. Stuart Koe	Managing Director	ICM Pharma Pte Ltd
Mr. Kwan Fook Weng	Member of Biomedical	SMF-Standards Development
	Standards Committee (BMSC)	Organisation