Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)
UDI Compliance Challenges (… and opportunities?)

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UDI Timeline

- 1999 December – US IOM Report – To Err is Human
- 2004 February – FDA Pharmaceutical Barcode Rule
- 2008 October – GHTF forms UDI ad-hoc Working Group
- 2011 September – GHTF UDI Guidance published
- 2012 February – IMDRF continues UDI WG
- 2012 July 10th – FDA publishes UDI Proposed Regulation
- 2012 July – FDASIA provisions added
- 2013 April – EU publishes UDI recommendations
- 2013 September 24 – US publishes UDI Final Rule and draft GUDID Guidance
- 2013 December – IMDRF publishes UDI guidance 2.0
Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.
Public Health Benefits
The UDI system provides global visibility and supports:
• Medical device recalls
• Adverse event reporting
• Tracking and tracing
• Supply chain security
• Anti-counterfeiting/diversion
• Disaster/terror preparation
• Shortages/substitutions
• Reduction of medical errors (e.g., bedside scanning)
• An easily accessible source of device information for patients and clinicians
US FDA UDI Rule Intent/Objective

• Provide standardized granular identification of medical devices and associated meta-data to support various public-health initiatives
• Most notably FDA’s postmarket surveillance activities – including:
  – adverse event reporting/aggregation
  – recalls
  – device and disease specific registries
  – EHRs
  – large population-based data sets, e.g., claims data
• Understand stakeholders/users needs and use
GHTF/IMDRF UDI AHWG

• Formed October 2008
• Members US, Europe, Japan, Canada – and AHWP
• GHTF Guidance published September 2011 - framework for regulator developing a UDI System
• Morphed into IMDRF
• Update to Guidance published December 2013
• Available at: [www.imdrf.org/consultations](http://www.imdrf.org/consultations)
• It is critical that these systems are implemented without regional or national differences.
• Intended to provide a single, globally harmonized system for positive identification of medical devices.
Driving to UDI Compliance

Work stream #1 – Assigning Unique Device Identifiers (UDIs) – and placing the UDI on the device’s label (and packaging) [and standardized date format]

Work stream #2 – Identifying, collecting, normalizing, validating – and finally submitting required data to FDA’s Global UDI Database (GUDID)

Not in any order – can and should be done in parallel
US FDA UDI Overview

1. Standardized Date Format
2. Establishing a UDI System
3. What Device Manufactures/Labelers Need To Do
Standardized Date Format

If label includes a date to be read by user (e.g., expiration, manufacturing):

• All numeric: YYYY-MM-DD (2013-06-19)
• **Day must always be included**
• Same Compliance Date as other UDI requirements
• Applies to all labels (even if exempt from UDI)
• If not subject to UDI – applies at year 5
• A combination product with NDC number is exempt.
• **Does NOT apply to date format in UDI.**
• HOWEVER – may need to update/change date format in UDI – from YYMM to YYMMDD
UDI Application Example
Establishing a US UDI System

Combination of 3 distinct steps:
1. Develop Unique Device Identifiers (UDIs) for all devices
2. Place UDI on the label in both plain text (HRI) and AIDC
3. Submit data to US FDA’s Global UDI Database (GUDID)
What is a UDI?

Identifier/code on device label and packaging (and, in some cases, on the device itself)

Two parts: UDI = DI+PI

• Device Identifier (DI) (static) – specific to a device version or model

• Production Identifier(s) (PI) (dynamic) – one or more currently used control/production identifiers that is lot/batch number, serial number, manufacturing date, expiration date
  – If on the label – then needs to be part of the PIs
  – Not requiring any changes to currently used PIs
UDI General Rule

• The label* of EVERY medical device (including all IVDs) must have a UDI.
• EVERY device package (contains a fixed quantity of a version or model) must have a UDI.

Any other approach is an exception to or alternative from these requirements.

* Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...
Who is the “Labeler”... (UDI/GUDID)?
Create and assign DIs

• Work with one (or more) FDA accredited issuing agencies – GS1, HIBCC, and ICCBBA/ISBT-128
• Assign Device Identifiers to all devices – including:
  – Kits
  – Complex systems
  – Combination products
  – Configurable devices
When to Assign a New DI

A new DI is required whenever:
• A change to a device results in a new version or model
• Create a new device package (including changes to #)
• Re-label

• No relationship to premarket requirements
Place UDI (DI+PI) on Device Label

• Different DI applied to the label (default location) AND (higher levels) device packages
• In plain text (HRI) AND encoded in AIDC technology
• No specific technology (technology neutral)
• If AIDC technology is not evident – requires that the label "disclose" the presence of AIDC technology.
Direct Marking

• In *addition* to label requirements – Direct Marking (DM) – not necessarily Direct Part Marking (DPM) for:
  • device intended to be used more than once, and
  • *reprocessed* (clean, clean + disinfected, or clean + sterilized) before use

• Direct Part Marking (DPM) – for certain devices where necessary
Stand-Alone Software

Need to determine if SaS is regulated as device. Means of displaying its UDI:
• through, for example, help, about, start-up screen
• If also packaged, needs labeled UDI too
• Version = lot
• Major vs minor revision (see IMDRF guidance)
• Major (new DI) – includes complex or significant changes affecting safety, intended use, performance or effectiveness.
• Minor (new PI) – generally bug fixes, usability enhancements (not safety), or security patches.
General Exemptions

• Class I Devices do NOT need to include PIs
• GMP-exempt Class I devices
• Existing inventory (finished device packaged and labeled prior to compliance date – 3 years)

and others...
SUD Packaging Exemption

UDI can go on SUD next higher level of packaging when:

The individual single-use devices (SUDs) are:
1. distributed together in a single device package,
2. intended to be stored in that package until used, and
3. which are not intended for individual distribution.

- Can *not* be used for implants (do you know if your device is an implant?)

Need to document above.

-- And Unit of Use (UofU/”virtual”) DI required in GUDID
Trays, sets, etc...

- Many different types of “kits” (or combination products)
- “Kit” (or CP) exception is only about **not** marking the individual devices within the kit.
- Still need to be able to provide visibility/traceability
- May need to change business processes and/or way kits are created and distributed.
“Shipping Container”

- Exception – UDI does not need to be on shipping container.
- Shipping container – means “a container used during shipment or transportation... and whose contents may vary from one shipment to another.”
- Shipping container ≠ “shipper”
- Higher levels of packaging requirement intended to end when no longer homogenous (e.g., pallet, tote).
A “1-in-1”

• Multiple packages at the unit of use (a 1-in-a-1) – not a higher level of packaging issue.
• UDI needs to be on the “label” to facilitate the identification of the device through “distribution and use.”
• Typically – outer pack is sufficient (assuming device is stored and “used” that way).
• But – need to look/document specific use cases.
Direct Marking Exceptions

1. Direct marking would interfere with the safety or effectiveness of the device;
2. Direct marking is not technologically feasible;
3. The device is a reprocessed single-use device
4. The device has been previously marked

Exception to be noted in design history file – do not need to submit exception request.
Exception/Alternative Process

1. Identify the device(s) subject to exception/alternative
2. Identify the provisions subject to the request
3. If exception – explain why the requirements are *not technologically feasible*.
4. If an alternative, describe the alternative and
   a. why it would *provide for more accurate, precise, or rapid device identification* – or
   b. how it *would better ensure the safety or effectiveness of the device*
5. Estimate the number of affected labelers and devices
GS1-UDI Application Example

MOSAIC® 305 CINCH® II

REF → 305C221
Size → 21 MM
Use By → 2016 – 07 – 12
SN → 21A11F4855

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

21 MM

Aortic

STERILE LC
Sterile LC: Device has been sterilized using Liquid Chemical Sterilants according to EN/ISO 14160.

PYROGEN Nonpyrogenic
Do Not Resterilize

Do Not Reuse

1 USA Rx only
For US Audiences Only

Quantity → 1
Temperature Limitation

3°C → +37°C

Check temperature indicator prior to use

Manufacturer:
Medtronic, Inc.
710 Medronic Parkway
Minneapolis, MN 55432
USA

Manufactured at:
Santa Ana, CA USA

© 2011 Medtronic
1211533002 Rev. 1B
GS1-UDI Application Example
HIBCC-UDI Application Example
ICCBBA-UDI Application Example
ISBT128

Device Identifier (Product Processor Identifier Code): A9997T9017Z012

• A9997 is the processor identifier assigned by ICCBBA ≡ manufacturer identifier
• T9017Z012 is the product identifier ≡ catalogue number

Production Identifier: A999912123456102

• A999912123456 is the donation identification number ≡ Lot no.
• 102 is the division number ≡ serial number
3rd – Submit data to FDA’s GUDID

For each Device Identifier

- The Medical Device Label:
  - Device Identifier (Device XYZ123)
  - Production Identifier (Lot #ABC)
  - Expiration date (YYYY-MM-DD)

- Manufacturer (Labeler) → Web based tool or HL7 SPL
- 3rd Parties (e.g., GDSN)

Business Rules → FDA’s GUDID

FDA Managed

Commercial Distribution

Public User Interface
## GUDID Data Attributes

### Device Identifier (DI) Information
- Issuing Agency
- Primary DI Number
- Device Count
- Unit of Use DI Number
- Labeler DUNS Number
- Company Name
- Company Physical Address
- Brand Name
- Version or Model Number
- Catalog Number
- Device Description (max 2000 characters)

### Commercial Distribution
- DI Record Publish Date (mm/dd/yyyy)
- Commercial Distribution End Date (mm/dd/yyyy)
- Commercial Distribution Status

### Secondary DI
- Secondary DI Issuing Agency
- Secondary DI Number

### Package DI
- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date
- Package Status

### Support Contact
- Support Contact Phone
- Support Contact Email

### Direct Marking (DM)
- Device Subject to Direct Marking (DM), but Exempt
- DM DI Different from Primary DI
- DM DI Number

### Device Status
- Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
- Kit
- Combination Product

### FDA Product Code
- Product Code
- Product Code Name

### FDA Listing
- FDA Listing Number

### Premarket
- Device Exempt from Premarket Submission
- FDA Premarket Submission Number
- Supplement Number

### GMDN (Global Medical Device Nomenclature)
- Code
- Name
- Definition

### Device Characteristics
- For Single-Use

### Production Identifier(s) on Label
- Lot or Batch Number
- Manufacturing Date
- Serial Number
- Expiration Date

### Latex Information
- Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)
- Device labeled as "Not made with natural rubber latex"

### Prescription Status
- Prescription Use (Rx)
- Over the Counter (OTC)

### MRI Safety Status
- Is the device labeled for MRI Safety?

### Clinically Relevant Size
- Size Type
- Size Value
- Size Unit of Measure
- Size Type Text

### Storage and Handling
- Storage and Handling Type
- High Value
- Low Value
- Unit of Measure
- Special Storage Conditions

### Sterilization Method
- Device Packaged as Sterile
- Requires Sterilization Prior to Use
GUDID-related Activities

1. Identify data locations, gaps, owners, formats – not all data will be in discrete, electronic format
2. Determine GUDID data submission method/tool
3. Collect, normalize, and validate source GUDID data
   - Will have to manually capture some data
   - Merge information from multiple sources
   - Normalize to business rules & controlled vocabularies
4. For Manual Entry: enter data via FDA GUDID Tool
5. For Automated Entry:
   - Create fully-valid SPL UDI submissions
   - Submit SPLs to FDA via ESG
GUDID Data Submission Models

- **Medical Device Labeler**
  - GUDID Submission Data
  - Tool Enhancement / Purchase
  - Mgmt’t

- Data Entry
- FDA GUDID Web Interface
- Hosted (SaaS) Tool
- Outsourced Service
- DB

- GUDID data at FDA
- SPL

- SaaS – Software as a Service

Compliments of Reed Technologies
Compliance Dates

Implementation (compliance) timeframes – September 24:
— 2014: class III and devices licensed under PHS Act
— 2015: class II/I implants and life-supporting/sustaining
— 2016: rest of class II
— 2018: class I

For Direct Marking:
— Compliance dates are extended by 2 years
— except for FDASIA (year 2) devices – still at year 2.
Conforming Amendments

Adds to each the requirement to use UDI:
• Part 803 – Medical Device Reporting
• Part 806 – Reports of Corrections And Removals
• Part 810 – Medical Device Recall Authority
• Part 814 – Premarket Approvals
• Part 820 – Quality System Regulation
• Part 821 – Medical Device Tracking Requirements
• Part 822 – Postmarket Surveillance
Other Issues to Consider

• Global landscape
• Private label – both for you and for others
• DUNS numbers (same product – multiple facilities)
• Packaging hierarchy
• MDM: locate, control, cleanse, transform, validate, load
• Accessories vs spare/service parts
• Classification vs premarket path
• Class II OTC
Thank you!

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