UDI Global Update

Medical Device
Supply Chain Council
May 2013

Karen Conway

UDI: A Global Issue

Regulatory bodies around the world are watching the US and beginning work on their own regulations

US FDA – final rule due this year
EU Commission - draft directive and vision for common UDI system
Other countries/regions – moving forward and/or discussing UDI

US and EU Following GHTF Guidelines

UDI: A Three-Part System

1. **Allocate the code to covered products at each UOM**
2. **Label the products with human and machine readable code or Direct Part Marking**
3. **Populate and maintain the UDI Database(s)**

International Medical Device Regulatory Forum (IMDRF) replaced Global Harmonization Task Force (GHTF)

Updating UDI guidance document

- Capital Equipment
- IVD Kits
- Non-IVD Kits
- Direct Part Marking
- Software

Comments accepted through July 31, 2013
Updated document by end of the year

http://www.imdrf.org/consultations/cons-udi.asp

US Regulatory Timetable

Proposed Timelines:

- **Final rule must be published within 6 months after end of comment period (FDASIA)**
- **Compliance Deadlines:**
  - **Class III devices –1 year after final rule***
  - **"*devices that are implantable, life-saving, and life sustaining*" – 2 years after final rule (FDASIA)***
  - **All other Class II devices – 3 years after final rule**
  - **Non-exempt Class I devices –5 years after final rule**

Amendment – as currently proposed- requires direct part marking for these categories 2 years after final rule

What's in that Second Bucket?

What items will be included in the group required to be in compliance 24 months after final rule?

Mostly Class II, but could be some class I

Proposed Product Types (sample)

- Catheters
- Surgical mesh
- Sutures
- Implantable staples
- Tubes (tracheal, bronchial)
- Infusion pumps
- Vascular clips

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UCM328694.pdf

GHX

Class I Product Exemptions

- Non prescription products (OTC) sold at retail establishments
- Individual, single use devices, of a single version or model, not intended for individual sale, that are distributed together in a single UDI-labeled package
- GMP-exempt Class I devices
- Devices used for research, teaching or chemical analysis and not for clinical use
- Devices intended for export from the U.S.
- Devices held by the National Strategic Stockpile

Class I devices do not require production data

GUDID: User Acceptance Testing

Conducted Fall 2012

Tested submission methods and attributes (Web Portal, HL7 SPL and GDSN)

Partial Attribute List used in UAT

- Device Identifier
- Brand/Trade Name/Model
- Description
- Manufacturer Contact (for FDA and customer/public)
- Controlled by? (Lot, Serial number, Manufacturer or Expiry Date)
- Storage and Handling Conditions
- Sterile Y/N?
- Contains Human Tissue Y/N?
- Contains Latex Y/N?
- Kit or combo product?
- Clinically relevant size

European Commission & UDI

- Follows GHTF framework (similar to US)
- Proposals include provisions on identification and traceability – using a one step up (who supplied), one step down (who received) approach

Possible timeline:

September 2012- Revision Proposal

April 2013 – Recommendation for a Common UDI System in EU

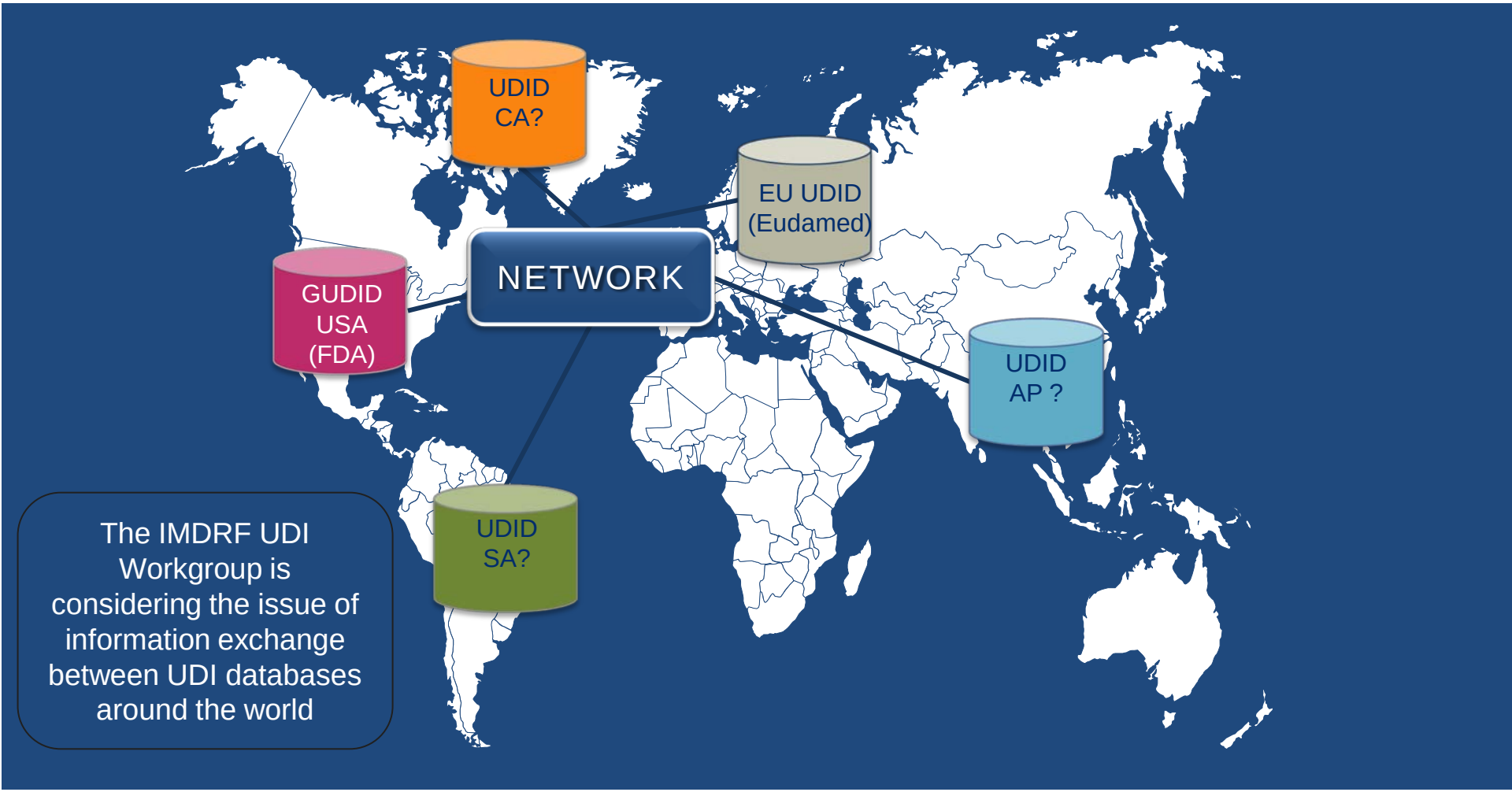
October 2013 – April 2015 - Ordinary Legislative Procedure

2014 or later – Adoption of the new regulation

2014 or later – Adoption of detailed traceability requirements

European Parliament elections could delay until 2016

A UDI Database Network?



The IMDRF UDI Workgroup is considering the issue of information exchange between UDI databases around the world

Who Else is Doing What and Where?

Individual European Countries - Netherlands, Italy, UK

China
Japan
Korea
India

Watching what happens:
Australia, Canada, Brazil

Preparing During Uncertain Times

Questions still to be answered in U.S.

- Which products will require direct part marking and when
- How to label kits and combo products
- Product Inventory - which finished products will be exempt, e.g., those in manufacturer warehouses or on consignment, or only those already purchased

Questions to ask yourself:

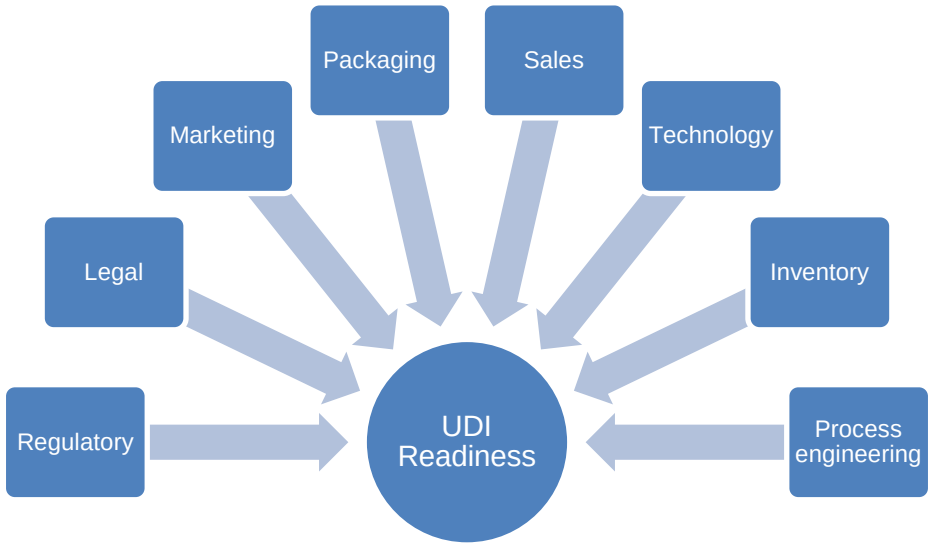
- Which products will be covered by UDI and when?
- Is production manual or automated?
- Where are those products produced? Into which markets are they sold?
- Will the label artwork or packaging need to change to accommodate the UDI?
- Do you need to add printing capabilities to accommodate dynamic (production) data? If so, how will that impact space and layout on the production floor?
- How will you handle validation of new IT equipment and processes?
- Do you perform late-stage labeling in warehouses or with third party logistics providers? How will their operations be affected?
- Do you have kits or combo products? Do you label each of them late-stage and then combine?
- Do you have multipacks? Will secondary or tertiary labeling be required?
- What kind of auto id carrier can your customers use?
- Do you have any products that could require direct part marking?
- Will you need to add a contingent workforce to prepare for UDI?

Maximizing Value

To Achieve Return from ***Required*** Investment,

Manufacturers need to view as a strategy, not a project

- Consider Objectives, Benefits, Impacts: Why are you doing this?
  - Regulatory compliance
  - Regulatory master data management
  - Customer demand/service
  - Post market surveillance
  - Supply chain efficiency
  - Other
- Who needs to be involved?
- Who, what is impacted?



Want to Learn More about UDI?

Visit the FDA's UDI information page/sign up for regular updates
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

National Medical Device Postmarket Surveillance Plan
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

Video series and case studies:
www.ghx.com/udi

Blog posts:
http://www.thehealthcarehub.com
Search on UDI under topics on right

Questions and Answers

Contact:
Karen Conway,
kconway@ghx.com