
GS1 Singapore Seminar – Understanding U.S. FDA UDI in Healthcare

The U.S. FDA released, in September 2013, a rule which establishes that a common worldwide system for product identification should be applied to all medical devices placed in the U.S. market. The rule established a Unique Device Identifier (UDI) Number should be assigned by the device manufacturer to each version or model of a device and that the unique device identifier should be both in human readable format and in AutoID format. By default, this information will be applied on the label of each device uniquely identified.

The implementation of UDI is expected to improve patient safety and healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.



GS1 Singapore, CEO, Mr Liew Wai Leong giving the opening address

In support of constant improvement in business processes, GS1 has obtained the authority of an FDA-Accredited Issuing Agency for UDI and thus, all GS1 Standards globally are authorised for use by manufacturers for UDI implementation. In view of this, GS1 Singapore held its Healthcare Seminar on 13 May 2016, discussing on the improvement of patient safety and raising healthcare quality.

The seminar saw the participation of more than 80 industry players from both public and private healthcare organisations, coming together for an exchange of expertise and industry knowledge under the common goal of improving the efficiency of healthcare services and quality of patient safety in Singapore. Attendee profiles included leading medical device distributors, manufacturers, brand owners, quality & regulatory affairs executives, and professionals from hospitals and healthcare organisations. Representatives from MOH Holdings, National Healthcare Group and Health Sciences Authority were also present at the forum.



Seminar was attended by more than 80 industry leaders from the healthcare sector

The seminar focused on the compliance dates for UDI requirements and the 5 basic keys of FDA's final rule, as well as featured a strong line-up of speakers discussing on various topics. Ms Joy Lee, Manager, Membership Services, Training and Support from GS1 Singapore, provided insights on how GS1 Standards for direct part-marking of small surgical instruments are used to ensure the traceability of those instruments in a reprocessing cycle. Through her presentation, the participants learnt about the advantages of achieving a global UDI system for global traceability.



Ms Joy Lee, Manager, Membership Services, Training and Support from GS1 Singapore, sharing with the participants on 'How GS1 Standards can comply with U.S. FDA requirements and timeline'

Mr Sim Wee Lee, Application Engineering Manager from Microscan Systems – Asia Pacific HQ, also gave a presentation on 'Understanding Print Techniques and Verification for Labels and Direct Part-Marking'. An exhibition booth was also set up to provide a 'live' demonstration to all participants on how to print barcodes and verify its print quality standards.



Participants learned and experienced printing and verification techniques during the 'live' demonstration

Another highlight during the seminar was the presentation on AuthenticateIT, a new authentication and traceability solution for GS1 members and businesses in Singapore. The solution comes with an easy-to-use smart device app that empowers consumers to better make informed decisions, by allowing them access to a product's detailed information, such as recall status and product origin.

"Healthcare costs are rising and are expected to grow faster than the national income in most countries, including Singapore, in the foreseeable future. One area of better controlling healthcare costs is in efficiently managing the healthcare supply chain through using global standards," concluded Mr Liew Wai Leong, Chief Executive Officer of GS1 Singapore Limited.



GS1 Singapore Limited and Zincode Technologies Pte Ltd posing for a team photo after a rewarding day