OMTEC 2015

UDI: The Ins and Outs of Global Compliance and Value

www.OMTECexpo.com
UDI: The Ins and Outs of Global Compliance and Value

Karen Conway
Executive Director
GHX

Jay Crowley
Vice President
USDM

OMTEC 2015
Introductions

Jay Crowley
VP of UDI Solutions and Services, USDM Life Sciences

At USDM Life Sciences, Crowley focuses exclusively on providing business process, technology and compliance solutions for the regulated life science industry. Prior to his current role, Crowley served as Senior Advisor for Patient Safety in FDA’s Center for Devices and Radiological Health, where he developed the framework and authored key requirements for the UDI system. Crowley held a variety of positions over his nearly 27 years at FDA, including work with design control regulations to reduce the chance of human errors with medical devices, patient safety and adverse event reporting.
Karen Conway, CMRP
Executive Director, Industry Relations, GHX

Karen Conway works internationally with standards bodies, government, analysts, academic researchers, trade associations, hospitals, healthcare systems and suppliers to optimize clinical and business performance through supply chain excellence. Conway’s work related to UDI is focused on how manufacturers and providers can realize value beyond compliance, including real world data on product performance, increased supply chain efficiencies, and the ability to sell and source products that improve both the cost and quality of patient care.
UDI: Why?

Preventable Medical Errors and Device Recalls
UDI: What?

** UDI = DI + PI

DI = Device Identifier (static industry-standard product identifier)
PI = Production Identifier (variable info, such as Lot, Expiry)

Device Identifiers
- GS1 GTIN
- HIBCC LIC
- ICCBBA

Text + Barcode
DI + PI **

Label every fixed packaging level

Direct mark some products

Load GUDID
----------------
Publish data attributes to the “Good-ID”
UDI Compliant Label: GTIN as a Linear Barcode

Device Identifier (GTIN)

Production Identifier
UDI Compliant Label:
GTIN as a Concatenated Barcode
UDI Compliant Label: HIBC-LIC Linear Barcode

Device Identifier (HIBC-LIC)

Production Identifier
UDI Compliant Code: ISBT as 2D Matrix Barcode

ICCBBA standard used for products of human origin
UDI Compliant Code: ISBT as 2D Matrix Barcode

ICCBBA standard used for products of human origin
UDI: When?

Risk-based Compliance Deadlines

September 24, 2014 - Class III devices/those licensed under PHS Act

September 24, 2015 - “…devices that are implantable, life-saving, and life sustaining” (FDASIA)

September 24, 2016 – Balance of Class II devices

September 24, 2018 – non-exempt Class I devices, unclassified

Direct Marking:

- Compliance dates are extended by 2 years, except for FDASIA (year 2) devices – still at year 2.
UDI: Where?

Global Initiative: Global Compliance

- International Medical Device Regulatory Forum
  - Objective: A single, globally harmonized system for positive identification of medical devices.
  - Members US, Europe, Japan, Canada – and AHWP
  - Latest Guidance Available at: [www.imdrf.org/consultations](http://www.imdrf.org/consultations)

**Regulations Under Development:**

- Canada
- European Union
- China
- South Africa
UDI: Who?
Manufacturers of medical devices sold in the United States

UDI: Who else?

Hospitals
Physicians
Payers
UDI and Meaningful Use

ONC and CMS Proposals

– Create a list of a patient’s implantable devices in the EHR
– Parse the device identifier and production data, (e.g., lot, serial number, expiry date) from the UDI
– Link to the Global UDI Database (GUDID) to retrieve additional device information
– Add the UDI to the CCDS to enable the list of implanted devices to be exchanged as part of a patient’s core medical history
US FDA UDI Rule Intent/Objective

- Administrative and Claims Data
- Evidence Generation Synthesis + Appraisal
- Modernize Reporting + Analysis
- National + International Device Registries
- UDI Incorporated into EHI
- Other Tools
- FDA Discretionary Studies
- Medical Device Reporting (MDR)
- Medical Product Safety Network (MEDSUN)
- Postmarket Surveillance Studies (522 Studies)
- Post-Approval Studies

© Copyright 2015 by USDM Life Sciences
From Intent to Compliance to Value

Penalties for failure to meet UDI requirements:

Devices for which there has been a failure or refusal to furnish any material or information required...are misbranded... and... is a prohibited act... Potential enforcement actions for violations of the UDI requirements include recall, seizure, injunction, and civil and criminal penalties.
From Intent to Compliance to Value

What is a Medical Device?

A device is ... "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals...."
Who is the “labeler”...?
Who is the “labeler”...?

• How does this affect your OEM/private label/contract manufacturing relationships?
• Who will have responsibility for which parts?
• What will this look like in the GUDID?
• How will this play out globally?

“Labeler” is any person who causes a label to be:
• applied to a device with the intent that the device will be commercially distributed; or
• replaced or modified with the intent that the device will be commercially distributed.
Who is the “labeler”…?

• EU definition “The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the Community market "under his own name" (or trademark).

• GHTF/IMDRF definition of manufacturer – “...any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).”
How do you label/package it?

• Where is the “label” (regulatory concept)?
• Is date in standard format – *even exempt levels/devices*?
• How many label templates do you have? Are any labels produced off-site?
• *Do you need UDI on label/package below the orderable/shippable unit?*
• How many levels of packaging do you have?
• Are you packaging the same device in different packages?
• Are you applying UDI the same/different than others?
Do you have quality barcodes?

• Deconstruct barcode – correct and formatted data.
• All issuing agencies require barcode quality of grade C or better.
• You need barcode verifiers!
• The rule ... amends the Quality System Regulation by requiring examination of the accuracy of the UDI as part of the scope of the labeling inspection, that the device history record include any UDI ...
Direct Marking (DM UDI)

• In addition to the label requirement – a “permanent marking” UDI is required on the device itself if:
  “...the device is intended to be used more than once and intended to be reprocessed before each use.”
• DM DI can be same of different as label DI.
• Can be AIDC or HRI – or both.
• DM Exceptions part of rule – manufacturers document in DHF.

DM is NOT required for implants – therefore exemptions not relevant.

Need to understand the difference between the UDI Label and the Direct Marking requirement!
“Convenience” Kit Exception

But... UDI on kit/CP assumes that:

• Manufacturer has traceability/visibility into all of the components
• All of the components are consumed (or discarded) when opened/used

If not – then need to reconsider use of kit exception (at least for some components)

• “Orthopedic procedure kits are a well-known example of a medical procedure kit.”
Existing Inventory Exception

• For finished devices manufactured, packaged and labeled prior to compliance date
• Existing inventory – regardless of where it is located
• Consignment is considered your inventory
• +3 years past applicable compliance date to distribute/use without being UDI compliant

Any device still in inventory after 3 years can NO longer be distributed – must be reworked (relabeled) or destroyed. Becomes a “new” device.

BUT – need process to identify and manage inventory
What is a Reprocessed Device...?

A reprocess device is one that is initially supplied:
• As sterile and requiring the end user to process the device after initial use (i.e., cleaning and disinfection or sterilization) prior to the subsequent patient use. 
• As non-sterile to the end user, and requiring the end user to disinfect or sterilize the initial packaged device and to subsequently reprocess the device after initial use.
• As a non-sterile SUD to the end user, and requiring the end user to sterilize the device prior to its use.
Non-Sterile Implant Extension

- On 19 Nov 2014 – FDA extended the “point of use” label compliance date for many class II (FDASIA) non-sterile implants from 2015 to 24 Sep 2016
- GUDID submissions are still required in 2015.
- AdvaMed had requested or 2 additional years (2017). The unchanged GUDID date was a concession for the additional year for label requirements.
- “Most of the devices that meet these ... criteria are supplied non-sterile by the manufacturer” and are “intended to be sterilized (or cleaned and sterilized) before use.”
Extension Device Types

Applies to device that are:

• Class II FDASIA devices (otherwise applicable 24 September 2015)
• Implants (as classified by FDA), and
• intended to be sterilized (or cleaned and sterilized) before use.
Reiterated Purpose of UDI Rule

• In keeping with the purpose and intent of the UDI rule, FDA reiterated that “the goal is to establish a system for the adequate identification of medical devices through their distribution and use, via the entire supply chain to point of use with patients.”

• Also stated that UDI direct marking for implants was not included in the final rule “… because it was presumed that implants would be accompanied by their UDI label or package … up to the point of implantation.”
Purpose of Time Extension

• FDA recognized that “… [non-sterile, kitted orthopedic] implants … are separated from their original label and packaging [and kitted in a tray] in order to undergo cleaning and sterilization.”

• Therefore, FDA has provided “… additional time … to allow the affected labelers to develop and implement approaches that will help ensure that the UDI is available at the point of use”

• For labelers who have already implemented UDI, the extension would “… apply to the requirement to convey the UDI to point of use/implantation
Purpose of Time Extension

“FDA is initiating this extension to allow time for the development and implementation of an alternative that would provide for more accurate and precise device identification than the requirements of 21 CFR 801 subpart B.” [Labeling Requirements for Unique Device Identification – which requires the label of every medical device to bear a UDI]
Impacts

• The use of the UDI kit exception is effective only if a manufacturer has visibility and lot traceability of ALL implants within the tray to the “point of use/implantation”
• This establishes the need to ensure continued lot traceability for kitted implants
• Lot traceability for these implants has not been traditionally maintained:
  a) For field replenished – because of lack of rep transaction discipline and/or unreadable or no etched lot number
  b) For DC/manufacturer replenished – when the lot number is not etched on the implant itself:
    • Lot # can only be identified at the time of replenishment
    • Returned implants cannot be verified during inspection
Assumptions

A manufacturer wishes to continue to:
• distribute products (e.g., non-sterile) as is done today,
• use the existing trays and caddies,
• allow field replenishment, and
• use existing processes and systems to manage all of this
Manufacturers’ Direction

Most are struggling (especially with field replenishment) – unless they:
• Always have their sets (trays/caddies) returned to them after each procedure – such that they can assess what has been used (and compliant if they have lot traceability),
• Use (or are moving to) sterile packaging,
• Are Medtronic – with their trademarked tag system and associated redesigned trays and caddies,
• Use Direct (Part) Marking (the complete UDI), or
• Use some sort of matrix or implant/inventory mapping and recording model (using sheets or similar with barcodes to represent devices in the tray) – without field replenishment.
Field Replenishment

Requires some sort of inference/transaction model that can accurately capture the specific UDI of both:
1. The individual implants that have been used, and
2. The subsequent replenished implants.

Important Definitions:
- **Consignment** – A set owned by the manufacturer but resides in the hospital or field; it will return to the point of origin (hospital/field) after use.
- **Equity** – A set purchased by a hospital and is their property.
- **Loaner** – A set owned by the manufacturer and distributed to a hospital; it will return to the manufacturer after usage.
More on challenges related to non-sterile implants tomorrow at OMTEC

11 am
Session Room 49
From Compliance to Value

How can I leverage UDI to:

• Increase operational efficiency
• Improve demand planning
• Improve customer service
• Streamline recall management
• Design a better product
Implantable Device Supply Chain is a $5B+ annual problem – shared equally by manufacturers and providers

Sources: PNC Healthcare; GHX Quantitative Research Study (Aug 2010; n=136 & n=25)
The GUDID is Open for Business
Your Data’s in Demand: Can You Supply It?

- **DB1**
- **DB2**
- **DB3**
- **DB4**

- **Product Data / Product Changes**
- **Internal Processes / Approvals**
- **Regulatory Submissions**
- **Market / e-commerce Data**

- **US Providers**
- **Group Purchasing Org’s**
- **Global Providers**

- **FDA**
- **Global Regulators**

- **New Geographies**
UDI is only a Key

- Procurement
  - Manufacturer
  - Device Identifier
  - Price

- Inventory; Logistics
  - Physical Size
  - Clinical Size

- Commercial Databases
  - Manufacturer
  - Device Identifier
  - Price

- Regulatory Databases
  - Lot #
  - Serial #
  - Expiration Date

- Financial Databases
  - UNSPSC
  - HCPCS
  - Clinically relevant attributes

- Clinical Databases
  - Physical Size
  - Clinical Size

- Sourcing; Reimbursement
  - Lot #
  - Serial #
  - Expiration Date

- Recalls; Comparative Effectiveness
If they use it, will you?

Are you ready to use demand data?
Full Circle Visibility

- Manufacturer designs and markets product
- Regulators and customers receive accurate information about product
- Product Purchased/Shipped/Received
- Demand and efficacy data available
- Product consumption documented at point of use in electronic patient record
- Product and clinical attribute efficacy understood; necessary actions taken
- Product data captured in registries

Visibility = Value
Questions?

Karen Conway
Executive Director
GHX
kconway@ghx.com

Jay Crowley
Vice President
USDM
jcrowley@usdm.com
View additional OMTEC 2015 presentations:

www.OMTECexpo.com