UDI Implementation Reality – AIDC
How to identify/mark my medical device products?
UDI Implementation Reality

...How to identify/mark my medical device products?...

Moderator
Ms. Jackie Rae Elkin
Global Process Owner - Standard Product Identification
Global Regulatory Operations
Medtronic, Inc.

Panelists
Mr. Dennis Black
Director, e-Business
BD - Becton, Dickinson and Company

Mr. Jithendra Nair
Director Information Technology, Asia Pacific
Cook Medical

Mr. Tom Werthwine
Global Process Owner - Auto ID Technology and Data Standards
Johnson & Johnson

GS1 GO Staff
Chuck Biss
Senior Director, AIDC Healthcare
UDI Implementation Reality – AIDC

...UDI in a GS1 “AIDC” world... the “theory”...
UDI
Unique Device Identification

...is enabled by...

GS1 Standards !!

NOTE: At the time of this presentation the US FDA Ruling has been published. As it is a detailed and in-depth document, it is recommended that you always refer to the final US FDA Ruling for all details specific to it at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
Unique Device Identification

1. A standardized system to develop **Unique Device Identification numbers** (UDI)
2. **UDI** in human readable and/or **bar code/RFID** on a device, its label, or both
3. **UDI Database** will be created and will need to be maintained
4. **Users** need your help to implement. The FDA expects GS1 as an “Issuing Agency” to play a major role

...the AIDC “bits” of UDI...
UDI system…

...AIDC “bits”...

UDI/UDID - System

AIDC Identifiers

- DI (static data)
- PI (dynamic data)

UDID (database)

Static Data Elements

- DI = primary access key
- ...
- ...
- ...
- ...

AIDC Data Carriers

Machine Readable

- 1D Bar Code
- 2D Bar Code
- RFID
- ...

DI = Device Identifier

PI = Production Identifiers (i.e. lot/batch no., serial no., expiry [use by] date, date of manufacture)
UDI system... and some non-AIDC “bits”...

UDI/UDID - System

AIDC Identifiers

- DI (static data)
- PI (dynamic data)

UDID (database)

Static Data Elements

- DI = primary access key
- ...
- ...
- ...
- ...

AIDC Data Carriers

Machine Readable

- 1D Bar Code
- 2D Bar Code
- RFID
- ...

DI = Device Identifier
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GDSN discussed NOW in a parallel breakout session!!

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AIDC – Unique Device Identification (UDI)

Goal of unambiguous identification of a specific medical device. From an AIDC standpoint this identification has two (2) parts:

- The **Device Identifier (DI)** – Meant to be the identification of the “generic” medical device – GS1 **GTIN** enables this.

- The **Production Identifier (PI)** – Meant to be whatever “control” numbers or data a manufacturer uses in their process – GS1 **Application Identifiers (AI’s)** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

**GTIN + AI(s) = UDI**
UDI in the GS1 system of standards

...UDI in GS1 terms...

AIDC - Data Carriers

ISO compliant machine-readable **Data Carriers** on the product (via label or DPM... Direct Part Marking) or its packaging, which contain the UDI – 1D / Linear & 2D / Matrix bar code symbols, RFID.

**NOTE:** Though “any” ISO compliant machine-readable Data Carrier is applicable... GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers...
UDI in the GS1 system of standards

...Bar Code Data Carriers “most” typically seen in UDI...

- EAN/UPC
- GS1 DataBar
- GS1-128
- GS1 DataMatrix
- ITF-14

Composite Component
# UDI in the GS1 system of standards

UDI in GS1 terms...

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td>(if applicable)</td>
<td></td>
</tr>
</tbody>
</table>

- Expiration Date AI(17) - e.g. 141120
- Lot/Batch AI(10) - e.g. 1234AB
- Serial Number AI(21) - e.g. 12345XYZ

*Production Identifier data will vary by medical device type and manufacturer current practice.*

DI + PI = UDI  
GTIN or GTIN + AI(s) = UDI

© 2013 GS1
Some (but not all) common reasons for a Device Identifier (DI = GTIN) to change are:

- Change in quantity of a device package
- Change to package sterility
- Re-labeling of the original labeler’s (mfg.) device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark

Refer to the appropriate UDI regulation in your area and the GS1 GTIN Allocation Rules for complete details on any regional influence for DI / GTIN change.
Packaging Levels – The UDI (a DI, i.e. GTIN and PIs i.e. AIs) should be in the AIDC data carriers (i.e. bar code symbol) and also in human-readable form on each applicable packaging level as defined by regulation. Each designated packaging level that is a trade item must have its own DI (GTIN). Logistics items are exempt.
Kits

Medical Device “kits” have their own UDI. The general rule is that only the packaged kit/combination product needs a UDI on its label, and that the individual devices contained within do not.

(NOTE: Refer to the FDA Rule for details and/or refer members to their compliance team for guidance specific to their products. Within GS1 additional definition & allocation rules for Healthcare kits are presently being clarified through the GSMP AIDC Healthcare Application Standard Updates Mission Specific Work Group.)

Data Carrier Placement

As with any AIDC data carrier in any sector overall placement is important. Bar code symbols, with their associated HRI, should be positioned to allow ready access for scanning when the product is stored, stocked on shelves or handled for PoC use.
UDI in the GS1 system of standards

...UDI in GS1 terms, carriers you might see at...

The Warehouse

GS1-128
“Concatenated” data

GS1-128
“Non-Concatenated” data

ITF-14

The Hospital

GS1-128
“Concatenated” data

GS1-128
“Non-Concatenated” data

GS1 DataMatrix

All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography -please refer to regional UDI regulations.
UDI in the GS1 system of standards

...UDI in GS1 terms, carriers you might see at...

The Point-of-Care

The Retail POS

GS1-128
"Concatenated" data

EAN 13

UPC-A

GS1 DataMatrix

ITF-14

All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography - please refer to regional UDI regulations.
UDI example - #1

16G Dual Lumen
Oocyte Recovery Set

Device Identifier (DI)
“Static” portion
GTIN (product identifier)

Production Identifier (PI)
“Dynamic” portion
Application Identifiers (e.g. serial, lot number & expiry date)
UDI example - #2

UDI Bar Code symbol

Device Identifier (DI)
“Static” portion
GTIN (product identifier)

Production Identifier (PI)
“Dynamic” portion
Application Identifiers (e.g. serial, lot number & expiry date)
UDI example - #3

Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)
UDI - Unique Device Identification

The GS1 System of Standards enables all stakeholders to efficiently and effectively meet UDI requirements to ensure interoperability and compliance with an organisation’s business processes. A single standard streamlines implementation and increases compliance with the UDI regulations.

What is UDI?

UDI is a unique code for medical devices, which can be used for accurate, automated identification and tracking throughout the supply chain.

UDI Leaflet

Are you ready for UDI? Click here to download the UDI Leaflet.

www.gs1.org/healthcare/udi
UDI Support: “Are you ready for UDI?”

- Introduction to UDI
- UDI in GS1 terms
- Presentation of industry practices
- Benefits of UDI

www.gs1.org/healthcare/udi
NOTE: Check out the GS1 Healthcare UDI web page at: http://www.gs1.org/healthcare/udi
UDI Implementation Reality – AIDC

...our Panelists and the “reality”...
UDI Implementation Reality

...How to identify/mark my medical device products?...

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Medtronic, Inc.
IMPLEMENTATION REALITY

“Medical Devices: How to identify/mark my products?”

Dennis Black
BD - Becton, Dickinson and Company

GS1 Global Meeting
01 April 2014 - Seoul
BD (Becton, Dickinson and Company)

- FORTUNE 500 company (#332)
- Locations in more than 50 countries
- Nearly 30,000 associates worldwide
- Serves healthcare institutions, life science researchers, clinical laboratories and the general public
- Sells a broad range of medical supplies and services, devices, laboratory equipment, diagnostic products, and pharmaceuticals
Current UDI Efforts Include:

- Reviewing all applicable UDI data, GTIN assignment, and labels to conduct a gap analysis
- Internal Education on UDI Requirements
- Confirming Nuances in FDA UDI Rule
- Verifying Non-US Requirements & IMDRF Guidance
- Revising ERP and Other System to Store UDI Data
- Retooling/Printing Processes/Reassigning GTINs if Necessary
- Revising Policies, Procedures and Processes to Comply with UDI
- Label Revision Process
- Populating UDID
- Revising Commercial Processes

Moving from voluntary adoption of data standards to compliance with a regulation.
Are We There Yet?
Driving data standards within the healthcare supply chain

Jithendra Nair
UDI & Traceability for Medical Devices
Seoul, Korea 1-3 April, 2014
Improved Patient Safety – using global standards

- Identifies: Right product, right patient, right time
- Is scanned at the bedside
- Helps prevent medication errors
- Combats counterfeit products
- Facilitates recalls

Image source: http://www.gs1eg.org/Sectors-Healthcare-100.htm
What is a data standard & What does it all mean?

- Data standard: A common language for trading partners to use about products that pass through the supply chain.

<table>
<thead>
<tr>
<th>SAME DATA. DIFFERENT NAMES.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UDI</strong></td>
</tr>
<tr>
<td><strong>DI</strong></td>
</tr>
<tr>
<td><strong>PI</strong></td>
</tr>
<tr>
<td><strong>Product Identifier</strong> (if applicable)</td>
</tr>
</tbody>
</table>

### DI + PI = UDI

- **AI**
  - Expiration Date AI(17) – e.g. 141120
  - Lot/Batch AI(10) – e.g. 1234AB
  - Serial Number A(21) – e.g. 12345XYZ

*Product identifier data will vary by medical device type and manufacturer current practice.*

<table>
<thead>
<tr>
<th><strong>GTIN</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>or</strong></td>
<td></td>
</tr>
<tr>
<td><strong>GTIN</strong></td>
<td><strong>AI(s)</strong> = UDI</td>
</tr>
</tbody>
</table>

**UDI** Unique Device Identification

**GS1 Standards** Product Identification

**DI** Device Identifier

**GTIN** Global Trade Item Number

**PI** Product Identifier

**AI** Application Identifier
Labeling challenges

Date format

YYYY-MM-DD for all dates displayed in the labeling
Cook will start using day within the date

For Cook product, must include DI + PI (at least one)

UDI does not dictate which PI is used
Exceptions for retail and some Class I devices

AIDC portion of the UDI

DI + PI (include all PI information shown on the label)
Can request FDA exception for some PIs
Must be human and machine readable
Labeling challenges

UDI is technology-neutral
  Linear barcodes, 2D data matrices, RFID, etc.
  As technologies evolve, supply chain will drive changes to the standards;

Standards are internationally recognized; GS1 is Cook’s Issuing Agency

GTIN-14 linear barcode is Cook’s AIDC format
Labels – Current Cook Label
By complying with GS1 and the GTIN-14 requirements, Cook is already complying, at least in part, with UDI!!!
Labels – GTIN-14 Format

- Application identifier (product code)
- Company ID
- Check digit
- Expiration date
- Lot number
- Packaging indicator
- GPN
- Application identifier (expiration date)
- Application identifier (Lot number)
Labels – GTIN-14 Format

• Additional changes moving forward:
  – AI (30) – Box quantity
  – AI (21) – Serial number
  – Which AIDC method(s) is best for customers?
    • Single, linear barcode (current)
    • Split, linear barcodes
    • 2D data matrices
    • RFID
    • Combination
GTIN-14 Challenges

- Create a global product database
- Manufacturers had to change barcode labeling logic
- Cook distribution systems had to change
- EDI systems had to be altered to pass data through all systems
- Packaging changed, resulting in going from a 1-to-1 relationship to a 1-to-many relationship between product number and packaging
- UOM changed, requiring inventory conversions
Cook Medical’s approach to implementing GS1 Standards

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify current systems’ capabilities</td>
<td>• GLN</td>
<td>• Use GS1 Standards in all transactions</td>
<td>• GTIN use at bedside</td>
</tr>
<tr>
<td>• Establish core business implementation team</td>
<td>• GTIN</td>
<td>• Work to achieve perfect order</td>
<td>• Integration into electronic health records</td>
</tr>
<tr>
<td></td>
<td>• GDSN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• E-commerce</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Start by building a plan and forming a team

**Milestones**

1. Scope project
2. Assess systems
3. Form implementation team
4. Timelines
## Setting up Global Location Numbers (GLNs)

<table>
<thead>
<tr>
<th><strong>Milestone</strong></th>
<th><strong>Milestone Steps</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>GLN</strong></td>
<td>1. Identify GLN location(s) / entity(ies)</td>
</tr>
<tr>
<td>2. GTIN</td>
<td>2. Request and assign GLNs from your GPO or GS1</td>
</tr>
<tr>
<td>3. GDSN</td>
<td><strong>GS1 GLN Quick Start Guide</strong></td>
</tr>
<tr>
<td>4. E-commerce</td>
<td><strong>GS1 Healthcare Provider GLN Tool Kit</strong></td>
</tr>
<tr>
<td></td>
<td>3. Exchange and upload GLN(s) with supplier</td>
</tr>
</tbody>
</table>

1. **Systems Assessment**
2. **Setup**
3. **Transact**
4. **Clinical Integration**
### Setting Up Global Trade Item Numbers (GTINs)

<table>
<thead>
<tr>
<th><strong>Milestone</strong></th>
<th><strong>Milestone Steps</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GLN</td>
<td>1. Perform an item master cleanup.</td>
</tr>
<tr>
<td><strong>2. GTIN</strong></td>
<td>2. Upload cleansed item master into the NPC/GS1 Catalogue</td>
</tr>
<tr>
<td>3. GDSN</td>
<td>3. <strong>Optional</strong>: Request supplier GTIN information through GDSN</td>
</tr>
<tr>
<td>4. E-commerce</td>
<td></td>
</tr>
</tbody>
</table>
## Setting Up Global Data Synchronization Network (GDSN)

<table>
<thead>
<tr>
<th><strong>Milestone</strong></th>
<th><strong>Milestone Steps</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GLN</td>
<td>1. Choose data pool provider</td>
</tr>
<tr>
<td>2. GTIN</td>
<td>2. Request Cook publish GTIN attributes from GDSN</td>
</tr>
<tr>
<td><strong>3. GDSN</strong></td>
<td></td>
</tr>
<tr>
<td>4. E-commerce</td>
<td></td>
</tr>
</tbody>
</table>

1. **Systems Assessment**
2. **Setup**
3. **Transact**
4. **Clinical Integration**
## Setting Up E-commerce

<table>
<thead>
<tr>
<th><strong>Milestone</strong></th>
<th><strong>Milestone Steps</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GLN</td>
<td>1. Choose e-commerce option</td>
</tr>
<tr>
<td>2. GTIN</td>
<td>2. Setup e-commerce</td>
</tr>
<tr>
<td>3. GDSN</td>
<td></td>
</tr>
<tr>
<td>4. E-commerce</td>
<td></td>
</tr>
</tbody>
</table>

1. Systems Assessment  
2. Setup  
3. Transact  
4. Clinical Integration
Thank You

Jithendra Nair
Director Information Technology (Asia Pacific)
Cook Medical
Unique Device Identification (UDI) Use Case

Tom Werthwine
GS1 Global Healthcare Conference Spring 2014
UDI - Objectives

• Develop a clear understanding of the rule
• Establish a common framework to drive consistency, standardization and clear ownership
• Develop an initial comprehensive view of resources, requirements and investments across all work streams – including: UDI data & database, labeling, direct part marking, conforming amendments, steady state organization, etc.
# Required Components for FDA Compliance

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Challenge</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bar Coding</td>
<td>GTIN and appropriate Application Identifiers</td>
<td>Migrating from HIBCC bar codes to GS1 bar codes</td>
<td></td>
</tr>
<tr>
<td>Date Format</td>
<td>YYYY-MM-DD</td>
<td>Many products carry month and year</td>
<td></td>
</tr>
<tr>
<td>GUDID Date Submission</td>
<td>GTIN, regulatory and labeling data</td>
<td>Need to associate “primary UDI” with other levels of packaging</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>May need GTINS for unpackaged and DPM units</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>US only product lack Global Medical Device Nomenclature RA data decentralized</td>
<td></td>
</tr>
<tr>
<td>Direct Part Marking</td>
<td>Bar code and/or human readable</td>
<td>Technology and space constraints</td>
<td></td>
</tr>
<tr>
<td>Conforming Amendments</td>
<td>Usage in Adverse Event Reports, Device Hx files</td>
<td>Change management</td>
<td></td>
</tr>
</tbody>
</table>
UDI Bar Coding

GS1 Linear 128 and Datamatrix

GS1 US Verification Report
## GUDID Database Support

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
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</thead>
<tbody>
<tr>
<td>Submitter DUNS</td>
<td>TBD</td>
</tr>
<tr>
<td>Labeler DUNS</td>
<td>002144145 (ETHICON)</td>
</tr>
<tr>
<td>RA Contact</td>
<td>TBD</td>
</tr>
<tr>
<td>Customer Contact</td>
<td>1-877-384-4266</td>
</tr>
<tr>
<td>UDI Issuing Agency</td>
<td>GS1</td>
</tr>
<tr>
<td>Primary UDI</td>
<td>10705031203532</td>
</tr>
<tr>
<td>Primary UDI Count</td>
<td>1 EA</td>
</tr>
<tr>
<td>Secondary UDI IA</td>
<td>HIBCC</td>
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<tr>
<td>Secondary Primary UDI</td>
<td>H206DNX121</td>
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<tr>
<td>FDA Authorization</td>
<td>K100423</td>
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<tr>
<td>FDA PROCODE</td>
<td>MPN</td>
</tr>
<tr>
<td>FDA PROCODE Name</td>
<td>Tissue adhesive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Listing</td>
<td>From FURLS</td>
</tr>
<tr>
<td>GMDN Code</td>
<td>TBD</td>
</tr>
<tr>
<td>GMDN Term</td>
<td>TBD</td>
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<tr>
<td>Brand Name</td>
<td>DERMABOND ADV</td>
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<tr>
<td>Model/REF</td>
<td>DNX12</td>
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<tr>
<td>Description</td>
<td>Topical Skin Adhesive</td>
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<tr>
<td>Market Status</td>
<td>Active</td>
</tr>
<tr>
<td>Combination Product</td>
<td>No</td>
</tr>
<tr>
<td>Contains Human Tissue</td>
<td>No</td>
</tr>
</tbody>
</table>
Sample 2D Bar Code Etches for DePuy Synthes
UDI and Conforming Amendments

<table>
<thead>
<tr>
<th>Part</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>803</td>
<td>Medical Device Reporting</td>
</tr>
<tr>
<td>806</td>
<td>Reports of Corrections and Removals</td>
</tr>
<tr>
<td>810</td>
<td>Medical Device Recall Authority</td>
</tr>
<tr>
<td>814</td>
<td>Premarket Approvals</td>
</tr>
<tr>
<td>820</td>
<td>Quality System Regulations</td>
</tr>
<tr>
<td>821</td>
<td>Medical Device Tracking Requirements</td>
</tr>
<tr>
<td>822</td>
<td>Post market Surveillance</td>
</tr>
</tbody>
</table>

Impacts Device History Records, Complaint Files, and Tracking Records.
§ 803.32 If I am a user facility, importer or manufacturer, what information must I submit in my individual adverse event reports?

(c) * * *

(6) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *
UDI Opportunities

For manufacturers:

- Supporting customer need for data
- Globally unique product identification versus product selection by color, package size, etc.
- Support “perfect order”
- Support implant registries
- Support electronic health records
- Increase efficiencies for evidenced-based medicine
US FDA UDI

Compliance ........................
some important things to think about

Jackie Rae Elkin, Medtronic, Inc. Global Regulatory Affairs
Unique Device Identification

Combination of 4 Distinct Ideas

1. Development of a standardized system of Unique Device Identifiers (UDI)

2. Place UDI in human readable and AutoID formats on package label and in some cases, on the device

3. Register UDI data in FDA GUDID public database

4. Implementation
Can you use more than one?

You might need to ..........................
The Date Format applies to All medical devices (not just those subject to UDI). Compliance timelines follow the classification of the product.

Bar code quality must be verified. Simply scanning for readability is not verification, nor is it sufficient. You must measure and verify the quality of the code to ISO/ANSI standards.

Medical device software version should be captured in the Lot or Batch Production Identifier (AI 10 for GS1).

Manufacturing date on the label. If you want an exception from FDA, the labeler needs to request it (industry groups cannot) or wait for the outcome of another labeler to be posted.

GUDID concept of “should” match what appears on the product label. UDI and GUDID do not have requirements for the label beyond date format and the UDI itself. But remember the intent to accommodate description to your customer. Should give the customer the “sense” that this is the same product.
Take the Opportunity to Fix Other Issues ……………………

If you must make label changes to be UDI compliant, e.g., date format, take the opportunity to fix other issues that may cause you problems in the future.
Reusable devices that require reprocessing (sterilization, cleaning) before reuse must have the UDI directly marked on the device.

- Remember the **exceptions** in the rule:
  - Interfere with safety and efficacy
  - Not technically feasible
  - SUD
  - Previously marked

- **Self exempt** and document in Design History File.

- Consider legacy products placed on market in consignment and remember the 3 years to deplete inventory begins to toll with the classification level for label and direct marking timelines
Who will be responsible for UDI submission to FDA?
✓ Using a solution provider to assist?

Data Governance needed - roles and responsibilities to be defined.
✓ Shared responsibility for data maintenance (business units, global/local)

All UDI data for a medical devices must be submitted to the GUDID before commercialization of the product – where is product release trigger?

FDA pushing for labelers to publish data now in order to provide insight to potential issues not anticipated. You can submit your data and push the publish date out 30 – 60 days which will allow you ample time to fix it before actual go-live or compliance dates.
* FDA highly recommend labelers “test the waters” before finishing system and process designs.

DUNs conundrum - it is up to the labeler to determine the responsible entity on the label, s/b the person responsible for interpretation of the rule. Primarily used to provide consistency of the responsible labeler name (trying avoid errors in manual entry).
Interpretation Required!

The **objective** of UDI is to establish a system to adequately identify devices through distribution and use. The **purpose** is to rapidly and definitively identify a device and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.

- Be able to identify a device through a UDI that will appear on the label and package of the device
- UDI, when provided through AIDC technology will allow rapid and accurate data acquisition, recording and retrieval.
- Eliminating the uncertainty concerning the identity of the device subject of an adverse report
- More effective FDA safety communication
- To be used in EHR of a patient implanted with device to strengthen the ability to identify a specific device and improve response to postmarket surveillance activities including adverse event reporting and recalls.
## Global Device Identification Monitoring

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| USA     | Implementation Timeline  
Class III: 2014  
LS / LS Implants: 2015  
Class II: 2016  
Class I: 2018 | GS1 HIBC ISBT | Device Identifier, Production Identifiers to Unit of Use Level Class II & III | UDI Database – US FDA |
| EU      | Recommendation Release 2013 | GS1 HIBC | Will Align with IMDRF | EUDAMED - European Commission |
| China   | TBD      | TBD | TBD | TBD - CFDA |
| Brazil  | TBD      | GS1 | Will Align with IMDRF | TBD - ANVISA |
| S. Korea| TBD      | GS1 | TBD | TBD - KFDA |

### Timeline
- **2006**: Spain introduces GS1 for identifying devices.
- **2009**: Turkey adopts GS1 HIBC for device identification.
- **2012**: Japan releases guidelines for GS1.
- **2012**: India implements GS1 for device identification in procurement.
- **2013**: IMDRF releases implementation guidelines.
- **2014 - 2015**: IMDRF recommendations align with global standards.
- **2016 - 2018**: USA implements UDI standards across different classes of medical devices.
- **2018 - Present**: Global implementation continues with TBD timelines for China, Brazil, and South Korea.
External Trends Affecting RIM

Regulators are Developing Master Data Strategies

- UDI requirements include electronic data about products.
- Regulated Product Submissions (RPS): standards for electronic submissions and electronic data about documents, common data elements for products.

Today

Product Data Reporting in Silos with no Standardization

Future

UDI Connects FDA Systems/Data

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More questions afterwards… ??

Check out more FAQ’s at:
http://helpdesk.gs1.org/ArticlesBySubject.aspx?UDI%20-%20Unique%20Device%20Identifier&id=3a55268a-c05a-e311-ba24-00155d644240

Or if you have additional questions:
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FDA Helpdesk Direct
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REMEMBER TO CHECK OUT:
…GS1 Healthcare UDI web page at: http://www.gs1.org/healthcare/udi
…U.S. FDA UDI general web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm