

GS1 US COMMENT

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
[Docket No. FDA-2008-N-0661]

EXECUTIVE SUMMARY	2
QUESTIONS PERTAINING TO THE UDI SYSTEM.....	2
FDA QUESTION 1A.....	2
FDA QUESTION 1B.....	3
FDA QUESTION 2A.....	3
FDA QUESTION 2B.....	3
FDA QUESTION 2C	4
FDA QUESTION 2D	4
FDA QUESTION 2E.....	5
FDA QUESTION 3A.....	5
FDA QUESTION 3B.....	7
FDA QUESTION 3C	8
FDA QUESTION 3D	9
FDA QUESTION 3E.....	10
FDA QUESTION 4A.....	10
FDA QUESTION 4A(I)	11
FDA QUESTION 4A(II)	11
FDA QUESTION 4C	12
FDA QUESTION 5	13
FDA QUESTION 5A.....	13
FDA QUESTION 5B.....	13
FDA QUESTION 5C	14
FDA QUESTION 5D	14
FDA QUESTION 6A.....	14
FDA QUESTION 6B.....	14
FDA QUESTION 6C	14

APPENDIX A

Additional information regarding the GS1 System

US

GS1 Healthcare and GS1 US™ appreciate 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

GS1 Healthcare and GS1 US support the FDA Center for Devices and Radiological Health in its consideration of implementing Unique Device Identification (UDI) for medical devices. Standardized Unique Device Identification will provide major advancements in patient safety, reducing medical errors, facilitating device recalls, and improving medical device reporting. The GS1 System of standards provides an excellent framework for UDI. Supporting that framework, Global GS1 Healthcare drives the development of GS1 standards and solutions to meet the particular needs of the global healthcare industry. Leveraging the expertise within the global healthcare community, GS1 Healthcare optimizes the GS1 System for standards-based solutions to meet healthcare's most pressing business needs. The GS1 System in general and the work of GS1 Healthcare in particular (especially their work on GTIN™ and GLN identifiers, data carriers, and GDSN database of attributes) provide a proven foundation for the FDA and the healthcare community to develop a Unique Device Identification system. We recognize the FDA UDI requirement has different levels of application; the assignment and registration of the UDI in the UDI database, marking of the UDI on the product package (considering all levels), and finally the marking of the product itself. Our responses are based on this layered approach.

Following the question and answer portion of this document, there is additional information in the Appendix concerning GS1, GS1 Healthcare, GS1 US and the GS1 System.

QUESTIONS PERTAINING TO THE UDI SYSTEM

FDA QUESTION 1a

**Should all devices be subject to the requirements of a UDI system?
Please explain your reasoning.**

GS1 recommends that all medical devices should have a UDI assigned using the Healthcare GS1 GTIN Allocation Rules. These allocation rules determine when a new UDI is required (e.g. variations of form, fit and function). A comprehensive, standardized

approach for all medical 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.

FDA QUESTION 1b

Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

Yes, even though the UDI requirement should apply to all medical devices, there may be certain types of medical devices that can be exempted from this rule; such examples could be items with low risk such as adhesive bandages, tongue depressors, cotton balls and the like. Such exemptions should be made by the FDA on a class, or case by case risk based analysis, and should be reviewed on a periodic basis to determine if the exception is still warranted. Such a policy would be in concert with the FDA pharmaceutical and biological rule in 2004 and make for easier interpretation and enforcement across the healthcare sector.

For example, a product that is considered too small to be UDI marked today may be able to be UDI marked in the future as marking and reading technologies evolve. The various data carrier options in the GS1 portfolio support the progression toward smaller marking. In fact, the GS1 DataBar, GS1 DataMatrix and EPC tags were all developed to support members requiring more data in less space to mark ever decreasing product sizes.

FDA QUESTION 2a

What characteristics are needed to uniquely identify a device?

For the purposes of unique identification, the UDI should not have characteristics or intelligence built into the number. Each product should be assigned with a UDI or in the case of the GS1 System a Global Trade Item Number (GTIN). This unique number should only be associated (as a pointer) to a device (UDI) database file.

Where required, additional production identifiers such as Lot Number and Serial Number should be encoded using GS1 Application Identifiers (AI) 10 and (AI) 21 respectively.

FDA QUESTION 2b

What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

The minimum data attributes for the UDI database are listed below (medical devices):

1. UDI/GTIN (Global Trade Item Number) = Primary Key
2. Manufacturer Name
3. Brand Name
4. Product / Catalog Number
5. Item Description
6. GMDN (nomenclature code)
7. Packaging unit (each, box, case etc.)

FDA QUESTION 2c

What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?

A change to an attribute may require a change to the UDI. Specific product changes that effect form, fit, function, package configuration, etc. necessitate a new UDI. UDI specifications must be detailed and need to be resolved through the use of clear, structured allocation rules for the UDI similar to those in the GS1 Healthcare GTIN Allocation Rules.

In addition, support materials should be available to guide users in answering questions about when to allocate a new UDI. The GS1 System provides clear, structured data standards and allocation rules for users. In addition, country based GS1 Member Organizations support users with rules, implementation guidelines and best practices for assigning individual numbers pursuant to the GS1 GTIN Allocation Rules. GS1 Member Organizations also support users with educational programs, tutorials, guidelines and best practices for addressing problems or concerns related to the implementation of the GS1 standards. Guidelines are made available on the GS1 web-site and are updated as needed whenever new questions, concerns or solutions are identified. In terms of packaging issues in particular, GS1 bar code standards provide detailed guidelines and best practices for each type of bar code based on specific environment, conditions, etc.

FDA QUESTION 2d

Should the UDI include a component that represents package size or packaging level?

GS1 US COMMENT
DHHS - DOCKET NO. FDA 2008-N-0661
FEBRUARY, 2009

The UDI/GTIN assigned and the UDI/GTIN marked on the product package should not include a component that represents a package count but should be unique to that product and its package count. This UDI/GTIN would then point to a UDI database that contains the differentiation in package count.

The GS1 System requires that each level of packaging be identified with a unique GTIN. Manufacturers using the GS1 specification correctly develop GTINs that are unique for each item and every level of packaging for that item. Receivers of these items can use the GTIN to uniquely identify their products, from unit of issue through all packaging counts. It must be emphasized that the GTIN is a dumb number and should not be parsed. The GTIN is used as a pointer to a database file that contains specific item attributes.

The unique GTIN is needed to distinguish a single medical device from a package of 10, or a package of 25 of these medical devices for ordering, recalls and track and trace. In order to optimize information across the supply chain, all levels of packaging from individual unit to case should be uniquely marked. Decades of GS1 experience has shown that identifying and marking all levels of packaging provides a much greater level of information, especially useful for recalls and tracking.

FDA QUESTION 2e

To what extent would or should the list of unique device characteristics vary depending on the type of device?

Mandatory attributes in the UDI database would not vary with the type of medical device. Additional medical device attributes in industry databases may vary depending on the type of medical device.

FDA QUESTION 3a

Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

Yes, existing standards such as GS1 could and should be used as a model for the UDI. They are in commercial use and adoption would be the least disruptive to the U.S. healthcare industry. The FDA should not develop its own nationally unique system. 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 GS1 standards work ongoing and completed including the processes developed for creating those standards wherever possible.

GS1 System is Global

The GS1 System is widely used in 26 sectors (it is important to note that the GS1 system is deployed extensively in major retail and grocery industries whose product categories crossover to healthcare) and in 150 countries. There are GS1 offices in 108 countries and there are one million members globally. The GS1 EAN/UPC bar code symbol is one of the most widely recognized symbols globally.

GS1 System is embraced in many industries

The GS1 System for identification of products is used for many products that a hospital purchases including clothing, toothpaste, medical devices, pharmaceuticals etc. This standardization of identification, marking and database files allows for greater efficiency in database processing.

The GS1 System has been recommended in several countries as the standard of choice in healthcare:

Japan - 2008

Director of Economic Affairs Division, Health Service Bureau, Ministry of Health, Labor and Welfare ... "The product codes should be based on internationally harmonized standards..... Above all, *the product codes of GS1 are recommended.*"

United Kingdom - 2007

The (United Kingdom) Department of Health endorses fully the (2003) NHS (National Health Service) PASA (Purchasing and Supplies Agency) recommendation that all supplies to the English NHS *should have a product code following the GS1 standard bar code format*, and recommends that all manufacturers of medicinal products and medical devices adopt this approach.

Spain Andalucía - 2005

Container and packing symbolization requirements for the Andalucía Health Service supplied products.

In general terms, *it will have to be coded with EAN-128. The information that must appear in the EAN-128 should be: the GTIN, the expiry date, Lot Number and/or the Serial Number.*

GS1 System used in Pharmaceutical and Biologics

Since the 1970's when GS1 US reserved company prefixes for National Drug Codes (NDC and the NHRIC), the GS1 System has been the standard of choice for pharmaceutical and biologics manufacturers globally. Members in the healthcare industry use the Global Trade Item Number (GTIN) to uniquely identify their products, from unit of issue through all packaging counts. The GTIN Allocation Rules provide specific guidelines for assigning GTINs, and the GS1 Global Healthcare User Group has been working diligently to identify attributes necessary for GTINs for healthcare products.

GS1 Specifications are detailed, extensive, evolved, and member supported

GS1 Standards are used by industry to govern the adoption and implementation of data and technology. They are mature and robust after 35 years of refinement in multiple industries and countries. To supplement the specification, there are guidelines written specifically for particular industries (e.g. the Global Healthcare GTIN Allocation Rules, the North American Guideline for marking small healthcare products). The GS1 US GTIN Provider Tool kit is specifically geared for healthcare providers in the U.S. This extensive document allows an engaged dialogue concerning GTIN use in healthcare by manufacturers, distributors and end users.

GS1 System has global and U.S. healthcare adoption momentum

There is great momentum around the GS1 System both in the global and the U.S. healthcare community. In fact, the U.S. healthcare community has rallied around December, 2012 as the sunrise date for the adoption of GTINs in the U.S. healthcare sector. This grassroots movement has widespread support from Group Purchasing Organizations (GPOs, i.e., Amerinet and Premier) and individual IDNs (i.e., Sisters of Mercy ROi, Mayo Clinic, Wellspan Health, Geisinger, and others). In support of this effort, 85 U.S. healthcare companies (including associations, manufacturers, distributors GPOs, retails and providers) are collaborating in GS1 work groups to prepare GTIN tool kits targeted specifically to the U.S. healthcare user. The "US Provider GTIN Tool Kit" was released July, 2008. A "US Supplier GTIN Tool Kit" will be released in April 2009.

GS1 US urges the FDA to leverage the momentum of the GS1 US Healthcare initiative to craft a UDI system for medical devices that uses a standard that is already embraced by U.S. healthcare.

FDA QUESTION 3b

Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the Lot or Serial Number). What should the device "identifier" component of the UDI cover or contain?

The UDI device identifier should contain no embedded intelligence. It should be a dumb number without inherent logic. The number should be a pointer or reference to a database for additional information about the item. The GTIN allocation process is designed to ensure GTIN uniqueness and is the responsibility of the product owner. Where required, additional production identifiers such as Lot Number and Serial Number should be encoded using GS1 Application Identifiers (AI) 10 and (AI) 21 respectively.

FDA Question 3c

With respect to the production identifier, we note that the statute says that the UDI may include information on the device's Lot or Serial Number. When should Lot or Serial Number information be required for a device?

For medical device items, it is recommended that the FDA and the user community consider the level of information granularity they may need for specific devices (or device classes) and/or specific needs.

An example of the granularity of data needed and already available in the GS1 System is displayed below in the "Ladder of Traceability." For example, if there was a need to recall all of a specific medical device (e.g. all syringes) with a particular GTIN, then a recall based only on GTIN would be sufficient. However, if there was a more focused recall of only a certain Lot of a medical device, then GTIN plus Lot Number would be best (as shown in the second rung of the traceability ladder). To carry the example further - if there was a need to recall or track only specific devices within a given production run, then the top rung of the ladder (i.e., GTIN plus Serial Number) would be needed. It is recommended that the FDA and the user community consider such issues as they evaluate the need to require "production identifiers" for various devices.

Item specific attributes such as expiration date, Lot Number or Serial Number can also be defined and encoded onto data carriers to provide item specific information *at the point where the carrier is read*. To communicate such item specific information (referred to as "production identifiers" in question 3c) the GS1 System provides what are known as "Application Identifiers" (AI) for including secondary data on data carriers. GS1 AIs are standardized throughout the world and are familiar to IT system developers. GS1-128, GS1 DataBar, GS1 DataMatrix, and Composite Component can all carry AIs, and more than one AI can be carried in a single 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 Application Identifiers to accommodate the evolving healthcare and business needs.

Traceability Ladder of Precision

GTIN and Serial Number identifies a precise product and packaging

- Suture plus serial number
- (01) 12345678901234(21) 1234ty

GTIN and Lot Number identifies Products within a defined group

- Suture plus lot number
- (01) 12345678901234(10) ascgd

GTIN identifies product and package

- Suture (01) 1234567890123



Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

For medical device items it is recommended that the FDA and the user community consider the level of information granularity they may need for specific devices (or device classes) and/or specific needs.

FDA QUESTION 3d

How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

The best method to ensure that the UDI is uniformly standard is to adopt an existing standard that is already widely implemented, documented and understood by the healthcare community, such as the GS1 System. The GS1 system is globally accepted in grocery, retail and healthcare. The FDA can leverage existing documents rules and guidelines for quicker, smoother and more cost effective adoption and implementation.

FDA QUESTION 3e

How should the UDI be created to ensure that UDIs are unique?

The UDI should be created through and adhere to a global standard that is widely understood and implemented. Ultimately, it is the products owner's responsibility to ensure the uniqueness of the identification numbers they assign to their products. GS1 supports product owners in that effort by providing clear data standards and rules for generating identification numbers. The UDI should be assigned only by the product owner. Data standards and structured data formats are essential when it comes to ensuring uniqueness.

GS1 System users are provided materials such as implementation guidelines and best practices to support them in assigning individual numbers pursuant to the GS1 standards. The GS1 System and GS1 Member Organizations provide clear, structured data standards and allocation rules for manufacturers to follow when allocating GTINs in order to ensure that their GTINs are globally unique and are in a consistent format.

Other industries ensure that GS1 standards are adhered to by incorporating their required use into the terms and conditions of individual customers contracting language.

FDA QUESTION 4a

Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.

The FDA should rely on existing commercial standards used throughout the global industry. Therefore the FDA should not specify where on the label the UDI should appear. Because of the variations and options available for data carriers, printing methods, scanning environments, etc. as well as the variations in the devices themselves and their packaging, it is recommended that the FDA not include regulations for issues like label placement, size, color, font, etc.

The GS1 System includes standards for data carriers and identifiers. Those standards specify the environments approved for each type of data carrier, and then establish specifications for their use in that environment based on the requirements of that environment. GS1 Healthcare is currently developing a recommendation for GTIN placement for medical devices.

FDA QUESTION 4a (i)

Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging?

The preferred method would be to have the GTIN and production identifiers in the same location; however, manufacturing capability and physical package constraints may dictate otherwise. GS1 provides a process where healthcare users can reach consensus on proper placement of the UDI.

FDA QUESTION 4a (ii)

For bar codes (whether linear or two-dimensional 2D), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?

The FDA should not mandate concatenated or stacked bar codes but should rely on the GS1 Global System standard. As long as standards for both concatenated and stacked options are provided with clear information for use, it is not necessary to mandate one format or the other. It is best to provide industry with the flexibility they need to select the best data carrier for their applications and requirements; the GS1 System provides the rules for selection, structure and placement.

FDA QUESTION 4b

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)?

For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

The requirements for direct part marking will vary from manufacturer to manufacturer and device to device. Direct part marking could have adverse effects on the product such as device integrity and human factors, Direct part marking decisions must be made by manufacturers, clinicians and other industry experts.

FDA QUESTION 4c

If we allow for “alternative placement” of the UDI for some particular devices or types of devices, what should be the general criteria for requiring “alternative placement” of the UDI, e.g., such as on the device itself or other location that is not on the label?

In general, the criteria for alternative placement may include requirements of the device, marking capabilities of the manufacturer, data capture convenience, practicality and reliability for the user. However, as long as standards for alternative placement are provided, it is not essential to define conditions or criteria under which the alternative placement standards can and cannot be used. The necessity of using an alternative placement can be determined by the product owner as long as the requirements of the underlying global standard are met.

FDA QUESTION 4d

d. What specific challenges or limitations exist regarding alternative placement?

For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

Most of the challenges with alternative placement (assuming it is defined as direct part marking) are based on the characteristics of device and the feasibility of marking on the product. Some of the characteristics that pose a problem are lack of physical space, incompatible material and the risk of weakening the integrity of the product. Other challenges have to do with the impracticalities of marking such as incompatible manufacturing process, cost of part marking outweighing the cost of the device, device classification or risk does not warrant such measures, and finally the marking has no practical application for capture in the clinical environment where used. The requirement for marking must have a definable application for capture that is in alignment with the hospital or end user process or practice.

FDA QUESTION 5

How should the UDI be presented?

We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e)(regarding pharmaceutical security and specifying promising technologies such as RFID (radio-frequency identification), nanotechnology, encryption technologies, and other track-and-trace or authentication technologies). Therefore:

FDA QUESTION 5a

Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human-readable UDIs alone? Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

Yes, wherever possible, it is recommended that the marking should be both human readable and encoded for automatic data capture. This provides an excellent backup/redundancy in case of failure of a bar code. 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. The North American Guideline for 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 device is waived. There are also certain situations where it would be sufficient to have human readable UDI alone.

FDA QUESTION 5b

Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning.

No, The FDA should not specify a particular type of automatic identification technology or data carrier. Selection of data carriers must consider the constraints of the individual application. Depending on the product and its use, some applications may only permit labeling, while others may allow for direct part marking on the device (e.g. laser etching). 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.

It is recommended that the FDA identify automatic identification standards that can be used for UDI. The GS1 System currently includes seven GS1 data carriers, providing flexibility for trading partners in selecting the best carrier for their applications. It is recommended that the FDA leverage the GS1 standards, and leave the selection of specific symbology and technology to the user community. By so doing, the FDA can leverage the benefits of optimal functionality and universal applicability in UDI data carriers, while still ensuring the unique identification of medical devices.

FDA QUESTION 5c

Should we allow the use of different automatic identification technologies to express different parts of the UDI?

The UDI or GTIN for a particular device should be in the same identification technology or symbology. Identical GTIN's and attributes could be carried by two AIDC technologies, e.g. bar code and RFID but systems development must be considered to ensure there is no duplication of the data gathering.

FDA QUESTION 5d

Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

Yes, the FDA should select the GS1 System. The GS1 System of standards provides an excellent framework for UDI, and is already widely used in healthcare and adjacent industries therefore; it is recommended that the FDA leverage the GS1 System for UDI. The GS1 System currently includes seven GS1 data carriers, providing flexibility for trading partners in selecting the best data carrier for their applications. Many in the healthcare industry today already use GS1 data carriers, from GS1 bar codes to GS1 DataMatrix and GS1 DataBar to mark their product packages. Many large medical/surgical device manufacturers use the GS1 System and actively participate in

GS1 US COMMENT
DHHS - DOCKET NO. FDA 2008-N-0661
FEBRUARY, 2009

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 device packages using Global Trade Item Number (GTIN), Lot or Serial Number and expiration date. The GS1 System would support the FDA in its effort to implement UDI in the same way.

The FDA selection of more than one system would not be efficient or effective. The selection of one system would provide the same benefits that one standard has created in the global grocery and retail industries. The selection of the GS1 standard would allow healthcare information technology systems to standardize data capture for all items that a hospital purchases from food to clothing to pharmaceutical to medical devices.

GS1 US supports the FDA Center for Devices and Radiological Health in its consideration of implementing Unique Device Identification (UDI) for medical devices. Standardized Unique Device Identification will provide major advancements in patient safety, reducing medical errors, facilitating device recalls, and improving medical device reporting. The GS1 System of standards provides an excellent foundation for UDI; and supporting that foundation, the GS1 Global Healthcare User Group drives the development of GS1 standards and solutions to meet the particular needs of the healthcare industry. Leveraging the expertise within the healthcare community, the GS1 Global Healthcare User Group optimizes the GS1 System for standards-based solutions to meet healthcare's most pressing business needs. The GS1 System in general and the work of the GS1 Global Healthcare User Group in particular (especially their work on GTINs, GLNs, data carriers and attributes) provide a "foundation" for the FDA and the healthcare community to develop a Unique Device Identification system.

FDA QUESTION 6

How should the UDI Database be developed and maintained?

For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:

a. How and when should we require UDIs and associated information to be entered into a database?

The information should be loaded electronically in one central database as the data is available.

How frequently should we require changes to information associated with or linked to a UDI to be reported?

The UDI should be perpetually updated as product changes are made by the manufacturers. If the database was connected to the GS1 GDSN via a certified data pool, this information could be automatically provided as updates are made by the source of the information. Any change to a product should be reported immediately. The Global Data Synchronization Network™ (GDSN™) is an automated, standards-based, global environment that enables secure and continuous data synchronization, allowing all partners to have consistent item data in their systems at the same time.

b. Aside from information that is necessary to uniquely identify a device, what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

No information should be included in the UDI database other than the attributes identified in the answer to question 2b. It is not recommended that the FDA UDI database contain optional attributes. The list of attributes, attribute definitions and attribute values should all be developed and updated using a formalized process in order to ensure responsiveness and relevance to user needs.

The GS1 System already has a process for this established in the Global Standards Management Process (GSMP). In order to clearly define a product, the required attributes should include core characteristics of the device as well as any aspect which can result in a variation (e.g., form, fit and function).

In addition to the mandatory attributes the GDSN contains over 400 optional attributes to support healthcare. The Global Healthcare User Group has recently reviewed the attributes available and made modifications for the unique needs of healthcare. This group has also requested that several new attributes be added to the GDSN by submitting them to GS1's standards review body (GSMP) for consideration.

The list of the recommended healthcare attributes in the GDSN is provided below. The GDSN provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy.

GDSN Required Attributes

GLN (Global Location Number) of source Data Pool
GLN of data source
GTIN
Parent GTIN
Child GTIN
Quantity of children
Target Market Country Code
Global Product Classification (GPC)
State
Date
GLN of manufacturer
Hierarchy level per GS1 code list
Brand name
Functional Name
Start Availability Date
Base unit? (Y/N)
Consumer unit? (Y/N)
Despatch unit? (Y/N)
Invoice unit? (Y/N)
Orderable unit? (Y/N)
Variable measure? (Y/N)
Returnable packaging? (Y/N)
Batch/lot number? (Y/N)
Height & UoM
Width & UoM
Depth & UoM

Additional Attributes for Healthcare

Additional Trade Item Description
Additional Trade Item Identification Type
Additional Trade Item Identification Value
Gross weight & UoM
Net weight
Net content & UoM
Brand owner
Brand owner GLN
Name of manufacturer
Name of information provider
Short Description
Long Description
Additional Classification Agency
Additional Classification Code
Effective Date
Non-sold item returnable? (Y/N)
Marked recyclable? (Y/N)
Package Markings Diet Allergen (Contains latex)
Package Markings Free From (Free from latex)
Package Marks Hygiene (Sterile)
Bar Code Type

c. If variable data (such as a Lot or Serial Number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

No, it would be difficult to maintain this dynamic data. This production identification information should be provided and maintained by the product owners.

Summary of GS1 Recommendations

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. 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-five 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.

Devices & Levels of Packaging: Unique device identifiers should be considered for all devices. Different devices as well as different variations of the same device (e.g., different sizes, package counts, functionality, 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 (e.g., individual unit shelf pack, inner packs, cases, pallets, 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.

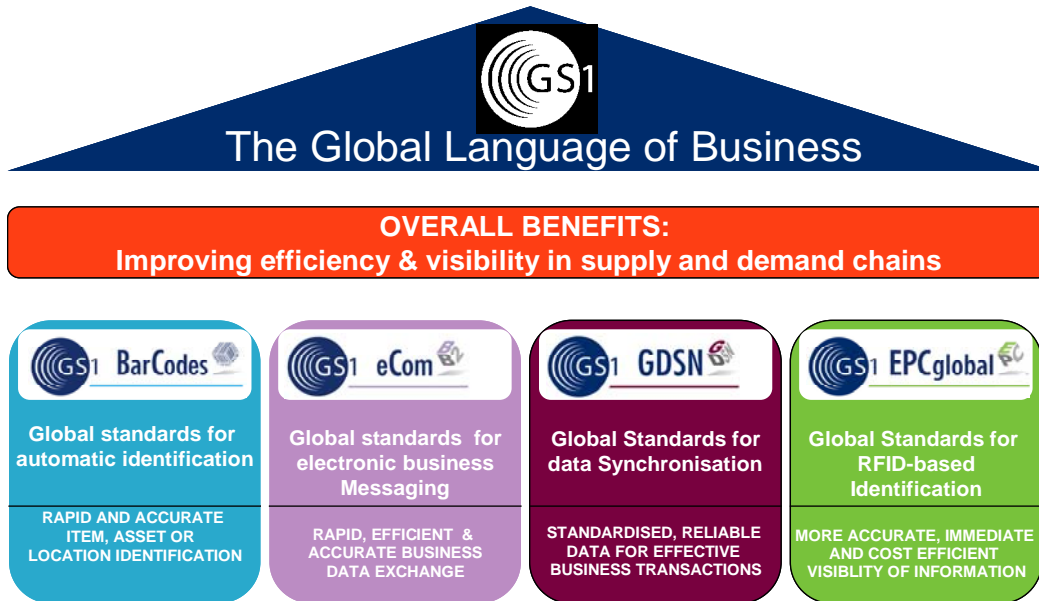
Human Readable & Encoded Format: Wherever possible, it is recommended that the marking of medical devices should be both human readable and encoded for automatic data capture. However, this is not always possible depending on the specific use (e.g., very small items where space limitations prohibit visual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

APPENDIX A

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, EPC/RFID, to business process automation standards, 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 108 Member Organizations serving over a million companies doing business across 150 countries. GS1 US [formerly the Uniform Code Council (UCC)] is the Member Organization of GS1 that serves users in the United States. As such, it is the national implementation organization of the GS1 System in the United States. GS1 US currently serves over 250,000 U.S. member companies, 16,000 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 bar codes, 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, <http://www.gs1.org/productssolutions/barcodes/overview/> the GS1 System has provided benefits to companies and consumers around the world for over thirty five 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 User Group to develop GS1 standards and solutions to meet the needs of the global healthcare industry. The objectives of the Global Healthcare User 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.
- 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.
- 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.

GS1 US COMMENT
DHHS - DOCKET No. FDA 2008-N-0661
FEBRUARY, 2009

There are currently over 300 participants in GS1 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).

GS1 US COMMENT
DHHS - DOCKET No. FDA 2008-N-0661
FEBRUARY, 2009

For additional information, please contact:

John Roberts
GS1 US
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648
(609) 620-4563



Michel van der Heijden
President, Healthcare
GS1 Global Office



Dennis W. Harrison
President, GS1 Healthcare US