The Global Language of Business

IMPLEMENTATION REALITY SESSION
Unique Device Identification (UDI)

Introductory Session – AIDC & GDSN

GS1 Healthcare Conference – Mexico City

22 April 2015

UDI Implementation "Reality"…

Our Panel…

- GS1 AIDC UDI Basics
  - Chuck Biss - GS1 Global Office
  - Senior Director, AIDC Healthcare
- GS1 Master Data and the GUDID Basics
  - Pete Alvarez - GS1 Global Office
  - Senior Director, Master Data Management
- UDI Regulatory Considerations
  - Jackie Rae Elkin - Medtronic, Inc.
  - Global Process Owner - Standard Product Identification - Global Regulatory Operations …also our Q& A Moderator
- UDI AIDC & GUDID Implementation Experiences
  - David Brooks - Medtronic, Inc.
  - Sr. Project Manager - Covidien Group, Strategic Project Management

UDI Implementation

To start, UDI & AIDC…

- UDI's purpose
- GS1 standards supporting UDI requirements
  - "Translation" of GS1 AIDC to UDI

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GS1 Global Office
Senior Director AIDC Healthcare
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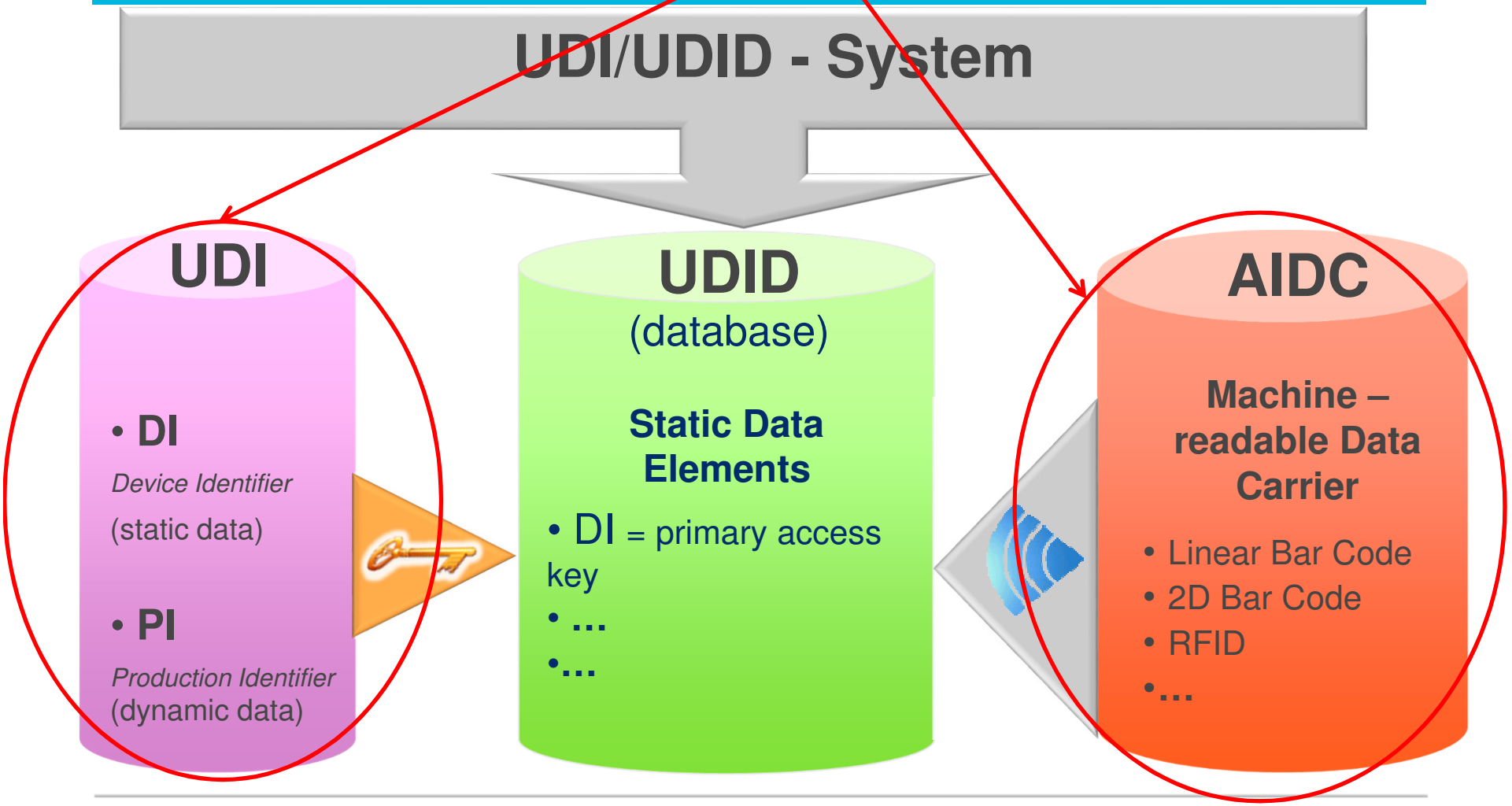
UDI purpose…

Objective…

A common, **worldwide system for product identification** should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.

UDI system…The AIDC "bits"…



UDI & the GS1 system…

UDI in GS1 identification (identify) terms…

Unambiguous identification of a specific medical device… in two (2) parts:

- **Device Identifier (DI)** – ID of the "generic" medical device (GS1 **GTIN**)
- **Production Identifier (PI)** – "control" numbers or data used in a mfg. process – (GS1 **AI's** - lot/batch, serial number, expiry, etc.)

UDI Unique Device Identification	→	**GS1 Standards** Product Identification
DI Device Identifier (DI)	→	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (If applicable)	→	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.		
DI + PI = UDI	→	**GTIN or GTIN + AI(s) = UDI**

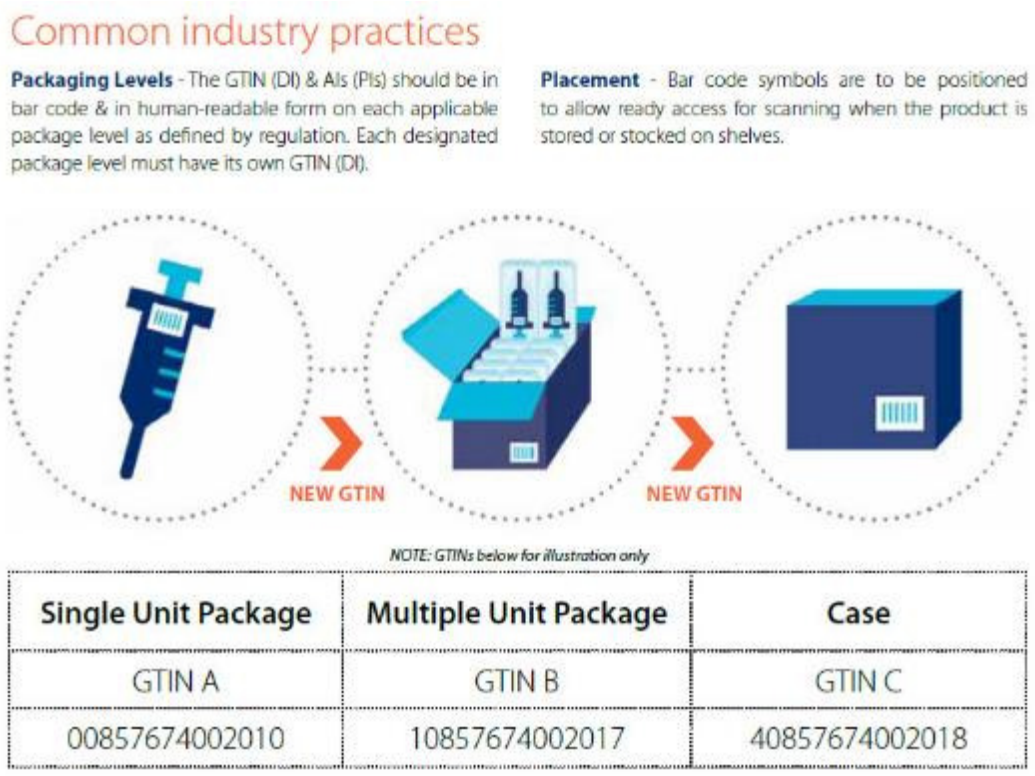
UDI & the GS1 system…

UDI in GS1 allocation (identify) terms…

Allocation - Some common reasons for a change are: Quantity, pack sterility change, re-labeling of an original device, languages, certification marks, etc.

Packaging Levels – A unique UDI s/b on each applicable packaging level as defined by regulation. Logistics items are exempt.

Always refer to local UDI regulations & GS1 GTIN Allocation Rules for details.



Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

Placement – Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.

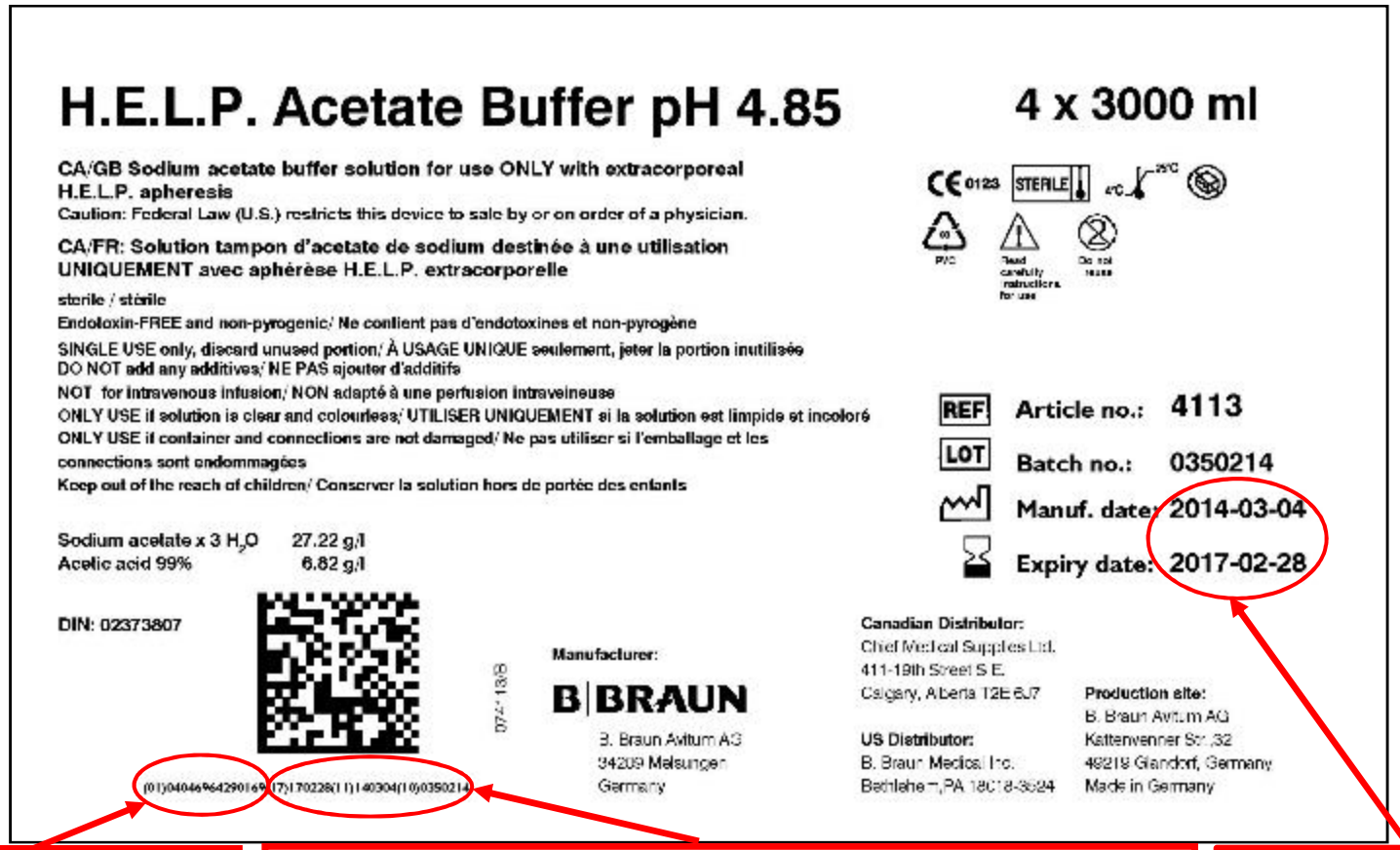
UDI & the GS1 system…

UDI in GS1 Data Carrier (capture) terms…

- Any ISO compliant machine-readable **Data Carrier** which contains the UDI is allowed, 1D/Linear & 2D/Matrix bar code symbols, RFID.
- "Direct Marking" in US FDA terms is not necessarily "direct PART marking"…

All data carriers are for illustration only, not to scale and not in proportional size to one another.
Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information.
UDI requirements may vary by geography -please refer to regional UDI regulations.

UDI label – an example from B.Braun…

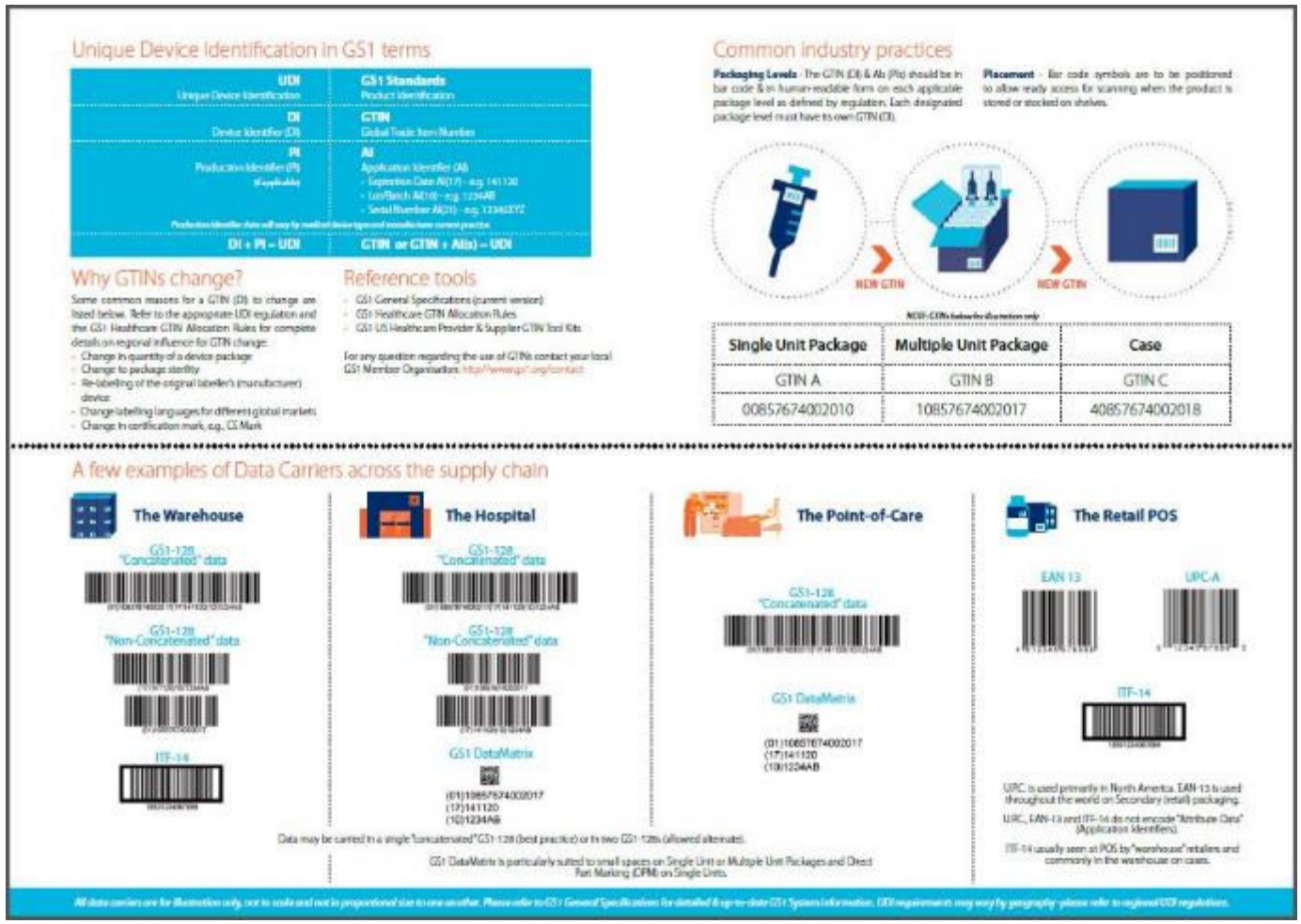


Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format

UDI / GS1 AIDC - the "snapshot"…



Available on-line at:
http://www.gs1.org/healthcare/udi
&
http://www.gs1.org/sites/default/files/docs/healthcare/UDI_Leaflet_Final.pdf

UDI Implementation

To continue, master data…

- GS1 standards supporting UDI requirements
  - GUDID, Data Management and GDSN

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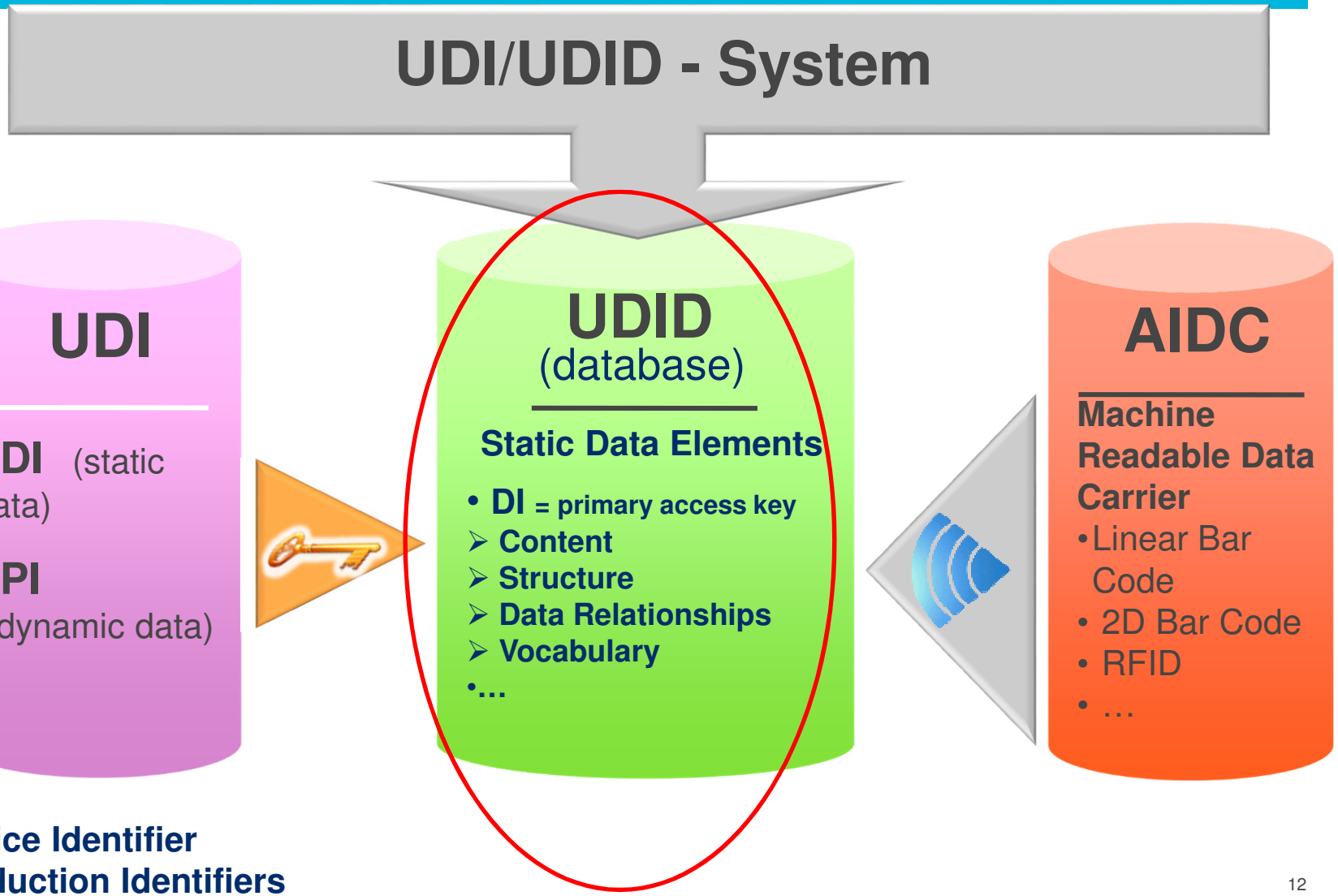
UDI system…

…Database components…

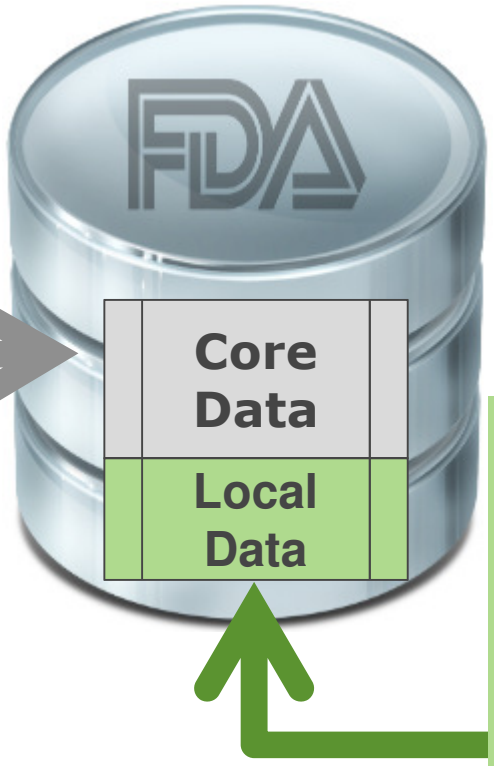


DI = Device Identifier
PI = Production Identifiers

UDI Databases:
Global Core Data + Local Data

- Packaging Hierarchy, per pack. level
  - DI / Unit of Measure / Quantity
- Unit of Use DI
- Manufacturer Name, Address, Contact info
- Authorized Representatives (list of countries)
- Nomenclature + Term (e.g. GMDN code)
- Brand Name
- Device Model or Version
- Reference Number (REF No./catalog no.)
- Controlled by (e.g. exp. date, lot no., serial no)
- Clinical Size (Size/Volume/Length/Gauge…)
- Special Storage Conditions
- Special Handling Conditions
- Labeled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use + Method
- Restricted number of reuses
- License / Marketing Authorization
- URL for additional information
- Critical warnings / contraindications as labeled
  - labeled as containing Latex
  - labeled as containing DEHP

Global core data elements defined by the IMDRF



Additional local data elements defined by the FDA

- DUNS Number
- Authorisation Number (510K)
- Product Code
- FDA Listing Number
- Product Exemption from PMA
- Prescription Product
- Kit Product
- Combo Product
- Contains Human Cell / Tissue
- MR Safety
- …

Master Data Quality

Data Governance

Roles and Responsibility

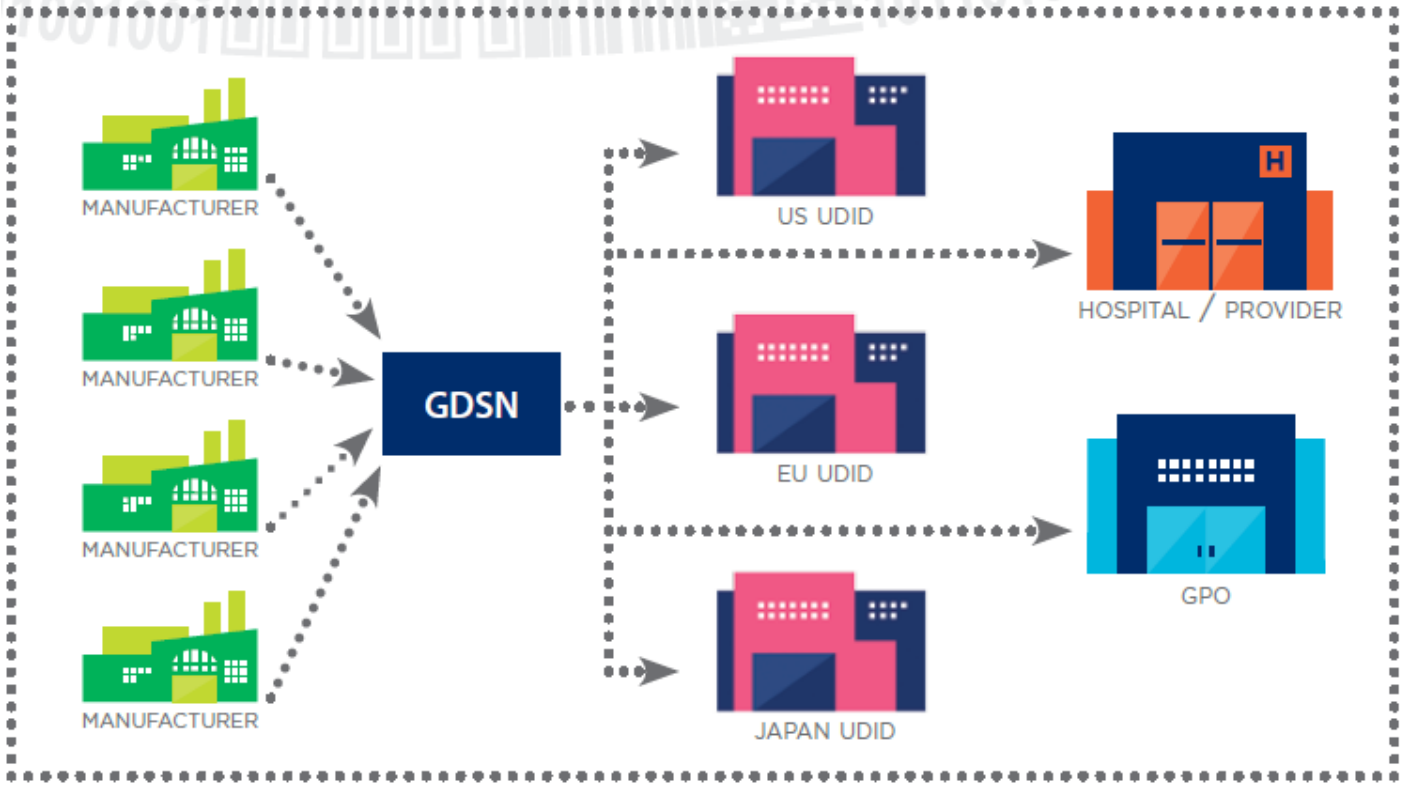
Enterprise wide Data Management

Data Quality

Every manufacturer is responsible for the quality of their data

GS1 Recommendation to the industry: Use GDSN

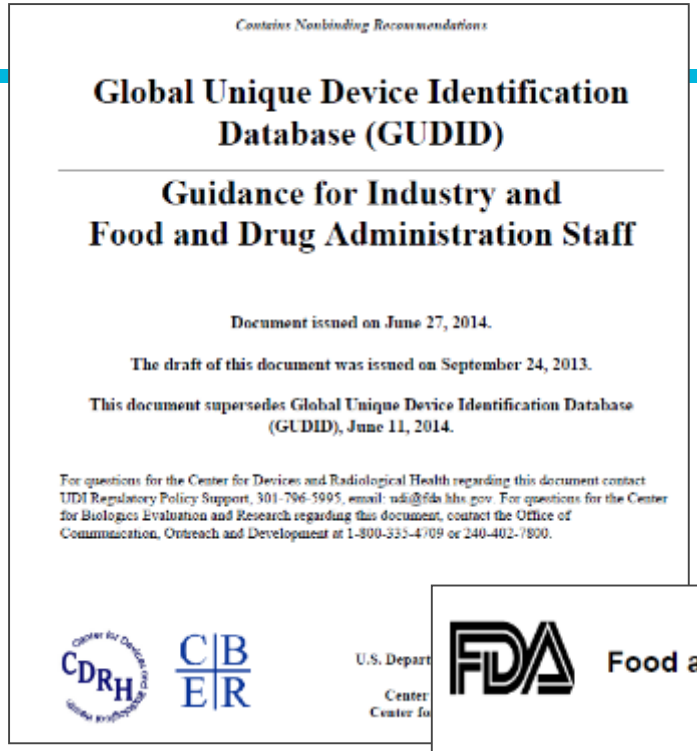
Data is registered in the GUDID by the Source Data Pool



Manufacturers are able to provide data to any UDI database and their customers (hospitals, distributors, wholesalers, GPOs), with a single connection.

The most important documents

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


Contains Nonbinding Recommendations

Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 27, 2014.

The draft of this document was issued on September 24, 2013.

This document supersedes Global Unique Device Identification Database (GUDID), June 11, 2014.

For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: udi@fda.hhs.gov. For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-7800.

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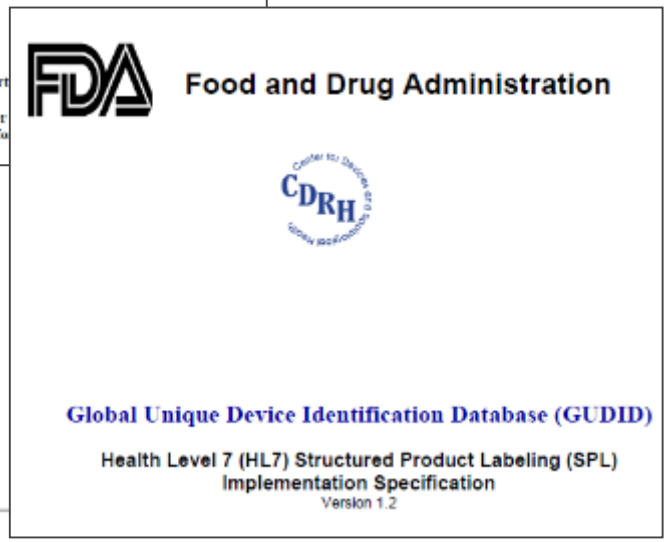
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification



UDI Implementation

To continue, regulatory…

- UDI Regulatory Considerations
  - the FDA rule, the nuances, other pending rules…

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Global Process Owner - Standard Product Identification
Global Regulatory Operations

FDA Unique Device Identification (UDI) AIDC Implementation Challenges and Considerations ……. a Regulatory Perspective

Jackie Rae Elkin
Global Regulatory Affairs
Medtronic

Unique Device Identification

Combination of 4 Distinct Ideas

1. **Development of a standardized system of Unique Device Identifiers(UDI)**
2. **Placing UDI in human readable and AutoID formats on package, label or device**
3. **GUDID – register UDI data in FDA public database**
4. **Implementation**

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US FDA Regulation
UDI AIDC Requirements

PENALTIES FOR FAILURE TO MEET UDI REQUIREMENTS:

Devices for which there has been a failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act respecting the device are **misbranded** under section 502(t)(2) of the FD&C Act. The failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act is a **prohibited act** under section 301(q)(1)(B) of the FD&C Act. Potential enforcement **actions for violations of UDI requirements include seizure, injunction, and civil and criminal penalties.**

1

Development of a standardized system of Unique Device Identifiers (UDI)

Choose an accredited **Issuing Agency** to develop/assign the **UDI (DI + PI)**

GS1 The global language of business

Do you have to use ICCBA for HTC/P products HTC/P?

PI Requirement: *HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).*

21 CFR 1271.290(c) requires that the manufacturer of each HCT/P assign and label the HCT/P with a distinct identification code that **allows the manufacturer to relate the HCT/P to the donor and to all records pertaining to the HCT/P.** The distinct identification code may take the form of a **donation identification number, serial number, lot number, or a combination of these Production Identifiers**.

ICCBBA

Develop UDI Assignment Criteria

Create a new Device Identifier when:

- A change that results in a **new Model or Version** of the device
- A change of the **Quantity** of devices within a device package
- A new Device Identifier is needed for the following changes reflected in the GUDID
  - ✓ Change in **Sterilization** indication on package label
  - ✓ Change in **Latex warning** on package label
  - ✓ Change in **Single Use** indication on package label
  - ✓ Change in **MRI safety** indication
  - ✓ Change in **Combination product** indicator field
  - ✓ Change in **Kit** indicator field

Note: Labeler may have additional assignment criteria

Governance Considerations

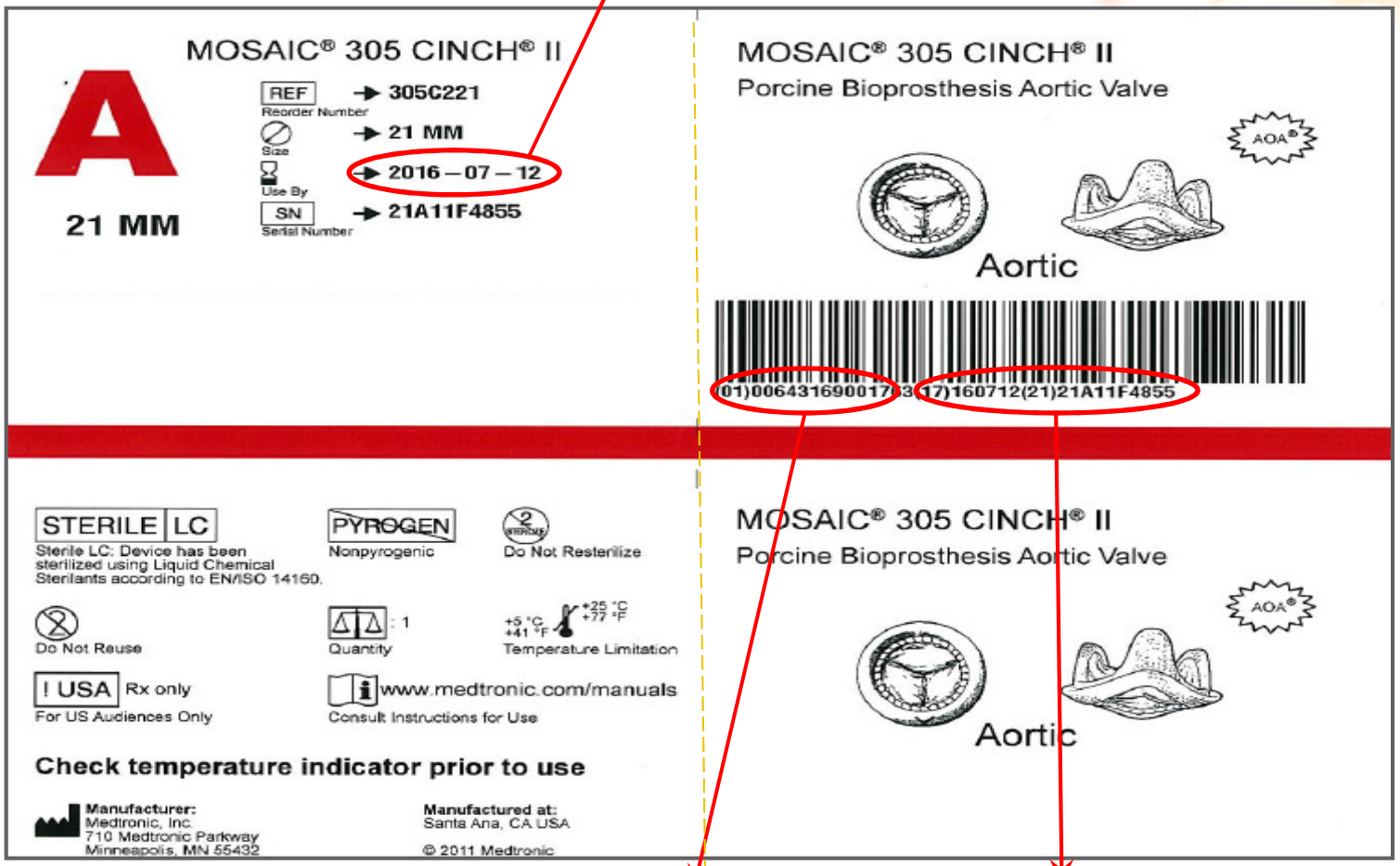
- Who will be responsible for maintaining **Interchangeability** rules and **change** records?
- **Remember UDI is required in the Device History Record under 820.184 along with the labeling inspection and verification in 820.120.**
- All UDI data for a medical devices must be submitted to the GUDID **before commercialization** of the device - where is product distribution control / release trigger?

2 Place UDI in human readable and AutoID formats on package label and in some cases, on the device

- Updates to labels to include date format YYYY-MM-DD (does not include bar code HRI). The Date Format applies to **All** medical devices (not just those subject to UDI)
- Medical device **software version** should be captured in the Lot or Batch Production Identifier (AI 10 for GS1).
- **Manufacturing Date** on the label. Exemptions have to be granted to exclude DOM (only available if not used as control).
- Bar code quality **must be verified**. Simply scanning for readability is not verification, nor is it sufficient. Measure and verify the quality of the code to ISO/ANSI standards.

UDI Compliant Label

Date Format = YYYY-MM-DD



Device Identifier

Production Identifiers

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UPC Concordance with the GTIN-14 on your Package Label

When the package is going to both retail and providers, it must have an EAN/UPC barcode for point-of-sale application.

- The EAN/UPC cannot contain secondary information; therefore, you must use a second barcode to carry secondary information
- The barcode with secondary information must also have the GTIN
- The GTIN in the secondary barcode must be same GTIN as in the EAN/UPC

Figure 1. GTIN-14 Structure Example

Figure 2. Segments of a GTIN-12 (based on the hypothetical GTIN "361414567894")

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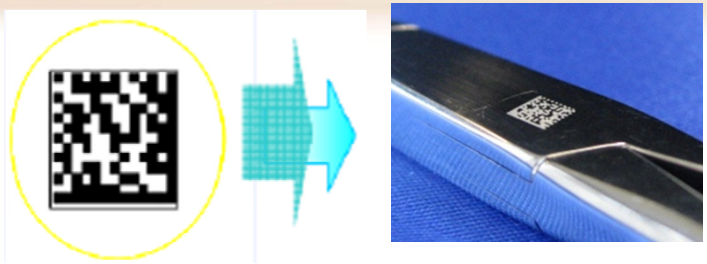
Direct Marking of UDI on the Device § 801.45



Reusable devices that **require reprocessing** (cleaning by disinfection or sterilization) before reuse (between patient), must have the UDI directly marked on the device.

- Direct Mark UDI can be the **same or different** than UDI on package label
- UDI can be in **Human Readable** or **AIDC** or **Both**
- Remember the **exceptions** in the rule:
  - ✓ Interfere with safety and efficacy
  - ✓ Not technically feasible
  - ✓ SUD
  - ✓ Previously marked
- **Self exempt** and document in **Design History File.**

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Follow the issuing agency AIDC format and symbology (GS1) …….. what does that mean?

AIs are to be included

(01)10681490224748 **(21)**9876543

If not, how do labelers represent UDI?

1 0681490224748 9876543 or

10681490224748 9876543

Direct Marking of UDI on Device Challenges

- Significant impact to develop new methods for direct marking of various device materials, create testing methods to prove continued safety and efficacy.
- May require **re-approval** of the device in markets around the world
- Feasibility of direct marking is an issue with many devices due to device surface size and/or material (may also compromise integrity of material).
- Consider legacy products placed on market in consignment and remember the 3 years to deplete inventory begins to toll with the compliance timelines
- Consignment product – how is that treated?

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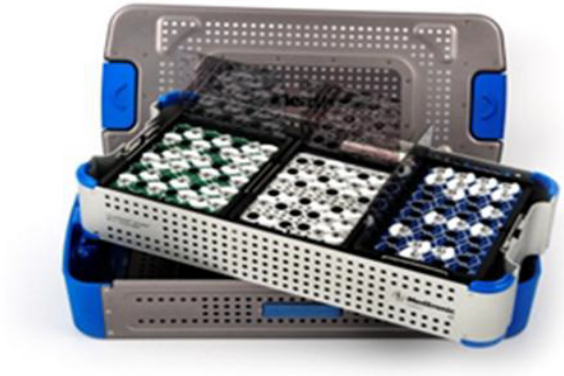
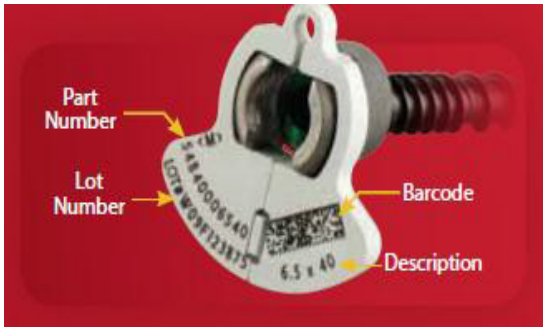
Direct Marking of UDI on Device

FDA grants extension for UDI labeling requirements to September 24, 2016, for medical devices that meet all of the following criteria:

- *classified with product codes in the notification,*
- *implants,*
- *intended to be sterilized (or cleaned and sterilized) before use.*





What if you have a device that is not subject to Direct Marking, but you Direct Mark as a solution – do you get to use the rules and exceptions under 801.45?

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4 Implementation

UDI Rule requires a lot of interpretation

The **objective** of UDI is to **establish a system to adequately identify devices through distribution and use.** The **purpose** is to **rapidly and definitively identify a device** and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.

in·ter·pret
\in-ˈtər-prət, -pət
: to explain the meaning of (something)
: to understand (something) in a specified way

Medtronic

Thank You!

Jackie Rae Elkin

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UDI Implementation

To continue, implementation experiences…

- UDI AIDC & GUDID (via GDSN) Implementation
  - one company's view to date, good and bad…

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The Global Language of Business

UDI AIDC & GUDID via GDSN Implementation

27th Global GS1 Healthcare Conference

April 22, 2015

David W. Brooks

Agenda

UDI Approach

- Where to Begin?
- Critical Success Factors
- Program/Project Management
- AIDC in Healthcare
- Data Quality and Management
- Information Publication

Where to Begin?

Get Educated

- UDI Final Rule
- GS1, HIBCC and ICCBBA standards
- IMDRF UDI Guidance
- EU Recommendations and others

Get Engaged

- Medical device industry groups
- Talk to your peers
- Standards organizations
- Implementation workgroups
- Industry projects
- Talk to the agency

Critical Success Factors

Organizational Awareness

- Understand UDI
- Identify beneficial business impact
- Recognize consequence of non-compliance

Organizational Support

- Engage senior leadership
- Secure resources to implement UDI changes
- Prioritize within the business

Establishing the Project

Scope
- Define what is in and out of scope
- Minimize scope creep
- Include label and data updates, data management, and equipment

Schedule
- Develop schedule based on availability of resources and compliance dates
- Priority by product risk class and impacts

Resource
- Establish consistent project management
- Build cross-functional team with company and industry knowledge
- Consider extended team of employees, temporary staff, and consultants

Budget
- Secure consensus that UDI compliance requires investment
- Determine available expense and capital budgets to support the project

Understanding the Initiative

US Regulations

- UDI
- Labeling
- Conforming amendments

Global Regulations

- Regional variation will be challenging
- Define strategy for regional compliance

Device Labeling

- Labeling artwork may need new AIDC (Automatic Information and Data Capture) marking
- Space may be an issue due to other regulatory requirements
- Consider options when developing an AIDC policy

Direct Marking

- Direct part marking may be required
- Understand the regulation
- Understand your capabilities
- Understand the exemption process when available

Understanding the Initiative

Data Quality

- Information may be unstructured
- Data that may have been for internal use now will reside in an FDA database
- Analyze the current state vs. future state and develop a plan

Data Management

- Creation, processing, storage and publication of data
- New platforms may be required
- Modification to existing data management systems may cause disruption in the business

Data Governance

- Data governance will be needed to control enterprise data
- Keeping the data quality level

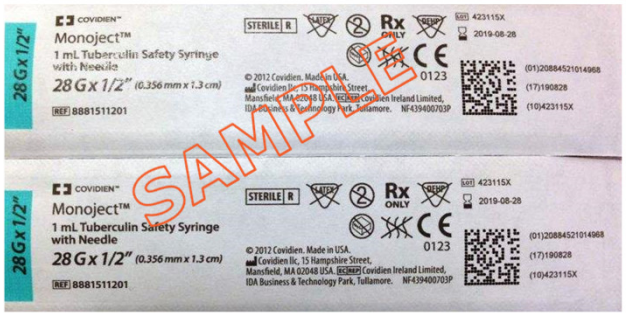
Business Process

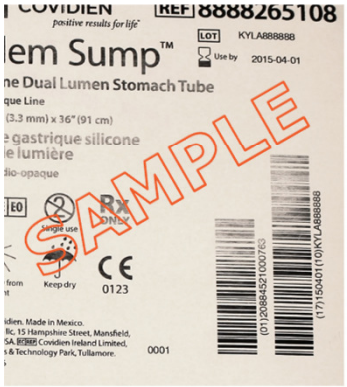
- Sustainable business processes will enable compliance
- Keeps focus after the project is over

AIDC in Healthcare

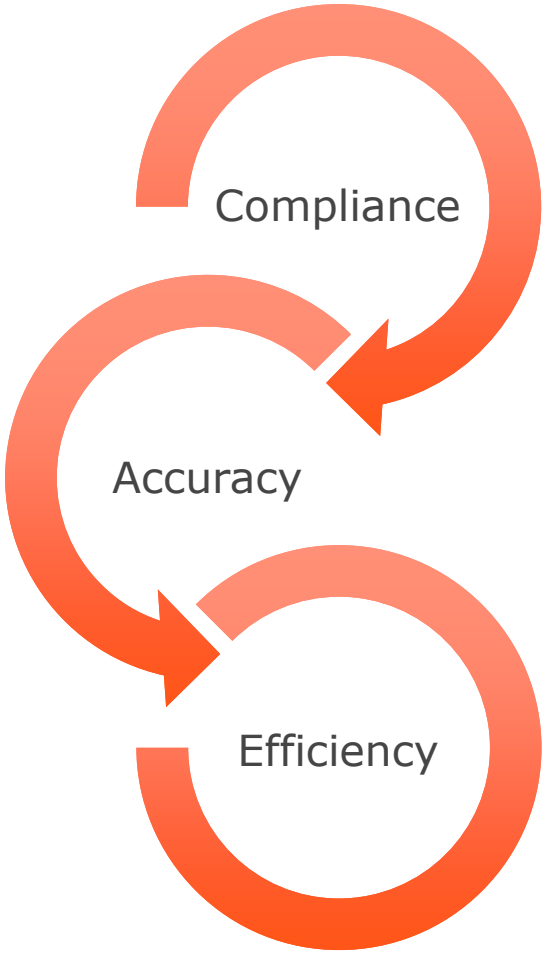
Application of UDI

- Multiple device package levels
- Preferred formats for distribution vs. point of use, or by customer
- Content requirements create space challenges
- Printing on primary packaging substrates: inkjet, thermal transfer
- Label application for inner and outer boxes
- Barcode verification for AIDC quality
- Documentation in Device History Record





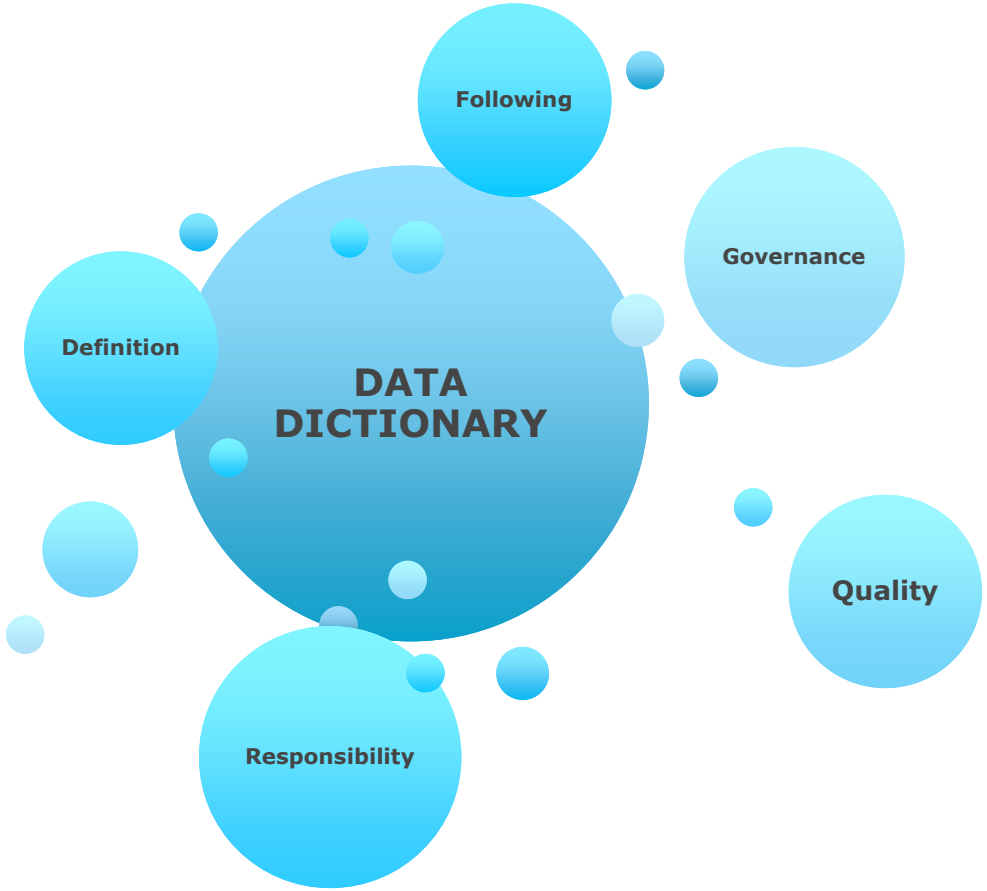
Why Data Quality?



Definition of Data

What is Product Data?

- Attributes
- Item Level
- Packaging Level
- Compliance and Standards
- “Data Dictionary”



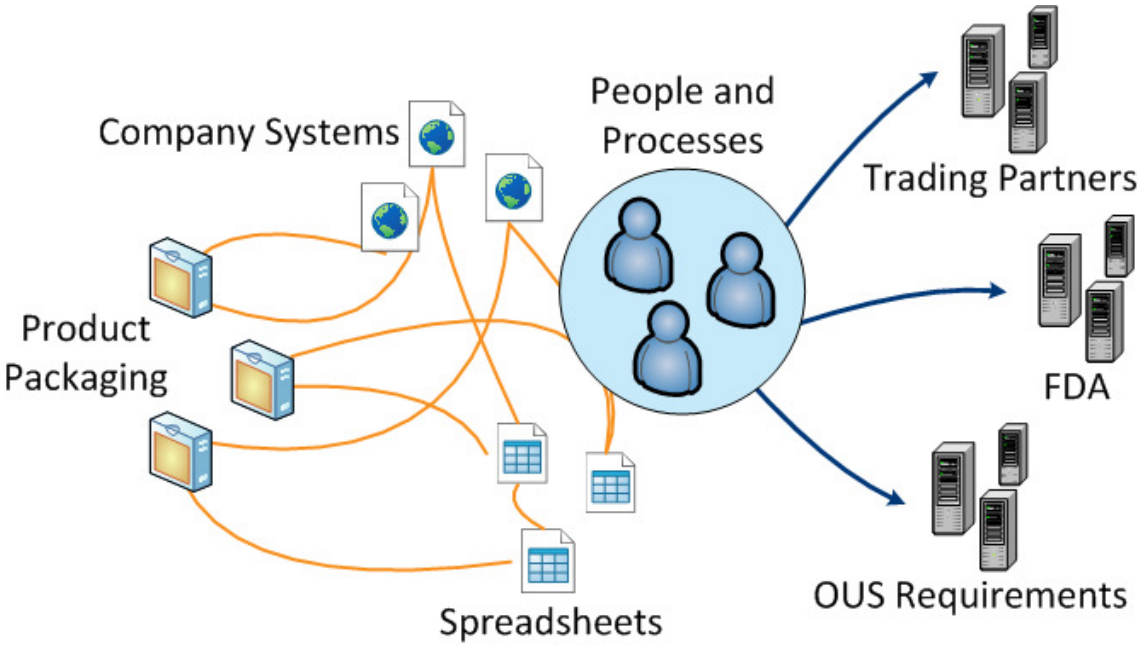
GTIN Hierarchy

Company	Reorder Code	UOM	QOM	GTIN
Covidien	9255	EA	1	10884521021914
Covidien	9255	CT	25	20884521021911
Covidien	9255	CA	100	30884521021918

Infrastructure and Systems

Starting Out…

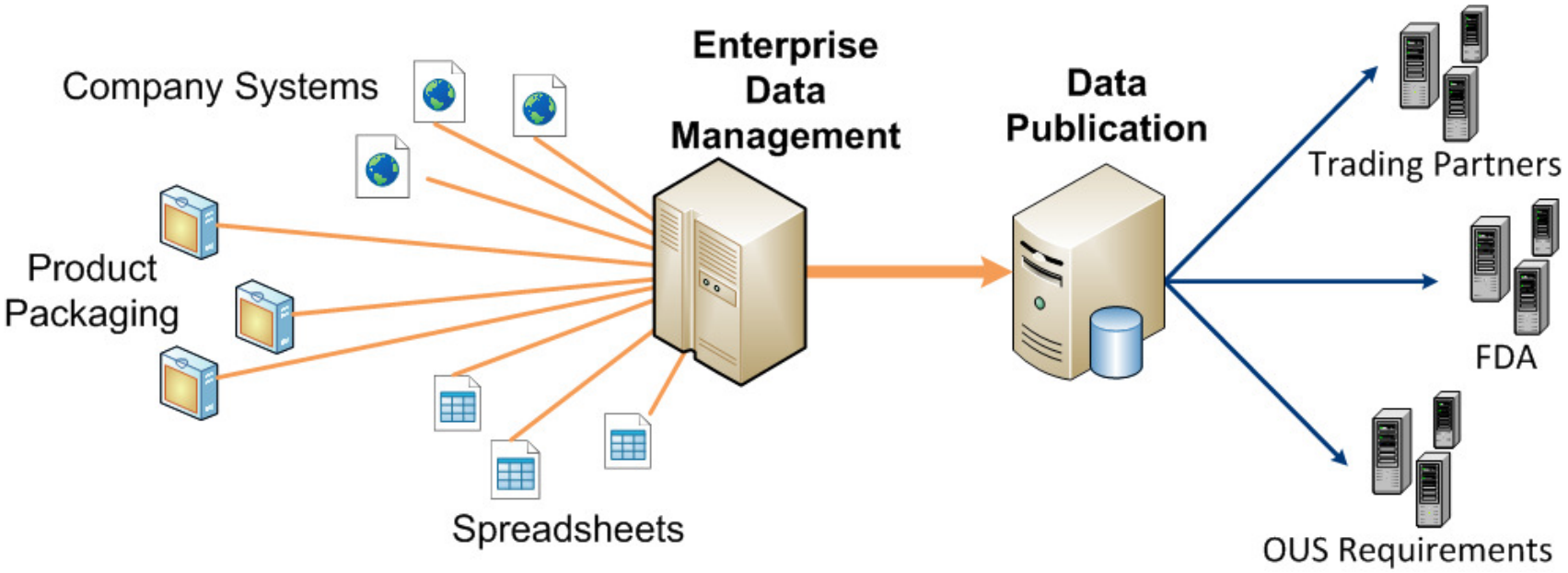
- Manual interactions
- Un-validated
- Lack of definition
- Disconnections
- Data degradation
- Multiple requirements



Future State

Strategic Approach…

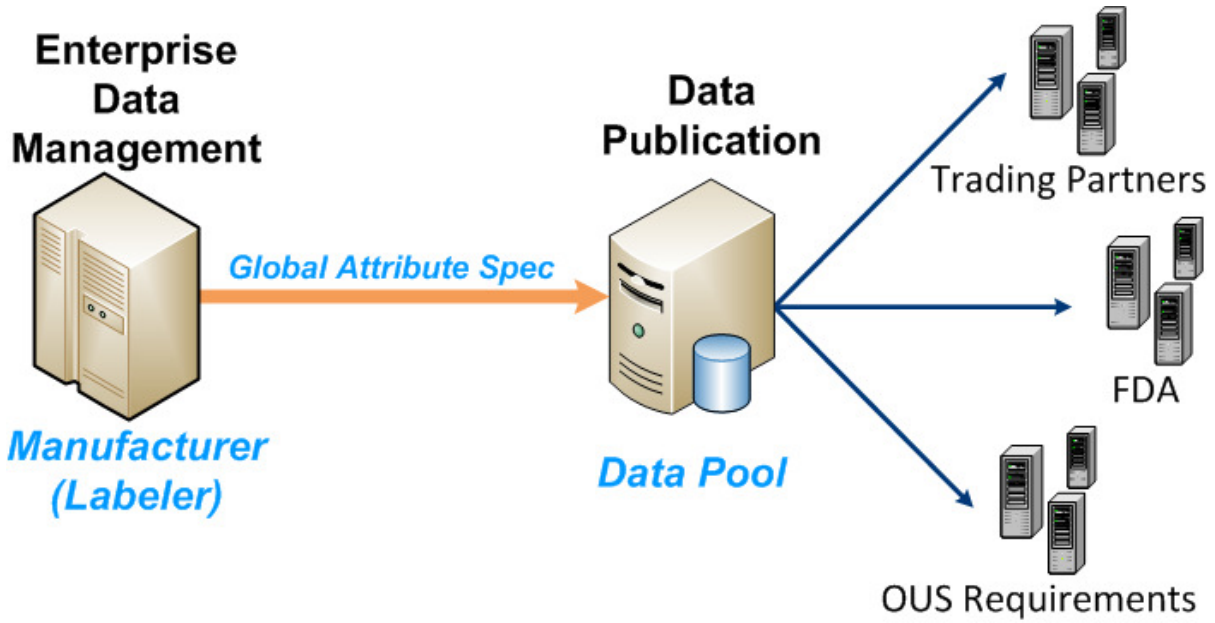
- Defined processes
- Data quality
- Validated interactions
- Model of publication and consumption



Data Publication

Best Practices…

- Global Attribute Spec for all UDI Data
- Scalable for UDI and GDSN publications
- Future applicability OUS
- Other Data Pool applications



Why Data Pool / GDSN for UDI?

Service	Compliance	Advantage
• Competency for transmitting data • Attribute definition • Existing supplier	• Compliance Reports • Traceability of submission • Validation of software	• One feed to your data pool may serve multiple recipients – take advantage of scale! • Investigate overlap with other 'product catalogs'

Take-aways

Key Points to Remember

- Understand the initiative – establish project
- UDI value is in the data
- AIDC implementation is different in Healthcare
- Data Pool / GDSN for UDI has advantages
- **Start early!**

To conclude… audience questions…