NAMSA®

Experience the Difference with the MRO™ Approach

FDA Guidance Hot Topics: Unique Device Identifier

AMDM-2013 IVD Focus Meeting

October 25, 2013

Valynda Machen, CQA, RAC
Medical Research Manager

NAMSA®

Agenda

- Background/History
- UDI Defined
- How to Create a UDI
- Where to Apply the UDI
- Exceptions
- How to Submit to the GUDID
- When Do I Need a New UDI
- Compliance Timelines
- Implementation Strategies

NAMSA®

Background/History

Background/History

- 2005 IOM Report
- 2007 FDA Amendments Act of 2007
- 2012 July 10: UDI Proposed Rule published
- 2012 July: FDASIA provisions added
- 2012 Nov 7: Original comment period closed
- 2012 Nov 19: FDASIA amendment published
- 2012 Dec 19: FDASIA comment period closed
- Then, we waited…
- And then….

NAMSA®

UDI Final Rule is Released!

September 20, 2013,

UDI Conference

- Jay Crowley

NAMSA®

UDI Benefits

- Reduce medical errors
- Simplify the integration of device use information into data systems
- More rapid ID of medical devices with AEs
- More rapid development of solutions to reported problems
- More rapid, more efficient resolution of device recalls
- Better focused more effective FDA safety communication

UDI Benefits

- Improve security of distribution chain
  - Better detection of counterfeit devices
  - ID alternatives in the event of shortages
- Document devices in EHRs and clinical info systems
- Development of medical ID system recognized world wide

"UDI represents a landmark step in improving patient safety, modernizing our postmarket surveillance system for medical devices, and facilitating medical device innovation."

Jeffrey Shuren, M.D., J.D., Director of FDA CDRH

UDI Defined

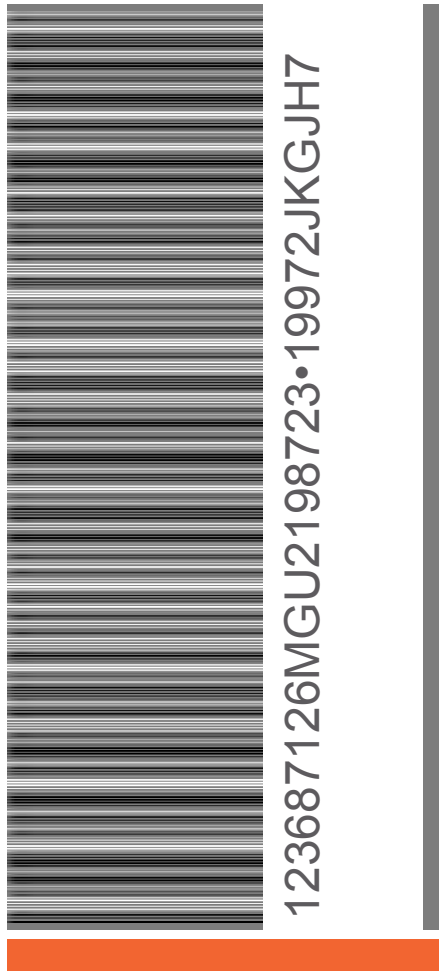
NAMSA®

UDI Defined

- 21 CFR 801.3: …an identifier that adequately identifies a device throughout its distribution and use…
- Two parts (21 CFR 801.40):
  - Device Identifier (static): version/model and labeler
  - Production Identifier: variable
    - Lot/batch
    - S/N
    - Expiration date/manufacturing date
    - HCT/P identification code
    - …when included on the label of the device
  - UDI = DI + PI

UDI Defined

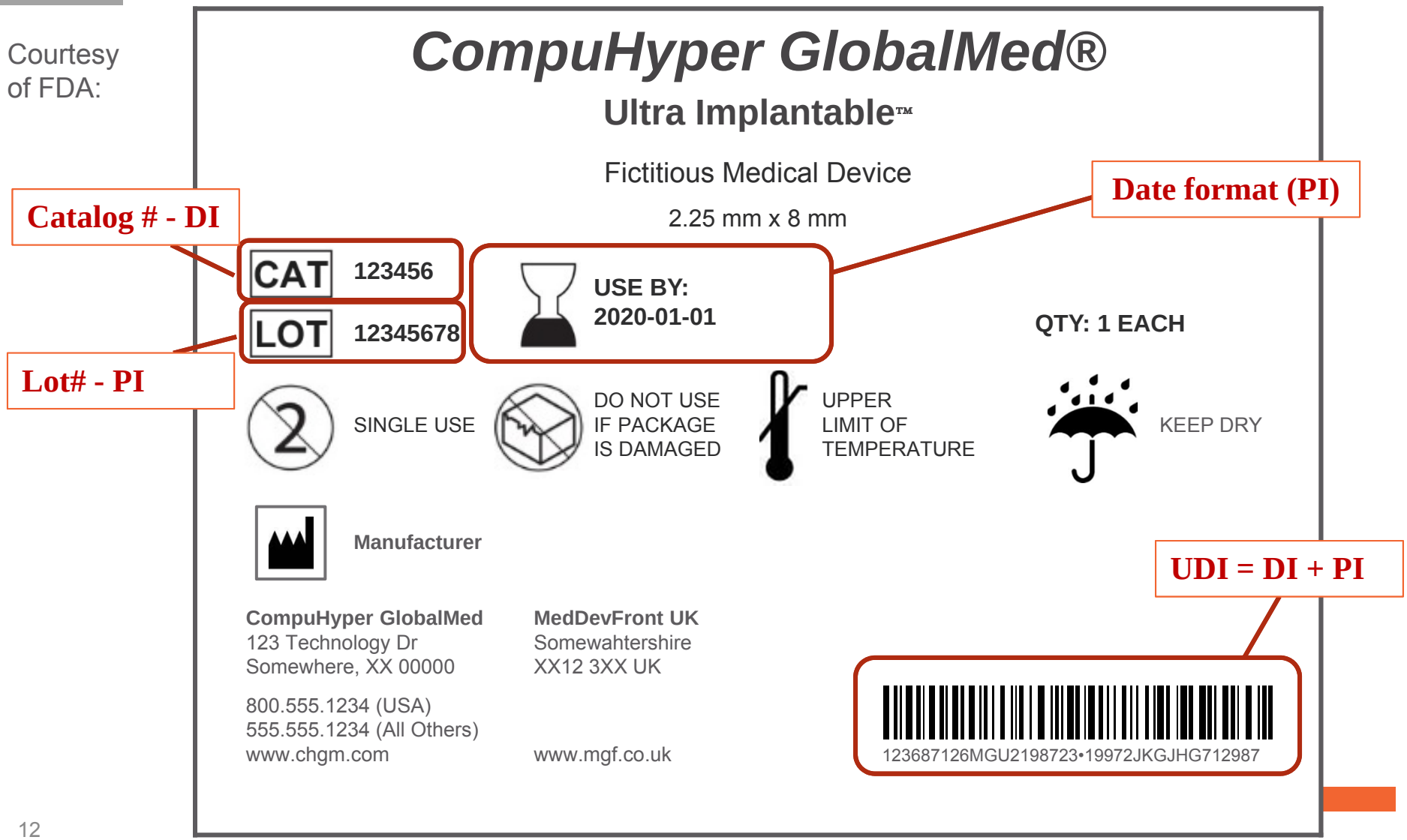
- Human Readable Form AND
- AIDC format (technology neutral)
  - Linear/2-D barcodes, RFID
  - No special symbol required (21 CFR 801.40(c)
- Date format: YYYY-MM-DD (21 CFR 801.18)
  - ISO 8601 alignment, but
  - Must include day
  - Implement date format change by compliance date
  - Applies to all labels (even if exempt from UDI)
    - UDI exempt devices must implement date by 9/24/18



NAMSA

UDI Defined

Courtesy of FDA:



UDI Defined

- Labeler: 21 CFR 801.3
  - Responsible for UDI application
  - Applies/replaces/modifies label
  - Intent of commercial distribution
  - Except: Adding name/contact info
    - No other changes to label

UDI Defined

- Applicable to IVDs? YES
  - IVDs regulated as medical devices
  - UDI applies to medical devices
  - UDI applies to IVDs
  - 21 CFR 801.119
- Global impact? YES
  - Not a US specific requirement
  - IMDRF guidance expected soon

NAMSA®

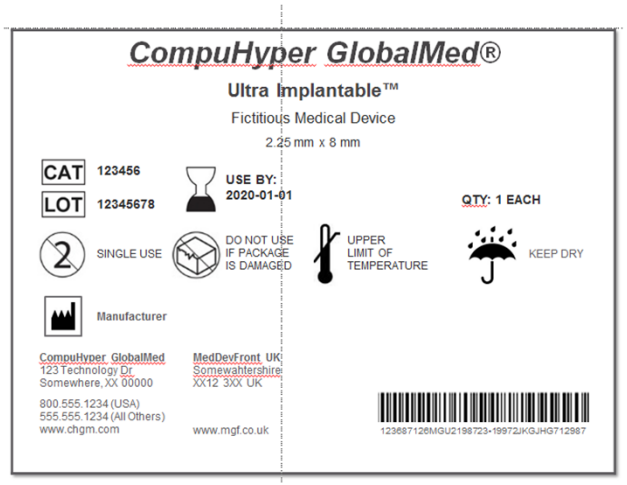
How to Create a UDI

NAMSA®

How to Create a UDI

- FDA Accredited Issuing Agencies
  - 21 CFR 830.100
  - ISO 15459
  - GS1/HIBCC/ICCBBA expected to be accredited
    - ICCBBA: Tissue products regulated as devices-need to know donor info
  - Choose agency/agencies
- Create and maintain UDI according to the standards
  - FDA not responsible for creation/maintenance
  - DIs can never be reassigned

Where to Apply the UDI



- Base package
  - Default location is label
- Subsequent saleable configurations
  - Box of 4 kits
  - Carton of 10 boxes
  - Shipping container does not require UDI
- Individual single use devices exemption (band-aids)
  - 21 CFR 801.30(a)(3)
  - Stored in device package
  - Not intended for individual sale
  - Device package contains UDI

Where to Apply the UDI

- IVD Kit Exception [21 CFR 801.30(a)(11)]
  - Only need UDI on kit box
  - Not individual kit components
    - Unless sold separately

Where to Apply the UDI

- Stand Alone Software (21 CFR 801.50)
  - UDI of S/W must be available to user
    - Label/package (if exists)-plain text and AIDC format AND Help/About Screen in plain text
    - No label-Help/About Screen in plain text
    - Compliance dates same as other devices

Exceptions (21 CFR 801.30)

- ☑ No PI for Class I devices
- ☑ GMP-exempt Class I devices
- ☑ Existing packaged/labeled inventory-3 years from compliance date
- ☑ Shipping containers
- ☑ Kits
- ☑ Single use devices distributed/stored together
- ☑ Those Class III devices granted 1 year exception

Exceptions (21 CFR 801.30)

- ☑ Class I devices with UPC
- ☑ Investigational device
- ☑ Custom device
- ☑ Veterinary device
- ☑ Export device
- ☑ Research Use Only
- ☑ Strategic National Stockpile
- ☑ DPM compliance dates-extended 2 years, except for FDASIA requirements

Exception/Alternate Placement Process

- 21 CFR 801.55
- FDA can initiate/grant exception on their own
- Can grant exception in response to labeler request
- Can rescind exceptions in the future
- Exceptions posted on website
- Anyone can take advantage of listed exceptions
- FDA to act on requests within 30 days

How to Submit to the GUDID

NAMSA®

How to Submit to the GUDID

- Global Unique Device Identification Database
  - Reference catalog for each device with a UDI
  - FDA administered
  - Public/searchable (search currently disabled)
    - Quick Search: DI, Company Name, Brand Name, Version, Model
    - Advanced Search: Any GUDID attribute
    - Database downloads (future)
  - Access initially limited to Class III/PHS Act devices

How to Submit to the GUDID

- Three ways to enter data
  - Secure, online web interface
    - 1 entry at a time
  - Health Level 7 (HL7) Structured Product Labeling (SPL) submission
    - xml format-multiple entries at a time
    - Need Electronic Submissions Gateway (ESG) account
  - 3rd party solution providers
    - Data owner still responsible for data

How to Submit to the GUDID

- Need to ensure data entry is accurate
  - Draft → Unpublished → Published
  - FDA to review data submissions and ask for changes
  - "Appears to be incorrect"
  - 10 days to make changes or explain
  - FDA may delete/replace info
- Draft guidance: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

How to Submit to the GUDID (cont.)

- Must have GUDID account
  - Need D&B DUNS number(s)
  - Need to assign “regulatory contact”
- Submit Device Identifier info only (no PI)

Required DI Information for GUDID

- ☑ Proprietary/brand/trade name
- ☑ Version/model/catalog number
- ☑ Previous DIs
- ☑ Size
- ☑ Type of PIs on label
- ☑ FDA premarket submission number
- ☑ FDA listing number
- ☑ GMND term
- ☑ FDA procode(s)

Required DI Information for GUDID (cont.)

- ☑ # of devices in each package
- ☑ Commercial distribution status
- ☑ Higher levels of packaging
- ☑ Kit/combination product info
- ☑ HCT/P info
- ☑ Sterile/sterilization required
- ☑ Latex
- ☑ MRI compatibility
- ☑ Rx/OTC status
- ☑ Direct marking info

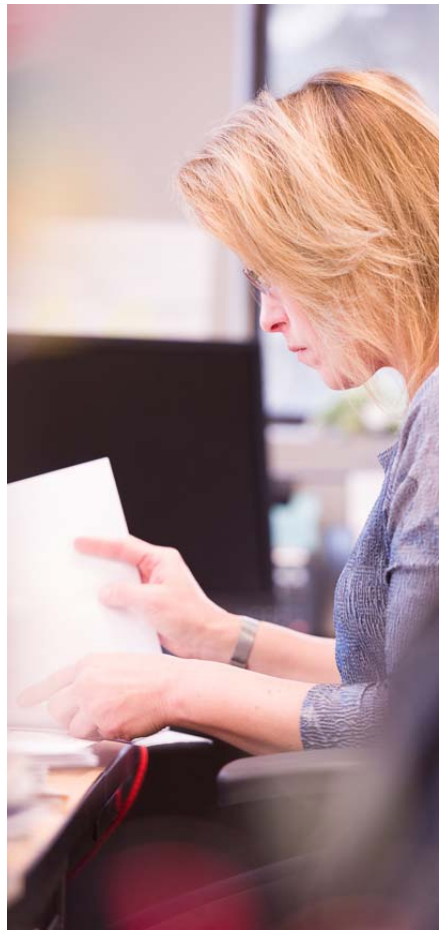
When Do I Need a New UDI

- 21 CFR 830.50
- Very different from proposed rule
  - "Impact to S&E"
- No relationship to premarket requirements in final rule
- New UDI needed whenever
  - Change to device results in new version/model
  - Creates a new device package

Compliance Timelines

Compliance Timelines

- Terminology change: not “effective dates”
- Implementation based on device classification



NAMSA®

Compliance Timelines

September 24, 2014 (Year 1)

- Class III Devices
- Devices under PHS Act
  - Donor screening assays
- Class III Stand Alone S/W
- Labels and packages contain UDI
- New date format
- Submitted to GUDID

NAMSA®

Compliance Timelines

September 24, 2015 (Year 2)

- Class II/I implants and life-supporting/sustaining devices
  - See final rule for list-Reference 12
  - Labels and packages contain UDI
  - New date format
- DPM for life supporting/sustaining
  - Reuse/Reprocessed
  - No 2 year grace period for DPM (FDASIA)
- Life-supporting/sustaining stand alone S/W UDI
- Submitted to GUDID

Compliance Timelines

September 24, 2016 (Year 3)

- Remainder of Class II
  - Labels and packages have UDI
  - New date format
  - Stand alone S/W UDI
- Class III DPM reused/reprocessed
- Submitted to GUDID

Compliance Timelines

- September 24, 2018 (Year 5)
  - Class I and Devices Not Classified
    - Labels and packages have UDI
    - New date format
    - Stand alone S/W UDI
    - Submitted to GUDID
  - Class II DPM reused/reprocessed
  - Date format for UDI exempt
- September 24, 2020 (Year 7)
  - Class I DPM reused/reprocessed

Compliance Timelines-Exceptions

- Class III/devices licensed under PHS act
  - Potential 1 year extension
  - “best interest of public health”
  - Process defined in final rule (21 CFR 801.55)
  - Must submit request by June 23, 2014
- Finished devices/existing inventory [21 CFR 801.30(a)(1)]
  - Manufactured/labeled prior to compliance date
  - 3 year exception to compliance date
  - Allows depletion of existing inventory
- Two years extension for DPM-except for FDASIA (Year 2) devices

Companion Amendments

- 21 CFR 801: Labeling
- 21 CFR 803: Medical Device Reporting
- 21 CFR 806: Corrections and Removals
- 21 CFR 810: Recall Authority
- 21 CFR 814: Annual Reports
- 21 CFR 820: Quality System Regulations
  - 21 CFR 820.120: Device Labeling
  - 21 CFR 820.184: Device History Record
  - 21 CFR 820.198: Complaint Files
  - 21 CFR 820.200: Servicing
- 21 CFR 821: Device Tracking
- 21 CFR 822: Postmarket Surveillance

Contacting FDA

- FDA UDI Website: www.fda.gov/UDI
- FDA UDI help desk

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm

- FDA ESG questions
  - Policy: esgprep@fda.hhs.gov
  - Technical questions: esgreg@gnsi.com

NAMSA®

Implementation Strategies

Implementation Strategies

- It takes a village
- Not a 1 time labeling project
  - New cross functional business process
  - On-going activity/maintenance
  - Information must be current/accurate
  - Data identification and management is critical
    - Many attributes for each UDI-data quality is key
  - Need to determine owner: business specific
  - Need to start now
    - Timeline-clock is now ticking
    - ID all needed resources
    - Don’t underestimate the complexity

NAMSA®

Thank you

NAMSA
Headquarters
6750 Wales Road
Northwood, OH 43619 USA

Telephone:
866.666.9455 (toll free)
+1 419.666.9455 (outside of USA)
+1 419.662.4386 (fax)
info@namsa.com

» For more information, please contact:

Valynda L. Machen, RAC
Medical Research Manager

Phone: 763.287.3830

Email: vmachen@namsa.com

NAMSA®

NAMSA

Beyond Contract Research, NAMSA is a Medical Research Organization with more than 600 Associates dedicated to translating great ideas into marketed medical products.

- Medical Devices
- Combination Products
- *In vitro* diagnostics (IVDs)
- Regenerative Medicine

Backup Slides

Combination Products

- UDI on combination product required
  - Device constituent parts exempt
- Combination product labeled with NDC # is exempt
  - Device constituent parts must have UDI
  - Unless combination product is a single entity, then parts are exempt

Direct Part Marking

- 21 CFR 801.45
- No requirement for implant DPM
- Devices intended for reuse and to be reprocessed between use
  - Cleaned/Disinfected/Sterilized
  - No DPM requirement for single use devices
- DPM either/or plain text, AIDC

Direct Part Marking (cont.)

- Exceptions
  - DPM interferes with S&E
  - Not technologically feasible
  - Previously marked
  - Document in DHF
- Compliance dates extended 2 years, except for FDASIA (Year 2)

NHRIC/NDC Numbers

- 21 CFR 801.57
- Can no longer be used
- Numbers rescinded in 5 years
- NHRIC labeler codes can continue to be used
  - Need to notify FDA within 1 year