UDI 101:
What You Need to Know About Unique Device Identifiers

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Presentation Objectives:

- Understanding the Problem
- Finding a Solution
- Implementing the Solution
- Impact to Quality
- Challenges Faced

Understanding the Problem

PROBLEM #1:

- similar/like products made by different manufacturers
  - made it difficult to quickly & definitively identify a device and its key attributes
    - caused confusion in the supply chain
      - and caused medical errors resulting from misidentification of a device or confusion about its intended use

Understanding the Problem

PROBLEM #2:

- data contained in adverse event reports was not centrally contained and wasn't easily or quickly extracted
  - difficult to pinpoint the particular device at issue
    - unable to identify the underlying problems or recurring problems
      - resulted in ineffective and/or inappropriate corrective actions

Did You Know?
From 2005-2009, the FDA received an average of 492,000 adverse event reports for devices each year.

Understanding the Problem

PROBLEM #3:

- adverse event reports can come from multiple sources and often lack accurate and/or essential information
  - reviewing of reports to find missing information and resolving inconsistencies was time consuming
    - resulted in slow & inefficient resolution of device recalls

Did You Know?
Between 2005-2009, more than 17,700 adverse event reports involved a death.

Understanding the Problem

PROBLEM #4:

- Devices were not always easily identifiable after being removed from their packaging
  - led to loss of identification & traceability of reusable devices
    - caused cross-contamination concerns & uncertainty
      - unhappy & unhealthy patients

Did You Know?
Between 2005-2009, more than 283,000 adverse event reports involved an injury.

Finding a Solution

2005

- CDRH meets to discuss UDI
- Issues White Paper

2006

- Public Notice of UDI Issued
- Comments requested
- Formal request sent to FDA by healthcare industry

2007

- FDAAA
- Requires FDA to issue regulations establishing a unique device identification system for medical devices

Finding a Solution

2009

- Comments submitted by healthcare industry are published

2012

- FDASIA
- Directed the FDA to establish implementation timeframes for UDI
- UDI Proposed Rule published
- 77 FR 4073

2013

- Sep 24, 2013: Final Rule published
- 78 FR 58786
- FDA issues draft guidance for GUDID

Implementing the Solution

A unique numeric or alphanumeric code consisting of 2 parts:

Device Identifier (DI)

\+ Production Identifier (PI)

Unique Device Identifier (UDI)

Implementing the Solution

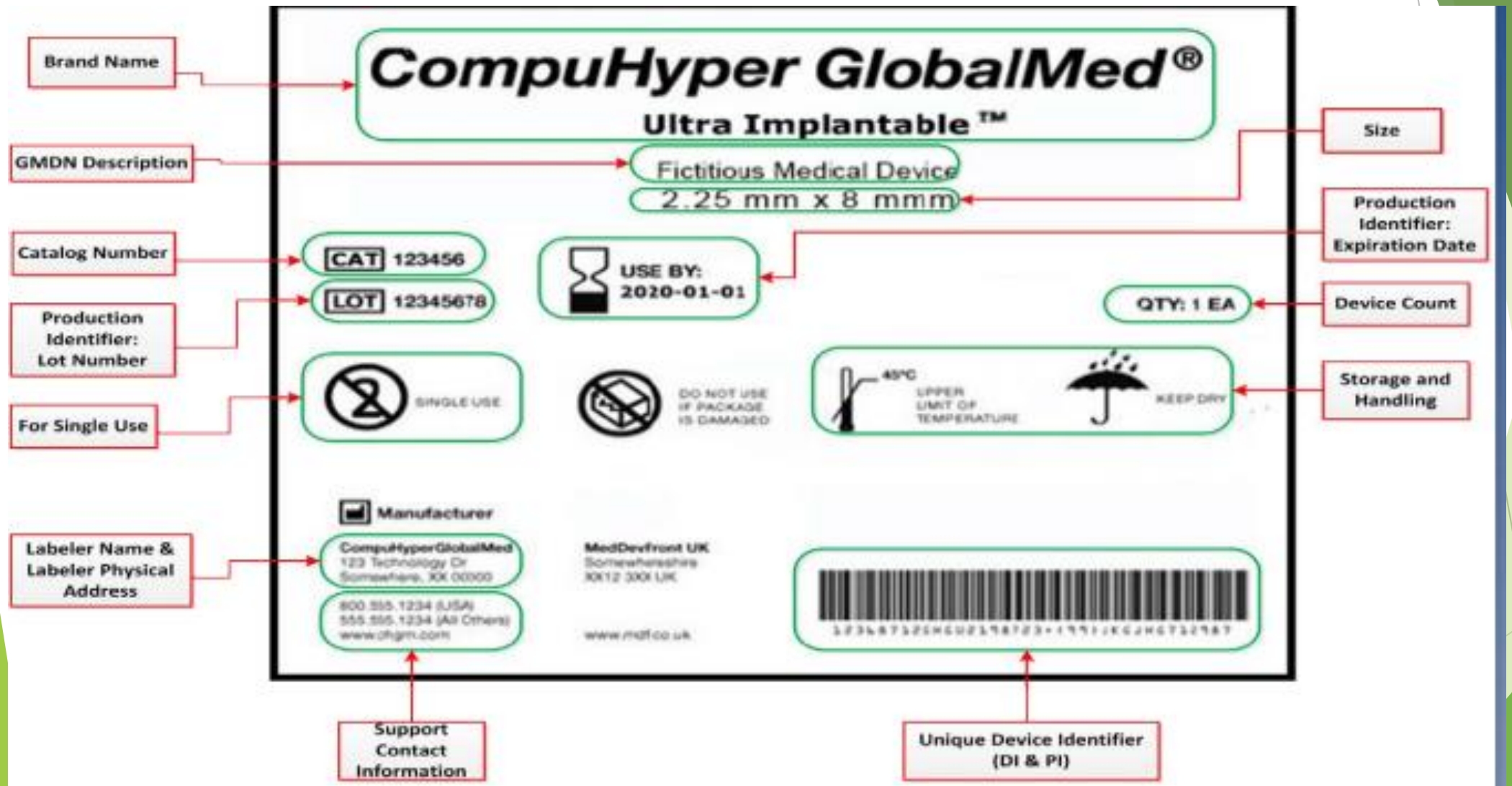
DI = the fixed portion of the UDI

Contains:

- Labeler Information (company prefix)
- Version/Model of Device
- Static data

Critical for IDENTIFICATION of DEVICE

and the DEVICE LABELER


Brand Name
CompuHyper GlobalMed®
Ultra Implantable™
GMDN Description
Fictitious Medical Device
Size
2.25 mm x 8 mmm
Catalog Number
CAT 123456
USE BY:
2020-01-01
Production Identifier: Expiration Date
Production Identifier: Lot Number
LOT 12345678
QTY: 1 EA
Device Count
For Single Use
SINGLE USE
DO NOT USE IF PACKAGE IS DAMAGED
45°C
UPPER LIMIT OF TEMPERATURE
KEEP DRY
Storage and Handling
Manufacturer
Labeler Name & Labeler Physical Address
CompuHyperGlobalMed
123 Technology Dr
Somewhere, XX 00000
800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com
MedDevfront UK
Somewhereshire
XX12 3XX UK
www.mdf.co.uk
Support Contact Information
Unique Device Identifier (DI & PI)

Implementing the Solution

PI = the variable portion of the UDI

Contains:

- Lot/Batch/Serial Information
- Expiration Date
- Manufactured Date
- Conditional data

Critical for TRACEABILITY of DEVICE to the PATIENT LEVEL

Implementing the Solution

GUDID = the FDA-administered database

- Global Unique Device Identification Database
- Contains a standard set of basic identifying elements for each device (DI portion on barcode)
- GUDID information does not contain patient information
- HL7 SPL Submissions OR manual submissions via the GUDID Web Interface

http://accessgudid.nlm.nih.gov/

IDENTIFICATION

- Pri DI Issuing Agency
- Primary DI #
- Brand Name
- Version / Model #
- Catalog #
- Device Description
- Sec DI Issuing Agency
- Secondary DI #
- DM Exempt (Y/N)
- DM DI Different (Y/N)
- DM DI #

LABELER

- Labeler DUNS #
- Labeler Name*
- Labeler Address*
- Contact Phone
- Contact E-mail

REGULATORY

- Publish Date
- Distribution End Date
- Distribution Status*
- Premrkt Exempt (Y/N)
- Premrkt Submission #
- Supplement #
- FDA Listing #
- Product Code
- Product Code Name*
- GMDN Code
- GMDN Code Name*
- GMDN Code Definition*
- RX (Y/N)
- OTC (Y/N)

PACKAGING

- Device Count
- Unit of Use DI #
- Kit (Y/N)
- Pkg DI #
- Pkg Quantity
- Pkg Contains DI #
- Pkg Type
- Pkg Discontinue Date
- Pkg Status*

PRODUCTION CONTROL

- Lot/Batch # (Y/N)
- Serial # (Y/N)
- Mfg Date (Y/N)
- Expiration Date (Y/N)
- Donation ID # (Y/N)

CHARACTERISTICS

- Single Use (Y/N)
- Combo Product (Y/N)
- HTC/P (Y/N)
- Labeled "Contains Rubber" (Y/N)
- Labeled "Not Made with Rubber" (Y/N)
- MRI Safety (Y/N)
- Size Type
- Size Value
- Size Unit
- Size Text
- Storage & Handling Type
- S & H Low Value
- S & H High Value
- S & H Unit
- Storage Conditions
- Sterile Pkg (Y/N)
- Sterile Req'd (Y/N)
- Sterile Method

REED TECH

Implementing the Solution

A UDI must…

be issued by an FDA-accredited issuing agency

- GS1
- HIBCC (Health Industry Business Communications Council)
- ICCBBA (International Council for Commonality in Blood Banking Automation)

Implementing the Solution

GS1

- (AI) codes = Application Identifiers
- Used to identify different pieces of data
  - (01) = GTIN (Global Trade Identification Number)
  - (10) = Lot/Batch Number
  - (17) = Expiration Date

http://www.idautomation.com/barcode-properties/definitions/gs1-application-identifiers.html

http://www.gs1.org/healthcare/udi

Implementing the Solution

HIBCC:

- “+” indicates HIBC barcode structure
- Primary Data Structure includes:
  - LIC = Labeler Identification Code (4 characters)
  - PCN = Product/Catalog Number (1-13 characters)
  - U/M = Unit of Measure Identifier (1 digit)
- Secondary Data Structure may include:
  - Quantity/Date Fields
  - Lot/Batch/Serial Number fields
  - Link Character

http://www.neodynamic.com/Products/Help/BarcodeWPF4.0/barcodes/HibcLic128.htm

http://www.hibcc.org/udi-resources/

Implementing the Solution

ICCBBA

- ISBT 128
  - Global standard for the identification, labelling, and information transfer of medical products of human origin

https://www.iccbba.org/isbt-128-basics/basic-educational-materials/basic-factsheets2

Implementing the Solution

A UDI must…

be presented on the label in two formats

- Human-readable (plain text)
- Automatic identification and data capture (AIDC)

Implementing the Solution

Direct Parts Marking (DPM)

UDI must be marked directly on a device that is:

- Intended for more than one use
- Intended to be (re)processed before each use

Date Formatting

Dates on device labels must be in a standard format consistent with international standards and practice

- YYYY-MM-DD

(ISO 8601)

Implementing the Solution

2014

- **June 27, 2014** FDA publishes finished guidance for GUDID
- **Sept 24, 2014** Class III device deadline for labels, packaging & GUDID Data

2015

- **Sep 24, 2015** Implantable, life-supporting & life-sustaining devices deadline for labels, packaging & GUDID Data

2016 - 2020

- **Sep 24, 2016** DPM for Class III
- **Sep 24, 20xx** Phased in deadlines for remainder of devices by risk classification

Impact to Quality of Healthcare

- More accurate reporting of Adverse Events
- Reduce medical errors by allowing more rapid & precise device identification
- Clear method of documenting device use in electronic health records, clinical studies, claim data sources, and registries
- More effective recall management
- Improved supply chain security & efficiency

Impact to Quality of Data

- Manufacturers have to identify all data sources and develop processes for Master Data Management
- Medical device data attributes required for the GUDID are leading to improved data standards across the industry
- Global harmonization of UDI regulations will lead to standardization

Impact to Quality

Barcode Standards

- ISO/IEC 15416 (linear) & ISO/IEC 15415 (2D)

  define the quality requirements for linear barcodes and 2D matrix barcodes

- ISO/IEC 15426-1 (linear) & ISO/IEC 15426-2 (2D)

  define the measuring accuracy of a barcode verifier

- ISO/IEC TR 29158

  Direct Parts Marking standard still under development

  (TR = Technical Report)

Challenges Faced

Long Implementation

- 8 years: IDEA to REQUIREMENT
- 7 years: REQUIREMENT to IMPLEMENTATION
- ?? years: IMPLEMENTATION to USE
- ?? years: USE to RESULTS

Transition of Inventory

- 36 hospitals = 3 million devices
- 10% addition/replacement of devices per year
- 50 years to complete the inventory transition

Challenges Faced

- No requirement for healthcare facilities to use UDI
- 3 issuing agencies with 3 different barcode scanners
- Cost of implementation to manufacturers
- Label Space vs Content Requirements
- Data quality
- Differences in interpretation of requirements
- Healthcare Networks requiring compliance prior to FDA deadlines
- Technical issues with GUDID and HL7 SPL configurations

What's Next?

We have:

- Regulation for manufacturers requiring the UDI on devices
- Standards for industry to create uniform & reliable barcodes
- Timelines for implementation

We don't have:

- Regulation for healthcare facilities to use the UDI*
- Standards or guidelines to help facilities implement UDI
- Timelines for implementation

Have Questions? Need Help? Want to Say Hi?

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“Quality in Everything”

Resources

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification
- http://www.gs1.org/healthcare/udi
- http://www.fda.gov/downloads/Training/CDRHLearn/UCM379672.pdf