

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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FDA DN 2006 0292 QUESTION 1

How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

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. 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. As described below, 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.

At a minimum, a unique device identification system requires standardized identifiers, standardized data carriers, and standardized attributes for the devices. The GS1 System of standards provides an excellent a framework for unique device identification. In addition, the GS1 global healthcare group provides a forum for the particular needs of the healthcare industry and optimizes the GS1 System to provide standards-based solutions to meet their most pressing business needs, including patient safety and ePedigree. That on-going work provides a “jumpstart” for the FDA and the healthcare community in their effort to develop a unique device identification system, including their work on identifiers (GTIN and GLN), data carriers and attributes. *(See response to FDA Question 9 below(attached)for discussion of UDI attributes.)*

FDA DN 2006 0292 QUESTION 2

What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

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. Unique device identification has the potential to benefit healthcare and patient safety as much as the pharmaceuticals regulation in 2004. 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, GS1 US looks forward to the FDA’s leadership in working with the states and other federal agencies, as well as regulatory agencies from around the globe.

As with most other items in global supply chains, medical devices are manufactured, traded and used by and in many countries around the world. The global convergence of supply chains for medical devices requires a global approach to standards. Rather than a patchwork quilt of overlapping and/or contrary national standards, the best solution is a uniform, global approach to standards that promotes worldwide application, ease of implementation and cost reduction. In order to achieve that, it is recommended that the FDA utilize a voluntary, consensus-based global standard, rather than a mandatory US standard.

Within a GS1 framework of consensus-based global standards development, FDA expertise can be shared with other countries benefiting consumers of medical devices in the US and around the world. FDA participation in a voluntary global system will encourage other countries to join the process rather than develop their own proprietary standards that would add complexity, cost and confusion. In addition, it will optimize the resulting standards for medical devices used in the US *regardless of where they were manufactured.*

FDA DN 2006 0292 QUESTION 3

What are the incentives for establishing a uniform, standardized system of unique device identifiers?

Beyond the benefits of patient safety, there are numerous incentives for the healthcare industry to embrace a uniform, standardized system of unique device identifiers. UDI provides business process improvements for the healthcare industry, most notably cost savings derived from improved supply chain management and recall processes. Adoption of standardized identification in other industries has illustrated that these incentives are quite effective in gaining industry interest and 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.

FDA DN 2006 -0292 QUESTION 4

What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

Barriers for establishing unique device identifiers include:

- Establishment of regional/national standards
- Adoption of more than one standard
- Ineffective, unresponsive, or non-neutral standards development

The establishment of regional/national standards is a barrier for unique device identifiers because it results in too many standards for companies to manage, adding cost and confusion to their business processes. For the same reason, adoption of more than one standard within a unique device identification system is also a barrier as companies seek simplicity and consistency for optimal results. Finally, ineffective, unresponsive, or non-neutral standards development is also a barrier to establishing unique device identifiers. Implementation of a standard-based system is an investment. Consequently, if the standards

development process does not provide a neutral forum where business needs can be addressed in an effective manner, companies will not invest in such a system.

Identification Numbers

The GS1 System supports six global Identification Numbers. Each GS1 Identification Number supports a distinct type of supply chain item (i.e., trade item, service, location, logistic unit, returnable container, etc.) and provides a link between the item and information pertaining to it.

GS1 Identification Number	Title	Type of Supply Chain Information
GTIN	Global Trade Item Number	<i>trade items (products and services)</i>
GLN	Global Location Number	<i>locations & trading partners</i>
SSCC	Serial Shipping Container Code	<i>logistics units</i>
GIAI	Global Individual Asset Identifier	<i>individual assets</i>
GRAI	Global Returnable Asset Identifier	<i>returnable assets</i>
GSRN	Global Service Relation Number	<i>service relationships</i>

The principles of GS1 Identification Number allocation ensure non-significant, secure and globally unique numbers that can be used by all trading partners, independent of industry sector or location. In order to do that, GS1 Member Organizations assign GS1 *Company Prefix* to each user company in their region. The GS1 *Company Prefix* provides the foundation for generating all of the GS1 Identification Numbers. GS1 Member Organizations also support users with rules, guidelines, best practices, etc. for assigning individual numbers pursuant to the GS1 allocation rules and standards.

Each GS1 user assigns/generates their own Identification Numbers based on their GS1 *Company Prefix* and the GS1 standards and allocation rules. Users can generate identification numbers manually, or use number generator software. (*Numerous vendors both in and outside the USA provide software for generating GS1 Identification Numbers for end users pursuant to GS1 standards and allocation rules.*)

FDA DN 2006 0292 QUESTION 5

Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.

GS1 Members in the healthcare industry use the Global Trade Item Number (GTIN) to uniquely identify their products, from unit of issue through all packaging sizes. The GTIN Allocation Rules, described above, provide specific guidelines for assigning GTINs. (A specific GTIN Allocation Rules for Healthcare is currently being vetted through the GS1 standards review process. In terms of data carriers, GS1 Members in the healthcare industry predominantly use EAN/UPC, Reduced Space Symbology, GS1-128 and Data Matrix. The data carrier is determined by the product, user requirements and the environment. In addition, GS1 healthcare members use Global Location Numbers (GLNs) to identify entities in their supply chain. At the urging of a leading healthcare organization [Coalition for Healthcare eStandards (CHeS)] and its members, the GLN Registry for Healthcare® was established by GS1 US to provide accurate, reliable identification of healthcare locations in the USA. The GLN Registry for Healthcare® is a directory of healthcare and healthcare-related facilities in the United States, with their corresponding GLNs.

The GS1 System of standards provides an excellent a framework for unique device identification. Many large medical/surgical device manufacturers, such as Medtronic, 3M, Tyco Healthcare, Guidant, Johnson & Johnson, Baxter and Cook, to name a few, use the GS1 System and actively participate in the GS1 standards development process for the global healthcare sector. In addition, the Japanese medical/surgical industry has selected the GS1 System for the identification and marking of medical devices in their country using Global Trade Item Number (GTIN), expiration date and quantity.

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FDA DN 2006 0292 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?

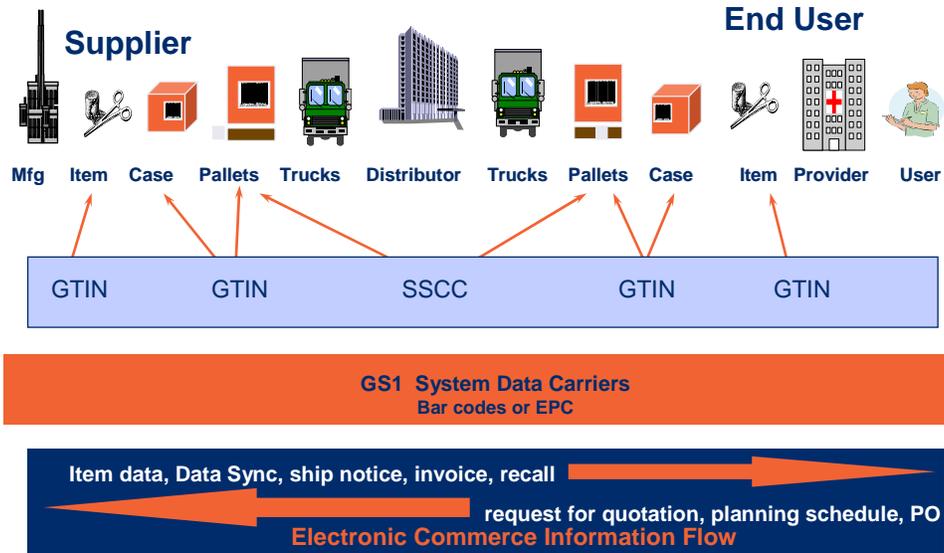
Unique device identifiers should be considered for all devices. In general, it is believed that all items can be identified and should be identified by the original manufacturer. Therefore, GS1 recommends that different devices, as well as variations (different sizes, colors, packaging counts, etc) of 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.

FDA DN 2006 0292 QUESTION 7

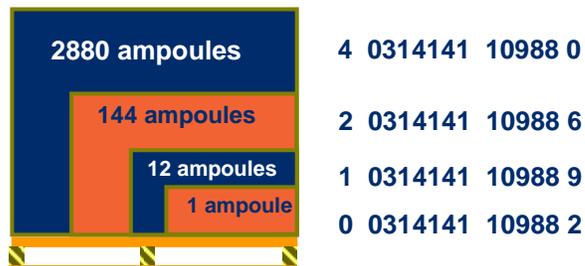
At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

In order to optimize information across the supply chain, all levels of packaging from individual unit to case should be marked, regardless of whether it is sold commercially. Experience has shown that identifying and marking all levels of packaging provides a much greater level of information, especially useful for recalls and tracking. To that end, the GS1 System provides Identification Numbers for logistics units (i.e., pallets; containers; etc.), packaging levels (i.e., boxes; cases; etc.), and individual items (i.e., unit of dose).

GS1: Product Identification through the Supply Chain



GTIN Assignment Rule: A unique GTIN for every packaging level of an item



FDA DN 2006 0292 QUESTION 8

What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

GS1 Member Organizations support users with educational programs, tutorials, guidelines and best practices for addressing problems or concerns related to the implementation of the GS1 standards. Many are common across all industries and geographies (e.g., *Should a new GTIN should be created when a unit weight changes? Where should a bar code be placed on a cylinder?*; etc.). Guidelines are made available on the web site or can be printed, and are updated as needed whenever new questions, concerns or solutions are identified. In terms of packaging issues in particular, GS1 BarCodes standards provide detailed guidelines and best practices for each type of bar code based on specific environment, conditions, etc.

Standardized Attributes

Once a user assigns a GS1 Identifier, they then define various attributes associated with that identifier (e.g., description, price, size, pack, name, address, etc.). The GS1 Standards for each GS1 Identification Number delineate the list of attributes to be defined for each Number. The GS1 Global Data Dictionary provides a precise definition of each attribute, as well as acceptable values and data formats for each attribute (known as *Attribute Values*). The list of attributes, attribute definitions and attribute values are all developed and updated using the formalized process of the GSMP in order to ensure responsiveness and relevance to user needs.

With regard to the definition of attributes, experience has shown that every identification system needs a system of classification. Classifying objects into sub-groups provides an organizational structure for the identification system, and facilitates evaluation and determination of what attributes should/need to be defined for objects within those sub-groups. The United Nations Standard Products and Services Code (UNSPSC) is a hierarchical scheme for classifying products and services. Jointly developed by the United Nations Development Programme (UNDP) and Dunn & Bradstreet Corporation (D & B) in 1998, the UNSPSC provides a classification framework for all products and services in all

industry sectors worldwide. The UNSPSC offers a single global classification system, and has over 4,000 members representing more than 80 countries. After a rigorous selection process, the United Nations appointed GS1 US as code manager in May 2003. As such, GS1 US is responsible for overseeing code change requests, industry revision projects, issuing regularly scheduled updates to the UNSPSC, communications with members, as well as special projects and initiatives as determined both by the UNDP and member requests.

NOTE: Product description attributes (e.g., size; color; shelf life; etc.) are consistent across all instances of the product, and are usually maintained in a database. In addition to those attributes, item specific attributes (e.g., expiration date; lot number; batch number; etc.) can also be defined and encoded onto data carriers to provide item specific information *at the point where the bar code / tag is scanned*. More information on item specific attributes encoded onto data carriers is provided below in the section titled *Data Carriers*.

FDA DN 2006 0293 QUESTION 9

What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

GS1 has found that a formalized, user driven, user focused process, like the Global Standards Maintenance Process GSMP, is the optimal forum for defining data sets and standards. Operational, regulatory, business and practical considerations are all important considerations for developing standards and minimum data sets. In order to define a data set that responds to all of those numerous considerations, GS1 has found that it is best to bring all of the interested parties to the table. Therefore, all players in the healthcare marketplace, including users, as well as any industry organizations and regulatory bodies, should participate in the standards development process to define the data set. By joining the process, the FDA could be the catalyst for change and evolution of standards. Beyond that recommendation, GS1 defers to the medical devices community to determine what specific attributes should be defined and what would improve patient safety.

Data Carriers

The GS1 Identification Numbers can be encoded into GS1 barcodes and EPC tags for identification and automatic data capture, and communicated between trading partners for electronic data processing. Barcodes are utilized for a variety of applications. Therefore, the GS1 System supports several types of bar codes, and GS1 supports users by providing guidelines for selecting the bar code that best fits the application.

The standardized data carriers in the GS1 System are detailed in the following table:

EAN/UPC	<ul style="list-style-type: none"> ▪ Are specified for retail Point-of-Sale (POS) because they are designed for the high volume scanning environment. ▪ When used in logistics, must be printed larger than the “target” size to accommodate logistics scanning. ▪ Limited to carrying GS1 Numbers and special identifiers for restricted applications like variable measure trade items and internal numbering.
RSS (Reduced Space Symbology)	<ul style="list-style-type: none"> ▪ A family of symbols that can be scanned at retail point-of-sale (POS) ▪ Smaller than EAN/UPC and can carry additional information such as serial numbers, lot numbers of expiration dates (i.e., benefit of more data at POS as well as the ability to bar code smaller items). ▪ RSS bar codes designed for use at POS were adopted in June, 2006 ▪ Approved for global use on healthcare items that do not cross POS
GS1-128	<ul style="list-style-type: none"> ▪ GS1-128 bar codes can carry all GS1 Identification Numbers and attributes. ▪ Per the standard, may not be used to identify items crossing POS.
ITF-14	<ul style="list-style-type: none"> ▪ ITF-14 bar codes can only carry GTINs. ▪ Can be printed directly on corrugated cartons. ▪ Per the standard, may not be used to identify items crossing POS.
Data Matrix	<ul style="list-style-type: none"> ▪ The only “2D Matrix” symbol specified for use by GS1 ▪ Hard surface printing (i.e., dot peening, laser etching, laser annealing) ▪ Requires camera based scanners ▪ Non-retail uses due to camera based scanner requirement ▪ Increasingly the symbol of choice for healthcare (items not crossing POS), electronic components and direct part marking
Composite Component	<ul style="list-style-type: none"> ▪ The only “2D linear” symbol specified by GS1 ▪ Only used with a linear bar code like GS1-128 or RSS
EPC Tag	<ul style="list-style-type: none"> ▪ RFID tag ▪ Capable of carrying all GS1 Identification Numbers ▪ Utilizes RFID readers ▪ No “line of sight” requirement

As discussed above, item specific attributes can be encoded onto data carriers to provide item specific information *at any point where its barcode/tag is scanned*. To communicate item specific information, the GS1 System provides what are known as “Application Identifiers” (AI) for including secondary data on data carriers (e.g., expiration date; lot number; batch number; etc.). GS1 AIs are standard throughout the world and are familiar to IT system developers. GS1-128, RSS, GS1-Data Matrix, and Composite Component can all carry AIs, and more than one AI can be carried in one bar code. (If helpful, the current list of GS1 AIs can be provided to the FDA.) In addition to the currently defined AIs, the GS1 GSMP has a process in place for developing new AIs to accommodate business needs.

FDA DN 2006 0292 QUESTION 10

How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

In order to support commercial transaction and collaborative business processes, companies have been collecting and maintaining standards-based information about their products for many years. Therefore, most medical device companies will already have proficiency and infrastructure established for collecting and maintaining standardized data about their products which they can optimize for maintaining the UDI data requirements once defined. Specifically, companies use data catalogs and/or data pools to maintain their product information. For example, 1SYNC, a not-for-profit subsidiary of GS1 US, is a Global Data Synchronization Network (GDSN)-certified Data Pool. 1SYNC eliminates the need to operate redundant technologies and cost structures. It uses the most flexible on-boarding options to implement data synchronization for companies of all sizes and needs. 1SYNC is a customer driven organization focused on adoption and implementation of data synchronization for ensuring data integrity.

NOTE: The Global Data Synchronization Network (GDSN) was developed in partnership with the global business community to address the high costs associated with inaccurate data. The GDSN is a network of interoperable data pools for communicating master data between trading partners. The GDSN is a global, Internet-based initiative that enables trading partners to quickly and efficiently exchange supply chain data that is accurate, up-to-date and compliant with GS1 System standards.

FDA DN 2006 0292 QUESTION 11

Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

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. For example, GS1 standards call for markings to be both human readable and encoded for automatic data capture. However, the

RSS application guideline for very small healthcare items provides that as long as the data in the bar code is provided somewhere else on the label, the human readable requirement for the RSS is waived.

Selection of data carriers must consider the constraints of the application. Depending on the product and its use, some applications may permit labeling, while others may require laser annealing. On point, the GS1 RSS Healthcare Implementation Team developed a guideline for the use of RSS for pharmaceutical products. The group, composed of healthcare manufacturers, providers, and scanner manufacturers, developed a guideline and three case studies on the use of RSS on healthcare products. The case studies can be found on the GS1 US website. <http://barcodes.gs1us.org/>.

FDA DN 2006 0292 QUESTION 12

Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?

There are currently seven GS1 data carriers (see table above), providing flexibility for trading partners in selecting the best carrier for their applications. 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.

Compatibility with carriers used for compliance with the pharmaceutical bar code rule can be a consideration for medical device data carriers, especially if the supply chains overlap (e.g., enabling a hospital to optimize the scanners it uses for pharmaceuticals and for medical devices as well). However, the specific requirements of the medical devices, first and foremost, will determine what data carrier options are viable, and that is the threshold determination for whether compatibility is possible based on differing requirements for pharmaceuticals versus medical devices.

UDI Benefits & Costs

FDA DN 2006 0292 QUESTION 13

From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

A standardized UDI system will make the connection between medical devices and the information needed about those devices. The implementation of product identification in other industries has shown that this connection is tremendously valuable, as discussed and analyzed at length in the article [17 Billion Reasons to Say Thanks](#) found at www.barcodes.gs1us.org in the *Document Library* in the *Commerce/General* folder. This connection has many benefits to public health and patient safety as well, including reducing medical errors, facilitating recalls, and improving medical device reporting. Automatic product identification on all product levels ensures a safe and secure supply chain by providing greater visibility, accuracy and velocity for the benefit of all parties involved.

GS1 US has been supporting healthcare for over thirty years, and has been proactive in promoting the adoption of standardized product identification in the healthcare sector for over twelve years. GS1 US has been a vocal advocate of standardized identification in the healthcare sector because GS1 US strongly believes it will save lives.

FDA DN 2006 0292 QUESTION 14

From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

Without more specifics, costs are difficult to project. However, it should be noted that much of the technology for a UDI system is not only already existing, but also well-

established. There are many tools readily available in the marketplace today for implementing a UDI system – and the marketplace is quite competitive. Moreover, much of the infrastructure for a UDI is already in place for many users. Many manufacturers already utilize bar codes and data pools, and are proficient users. In addition, many hospitals have already implemented standards-based identification for pharmaceuticals, and therefore have tools, equipment and expertise as well.

The real costs will be associated with integrating the UDI information into their business systems, and building up their existing infrastructure to support it. Nonetheless, there is an opportunity to phase in implementation efforts based on priorities and key areas. For example, a hospital may begin implementing in certain areas, departments and wards based on varying needs and risks for UDI. This will assist with budgetary considerations for implementing a UDI.

FDA DN 2006 0292 QUESTION 15

If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

Not applicable. (GS1 is a standards organization, not a user.)

FDA DN 2006 0292 QUESTION 16

From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

The expected rate of technology acceptance in implementing or using a UDI system will depend on the specific standards implemented. If the FDA endorses an established set of standards, the expected rate of acceptance can be quite rapid. For example, if the UDI leveraged the GS1 System, there is already an existing vendor base ready to provide the necessary hardware and software to implement a GS1 standards-based UDI system. In addition, because the GS1 System is already widely implemented across numerous supply

chains, including healthcare, many users will already have various hardware (e.g., readers; scanners; printers; etc.) and software necessary for implementing the UDI system. This also increases the expected rate of technology acceptance in implementing or using a UDI system. Conversely, implementing dual standards or a new standard would have the most prolonged rate of technology acceptance.

FDA DN 2006 0292 QUESTION 17

From your perspective, what are the obstacles to implementing or using a UDI system in your location?

Not applicable. (GS1 is a standards organization, not a user.)

FDA DN 2006 0292 QUESTION 18

For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside bar-coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

Priorities for the various advancements proposed for the healthcare industry must be determined by the healthcare community. However, in general, standardized, accurate identification of products is usually the first step to the more advanced applications as they provide the base on which those applications can be built. For example, electronic health records and bedside bar-coding for dispensing pharmaceuticals are best if based on standardized identifiers for medical devices and pharmaceuticals. Therefore, it is recommended that the community consider a phased approach where the groundwork for more advanced solutions is established through a standards-based identification system that can support and optimize those solutions.

FDA DN 2006 0292 QUESTION 19

What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

Much of the technology for a UDI system is not only already existing, but also well-established. From bar codes to scanners to data pools, there are many tools readily available in the marketplace today for implementing a UDI system – and the marketplace is quite competitive. Moreover, much of the infrastructure for a UDI is already in place for many users. Many manufacturers already utilize bar codes and data pools. In addition, many hospitals have already implemented standards-based identification for pharmaceuticals, and therefore have tools, equipment and expertise as well. With tools readily available and much infrastructure in place, the real effort will be building up existing infrastructure to support UDI.

FDA DN 2006 0292 QUESTION 20

Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

Not applicable. (GS1 is a standards organization, not a user.)