UDI

Getting Ready for Implementation

04 October 2011

15:45 – 17:15 hrs

Amsterdam NL

GS1 Global Healthcare Conference
Amsterdam – UDI Implementation Breakout…

- OUR PANELISTS - Presenting:
  - …from the Regulator's "PoV", **Jay Crowley** – Senior Advisor for Patient Safety at the US FDA
  - …from the Manufacturer's "PoV", **Volker Zeinar** – Global Coordination of Auto-ID Affairs at B. Braun
  - …from the Care Provider's "PoV", **Jean Sargent** – Director Supply Chain at University of Southern California Health Sciences Campus

- OUR MODERATOR:
  - **Jackie Elkin** – Regulatory Compliance Manager at Medtronic Inc.

- YOUR GS1 HOST:
  - Chuck Biss – GS1 Global Office

Develop and Assign the UDI - Regulator

- Develop UDI code according to ISO 15459
  [GS1, HIBCC, ICCBBA]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date

Develop and Assign the UDI - Manufacturer

- Membership Standards Development Organizations (GS1, HIBC)
- Definition numbering schema (e.g., GS1 : GTIN13 or 14)
- ERP systems preparation
- Define which products need a UDI (e.g., only finished goods)
- Define the packaging levels which need a UDI
  - e.g., pack of each (CU), shelf-pack, case …
  - clarify whether an unpackaged product needs a separate UDI
- Implementation of internal process for UDI maintenance
  - responsibilities
  - who triggers the allocation of a new UDI code and when?
  - which changes require a new UDI code?

Master Data Governance / ERP Systems

Develop and Assign the UDI - Provider

- Assignment will occur at the manufacturer
- Created and maintained by the manufacturer

Concatenating Device and Production Identifier

- Systems must have capabilities built in to parse information

Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date

- Static information obtained from manufacturer via EDI, GHX, GDSN, etc.
- Variable information will be captured at receipt

Place UDI on Product / Package - Regulator

- UDI applies to device and/or label
- Unique UDI applied to all levels of packaging, down to the lowest level (patient use/unit of use)
- Human readable and/or encoded in a form of automatic identification technology
- No specific technology would be identified (technology neutral)
- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)
- Direct Part Marking (DPM) for some devices

Place UDI on Product / Package - Regulator

A Risk Based Approach ……..

- Production identifier reflects current control (label) – not requiring serialization.
- Granularity of marking based on risk of device -
  UDI for some devices on multi-packs or higher levels of packaging
- Not all devices require production identifiers
- Take into account realities of retail environment
- Robust alternative placement and exception processes

Place UDI on Product / Package - Regulator

Combination Products and Kits

Like other devices – intended to facilitate identification:

- Combination product (device) has its own UDI; each device should have its own UDI
- Each kit (devices only) has its own UDI; each device in a kit should also have its own UDI

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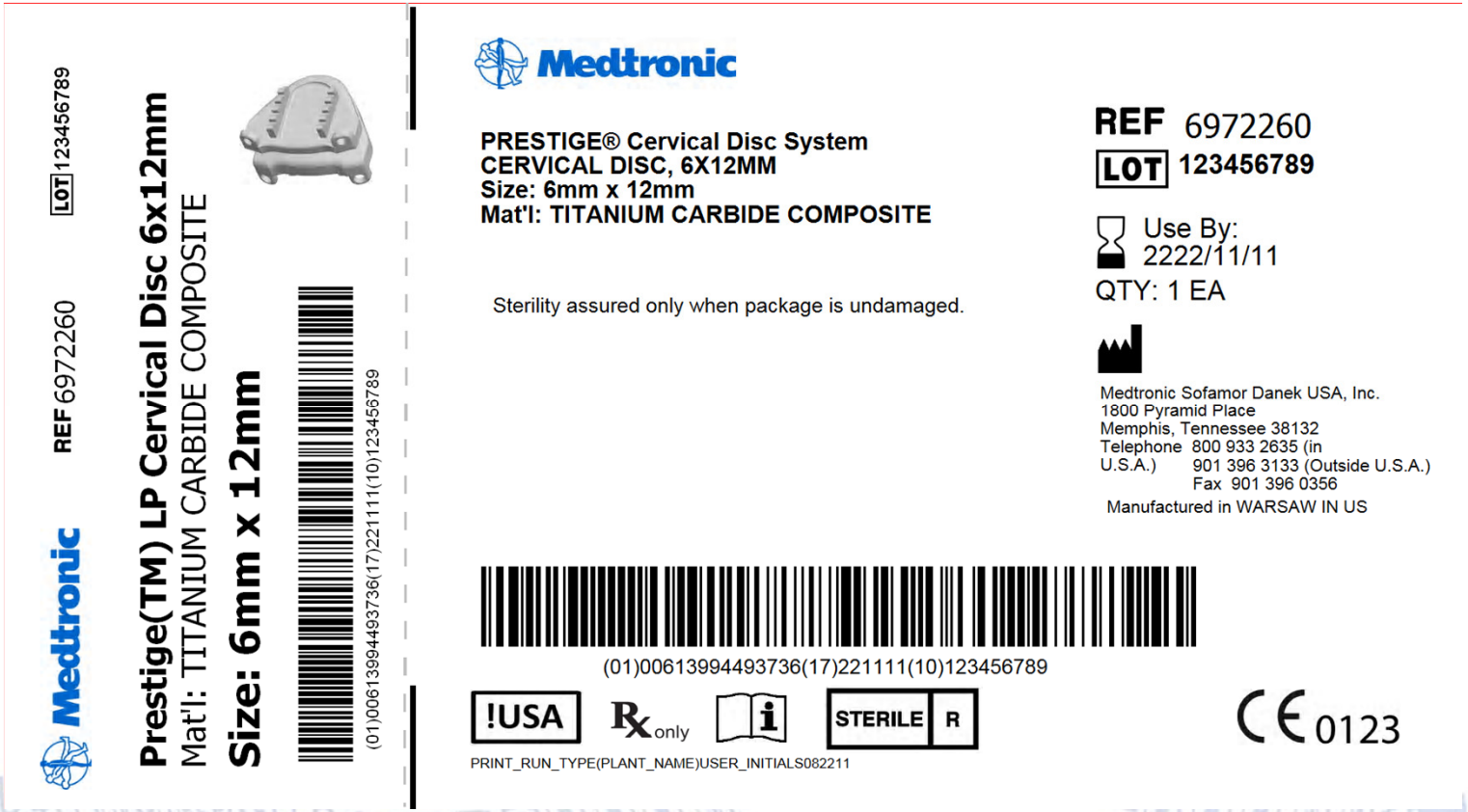
UDI Application Example - Regulator



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UDI Application Example - Regulator

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Place UDI on Product / Package - Manufacturer

- Challenge: online printing due to BC with variable data (CU level)
- Checking all labels concerned (space for AIDC/HRI), artwork changes
- Define AIDC format per label (e.g., 2D or linear)
  - ➢ no mandate of a specific carrier and its placement, avoid multiple BC
- Label changing procedure
  - ➢ complex approval process and documentation needs
- Checking print technology, pack material and ink (ready for AIDC ?)
  - ➢ e.g. absorptive, translucent, preprinted on back side, only validated ink, …
- Feasibility studies (print technology, AIDC carrier, line speed, ISO qual.)
- Check and ensure AIDC quality during routine production processes
- Replacement of print technology if necessary
  - ➢ investments, HW/SW installation/qualification/validation, consider 24/7
- Need AIDC incl. variable data on lowest pack level (low-risk device) ?

Place UDI on Product / Package - Manufacturer

- Line worker education on new SOP's / work instructions
  - ➢ printer adj., quality checks, data download, failure handling, etc.
- New process steps (avoid negative impact on production costs)
- Watch carefully rate of degraded material (start actions if required)
- Higher efforts for printer maintenance to ensure high AIDC quality

Direct Part Marking

- Only 2D possible
- Size is a major issue (3x3mm plan surface needed for reading)
- Usage of global standards (e.g., sGTIN) means high data density
  - ➢ e.g. AI + GTIN + AI + Serial No = easily >26 characters
- not all products can be AIDC marked (size, surface, material, …)
- consider legacy products placed on market

Engineering / Quality Issues / Line Performance / Education

Place UDI on Product / Package - Provider

UDI applies to device and/or label

- Clinicians will become familiar with the "look" of the identifiers enabling ease of use of implementation of scanning

Unique UDI applied to all levels of packaging, down to the lowest level (patient use/unit of use)

- Clinicians will not be familiar with the UDI/GTIN variables – not necessary

Human readable and/or encoded in a form of automatic identification technology

- Processes will need to be defined when a bar code is illegible or bad – clinicians will not have the time to type in info such as in the grocery industry

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Place UDI on Product / Package - Provider

No specific technology would be identified (tech neutral)

- IT and Supply Chain will need to work with clinicians to determine what bar code scanner allows the functionality required to complete the task of scanning

Identify a series of standards (linear barcode, 2D barcode, RFID)

- Scanners will need to have capability to read either linear or 2D. Use of RFID will require a separate technology which will add to the confusion unless utilized for a specific product type

Direct Part Marking (DPM) for some devices

- How will manufacturer's create a bar code that will last the duration of the product such as a PICC line?
- Caregivers will need capability to scan the bar code in all patient care environments (hospital, nursing home, home)

Place UDI on Product / Package - Provider

- Need to keep in mind how this will affect the clinician's time
- What is the need to have this level of tracking?
- What is the affect on the clinicians work load?
- Location of bar code must be consistent in order to have adherence to scanning
- Granularity of marking based on risk of device -
  - UDI for some devices on multi-packs or higher levels of packaging
- Easily identifiable

Place UDI on Product / Package - Provider

Like other devices – intended to facilitate identification:

- *Combination product (device) has its own UDI; each device should have its own UDI.*
- *Each kit (devices only) has its own UDI; each device in a kit should also have its own UDI.*

- This information should be maintained by the kit manufacturer
- Provider should only need to track UDI for pack

UDI Database - Regulator

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Size; Description
- Device model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility
- Contains known, labeled allergen (e.g., latex)
- FDA premarket authorization (510k, PMA)

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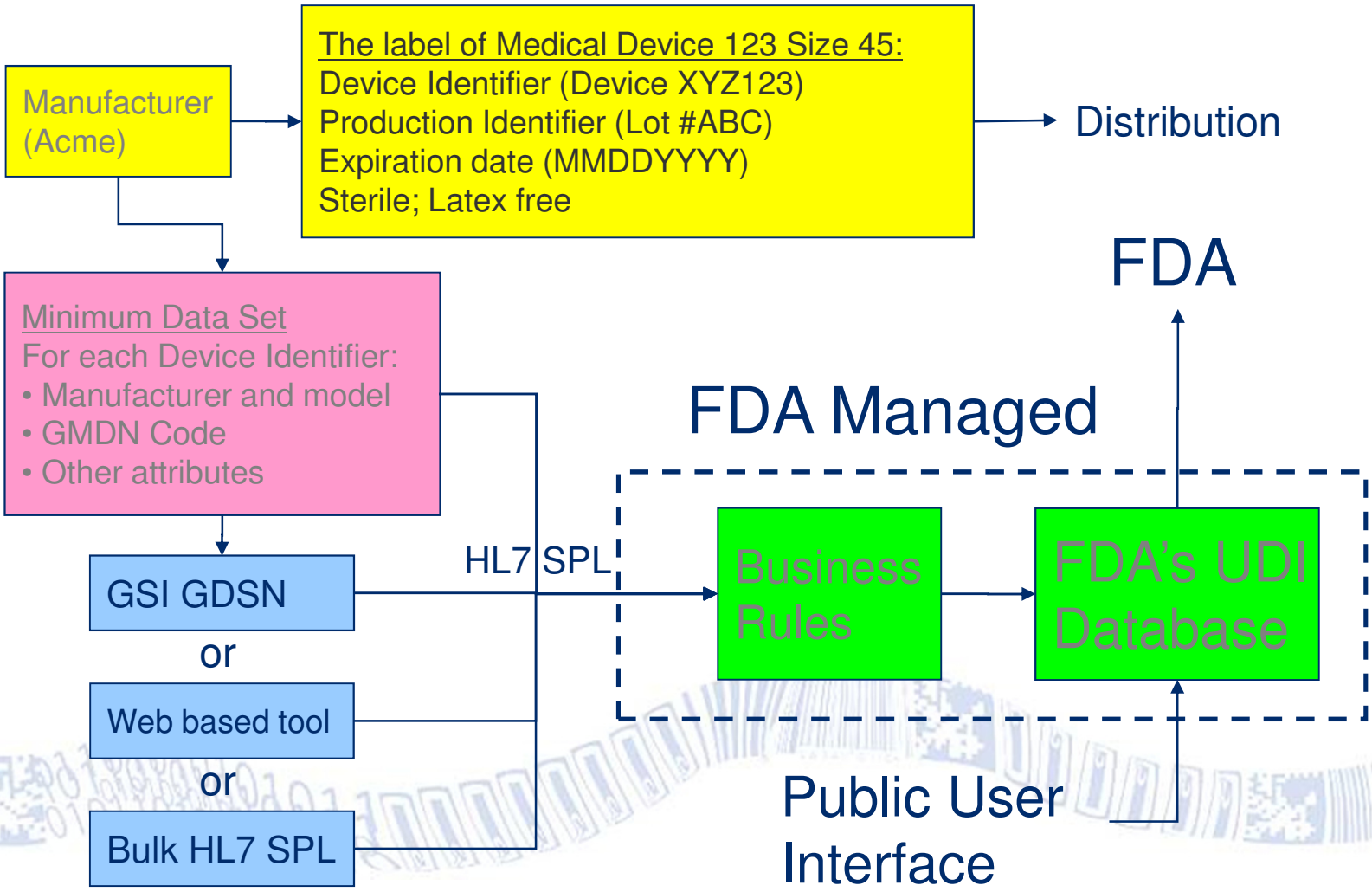
FDA UDI Database - Regulator



UDI Database – Manufacturer

Current Situation

- Availability of data in discrete format?
- Several internal sources (ERP, isolated DB‘s, paper files, ..)
- Shared responsibility for data maintenance (business units, global/local)

To Do‘s

- Re-organization of data governance and maintenance
- Data mapping into an internal UDID (consolidation)
- Convert data from in-house format into HL7 (SPL/CPM)
- GDSN and providers (e.g., GHX) could support

UDI Database – Manufacturer

Open Issues:

- How many UDIDs worldwide / single point of entry?
- Regional add-ons ?
- Need clearer definitions of the data elements

UDI Database - Provider

- Access to product specific information
- Access to recall information
- Understanding the type of data elements in the registry and how provider will use the information
- Information will be useful to clinicians and patients
  - Contact name, phone, email
  - GMDN Classification code/term
  - Storage condition; Single Use; Sterility
  - Contains known, labeled allergen (e.g., latex)
  - FDA premarket authorization (510k, PMA)

UDI Implementation - Regulator

- Based on premarket risk class:
  - class III – 12 months after final rule (implants)
  - class II – 36 months after final rule (equipment)
  - class I – 60 months after final rule (disposables)
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process

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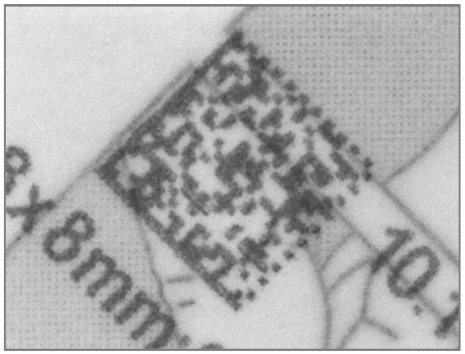
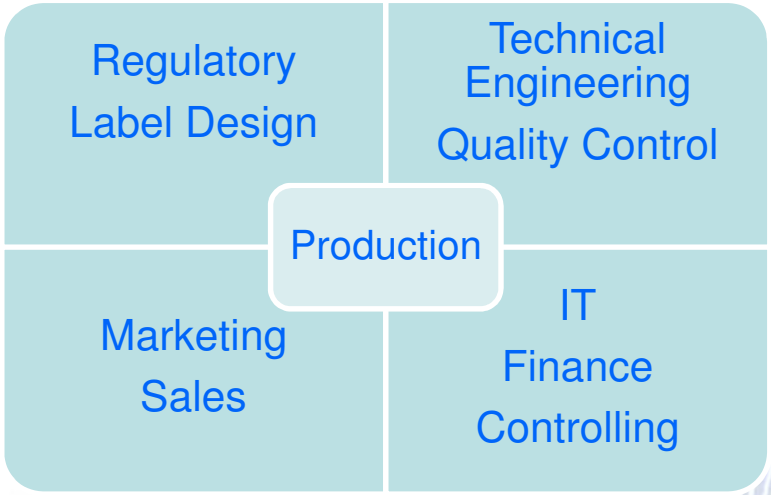
UDI Implementation - Manufacturer

- UDI implementation will be extremely complex
- many production lines will be affected at the same time
- cross-functional project teams required





Stepwise Implementation (from high to low risk) is a must !

UDI Implementation - Provider

- Training of staff:
  - Leadership
  - Materials
  - Information technology
  - Clinicians
  - Ancillary
- Determine software requirements
- Determine interfaces
- Determine hard ware requirements
- Determine how feedback will be accumulated and to whom the feedback should go to

Contact Details

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