FDA DN 2006 0293 Question 6

Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

Unique device identifiers should be considered for all devices. In general, it is believed that all items can be identified and should be identified by the original manufacturer. Therefore, GS1 recommends that different devices, as well as variations (different sizes, colors, packaging counts, etc) of the same device, should all be assigned different UDIs. A comprehensive, standardized approach to identification across all devices will optimize the benefits to patient safety by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting for all devices. Every device may not require that same information, it might vary depending on the medical device class.

GS1 US™ appreciates the opportunity to provide this comment to the FDA Center for Devices and Radiological Health in order to support the FDA in its consideration of Unique Device Identification (UDI) for medical devices to improve patient safety.

EXECUTIVE SUMMARY

Standards Development: Standards development is a complex endeavor that requires a structured, formalized methodology and the participation of all interested parties to ensure that the standards developed meet the intended goals of the global user community. It is recommended that rather than start from scratch, the FDA should optimize the standards work already completed and the processes developed for creating those standards wherever possible. GS1 has worked successfully as the premiere standards development partner for numerous industries, including healthcare, for over thirty years. The product of those diligent efforts is not only the standards, but even more importantly the process for standards development, specifically the GSMP. This highly successful, highly respected standards development process can be leveraged to help the healthcare community and the FDA implement a unique device identification system to meet its needs.

Role of the FDA: GS1 US commends the FDA for its commitment to support industry in the development of standards, and for its leadership in pursuing unique device identification in the United States. Looking to the future, GS1 US looks forward to the FDA expanding and continuing its leadership by endorsing standards and supporting industry in its on-going effort to develop consensus–based standards. In addition, the FDA can provide leadership in working with the states and other federal agencies, as well as regulatory agencies from around the globe.

Incentives for Implementing a UDI System: Beyond the benefits of patient safety, there are numerous incentives for the healthcare industry to embrace a uniform, standardized system of unique device identification. UDI provides business process improvements for the healthcare industry, most notably cost savings derived from improved supply chain management and recall processes. As the adoption of standardized identification systems for other industries indicate, these incentives are quite effective in gaining industry support for the adoption of such a system. In addition to those incentives, a regulatory requirement is also a key incentive for promoting adoption of a standards-based identification system.

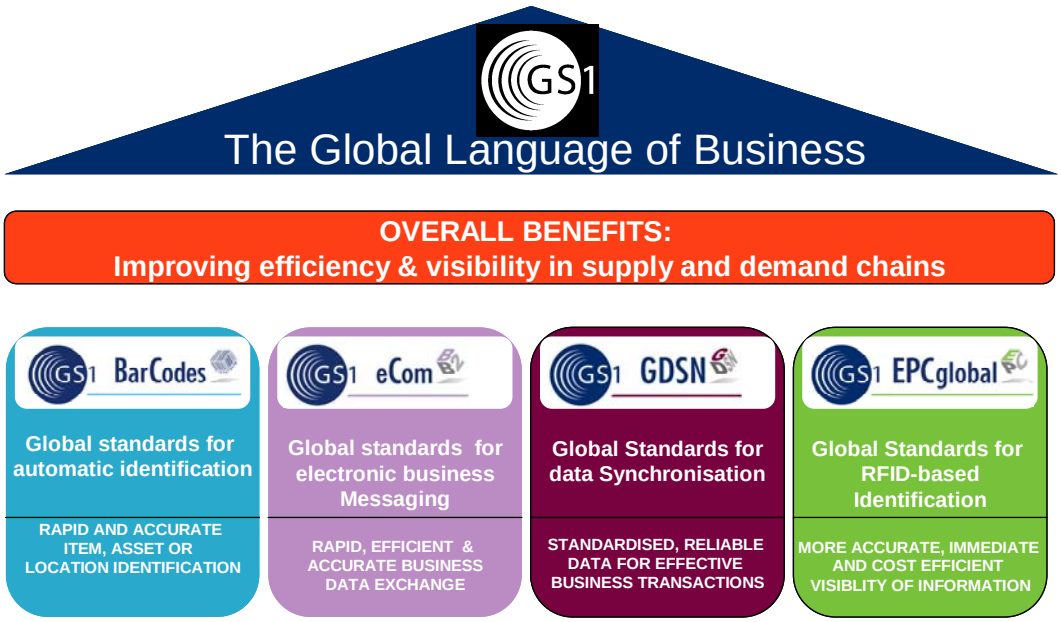
Devices & Levels of Packaging: Unique device identifiers should be considered for all devices. Different devices as well as different variations of the same device such as different sizes, packages counts, color, etc., should all be assigned different UDIs. A comprehensive, standardized approach to identification across all devices will optimize the benefits to patient safety by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting for all devices. In addition, GS1 recommends that all levels of packaging (individual unit shelf pack, inner packs and cases, etc) should be marked in order to optimize information across the supply chain. Experience has shown that identifying and marking all levels of packaging provides a much greater level of information, especially useful for recalls and tracking.

Human Readable & Encoded Format: Wherever possible, it is recommended that the marking of medical devices should be both human readable and encoded for automatic data capture. However, this is not always possible depending on the specific use (e.g., very small items where space limitations prohibit visual representations of the identifier). In such instances, standards should still be developed for how to provide the information via a users group.

Specific Technology & Symbology: The best way to determine the right data carrier for the right product is to embrace a user driven, global process where data carrier selections are based on the operational, regulatory, business and practical considerations of the trading partners and the devices themselves. Therefore, the UDI should not be based on a specific technology or a specific symbology. Rather, it is only necessary to embrace unique identification for medical devices based on global standards, and leave the selection of symbology and technology to the user community.

WHO IS GS1?

GS1 is a leading global organization dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply and demand chains. GS1 and its subsidiaries and partnerships connect companies with standards-based solutions that are open, consensus-based, and universally endorsed. From bar codes, eCommerce, data synchronization to EPC/RFID, GS1 is the trusted source to deliver innovative standards, services and solutions for business' most pressing supply chain challenges.



GS1 is a fully integrated global organization, with 104 Member Organizations serving over a million companies doing business across 145 countries. GS1 US *[formerly the Uniform Code Council (UCC)]* is the Member Organization of GS1 that serves users in the United States of America. As such, it is the national implementation organization of the GS1 System in the United States. GS1 US currently serves over 260,000 U.S. member companies, 18,000 of which are in healthcare.

WHAT IS THE GS1 SYSTEM?

The GS1 System is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. Using GS1 Identification Numbers, companies around the world are able to globally and uniquely identify physical things like trade items, assets, logistic units, shipments, and physical locations, as well as logical things like corporations or a service relationship between provider and recipient. When this powerful identification system is combined with GS1 BarCodes, eCom business messages, the Global Data Synchronization Network (GDSN), and EPC/RFID, the connection is made between these physical or logical things and the information the supply chain needs about them.

The GS1 System is the most widely used supply chain standards system in the world. Utilized in over thirty sectors and industries including healthcare, fast moving consumer goods (FMCG), transport, defense, and many others, the GS1 System has provided benefits to companies and consumers around the world for over thirty years.

GS1 & THE HEALTHCARE INDUSTRY

GS1 is the leading global standards organization in the healthcare industry. In 56 countries worldwide, GS1 standards have been chosen to uniquely identify pharmaceutical products. In addition, national and regional healthcare associations and organizations around the world have endorsed GS1 standards, including regulatory bodies in the United States, Japan and the United Kingdom. GS1 standards will improve patient safety and reduce costs in the global healthcare supply chain. Automatic product identification on all product levels and full traceability ensure a safe and secure supply chain by providing greater visibility, accuracy and velocity for the benefit of all parties involved. Preventing medical errors and combating counterfeiting are top-of-mind concerns facing the healthcare sector, and GS1 standards are helping to solve these issues.

STANDARDS DEVELOPMENT

The hallmark of the GS1 System is the user-driven, user focused standards development process known as the Global Standards Management Process (GSMP). The GSMP is the pre-eminent worldwide collaborative forum where GS1 standards are built and maintained. Since it was created in 2002, the GSMP has been the engine that powers the entire GS1 System of standards.

Building standards that improve the supply chain is a collaborative effort. To that end, the GSMP brings together users from all industries and from around the world to identify needs for standards, gather business requirements, document best practices, obtain consensus on solutions, and then develop and implement the resulting supply chain standards. It is an open and transparent process made possible by the participation of companies who seek to improve the efficiency of supply chains.

HEALTHCARE USERS

Since 2004, GS1 has had a formal global healthcare group to develop GS1 standards and solutions to meet the needs of the global healthcare industry. The objectives of the global healthcare group are:

- Lead the healthcare industry to the effective utilization and development of global standards with the primary focus on automatic identification to improve patient safety.
- Define business applications of EPC technology for the global healthcare industry, which includes establishing business requirements, use cases and standards to support the implementation and use of the EPCglobal Network.
- Work with key partners in the global healthcare supply chain to develop and optimize the use of global standards to ensure accurate and fast movement of goods from manufacturer to distributor to healthcare providers (such as hospitals or retail pharmacies).
- Facilitate awareness in the healthcare sector of new technologies and methods of doing e-business.
- Provide advice and recommendations to GS1 on issues and opportunities in the healthcare sector.
- Promote best practice implementation of the GS1 System in the healthcare industry.
- Promote the implementation of GS1 voluntary, global business standards throughout the healthcare sector.

There are currently over 300 participants representing over 150 companies, including thirty of the forty largest global manufacturers, the three largest U.S. distributors, and three of the four largest U.S. retail pharmacies. The group was formed in association with leading industry groups, including AdvaMed, Medical Device Council, HDMA, NACDS, PhRMA and others, and benefits from the active participation from all key supply chain roles (i.e., manufacturers, distributors, retailers, and hospitals/providers).

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