UDI Implementation Reality – AIDC

Medical devices: How to identify/mark my products?

UDI Implementation Reality

…Medical devices: How to identify/mark my products?…

Moderator

Ms. Jackie Rae Elkin
Global Process Owner - Standard Product Identification
Global Regulatory Operations
Medtronic, Inc.

Panelists

Mr. Georg Keller
Manager Regulatory Affairs / Labeling Coordinator
Aesculap AG

Mr. Dennis Black
Director, e-Business
BD - Becton, Dickinson and Company

Mr. Jay Crowley
Vice President and Practice Lead – UDI
USDM Life Sciences

GS1 GO Staff

Chuck Biss
Senior Director, AIDC Healthcare

UDI Implementation Reality – AIDC

…UDI in a GS1 "AIDC" world… the "theory"…

UDI
Unique Device Identification

...is enabled by…

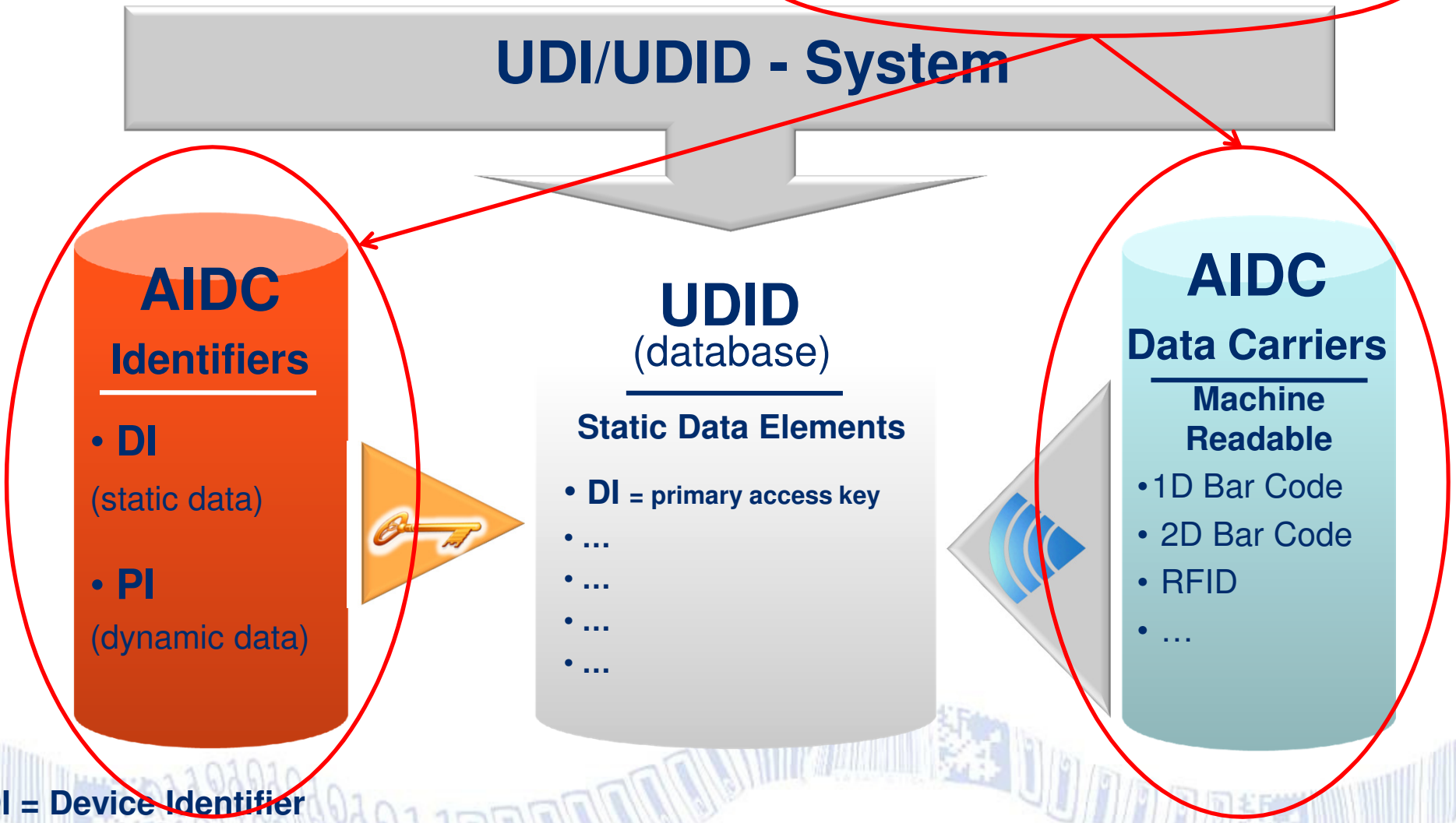
GS1 Standards !!

NOTE: At the time of this presentation the US FDA Ruling has been published. As it is a detailed and in-depth document, it is recommended that you always refer to the final US FDA Ruling for all details specific to it at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

UDI system…

…AIDC "bits"…

…the AIDC "bits"…



DI = Device Identifier

PI = Production Identifiers (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

UDI in the GS1 system of standards

…UDI in GS1 terms…

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 in the GS1 system of standards

…UDI in GS1 terms…

Allocation - Device Identifier / GTIN

Some (but not all) common reasons for a Device Identifier (DI = GTIN) to change are:

- Change in quantity of a device package
- Change to package sterility
- Re-labeling of the original labeler's (mfg.) device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark

Refer to the appropriate UDI regulation in you area and the GS1 GTIN Allocation Rules for complete details on any regional influence for DI / GTIN change.

UDI in the GS1 system of standards

…UDI in GS1 terms…

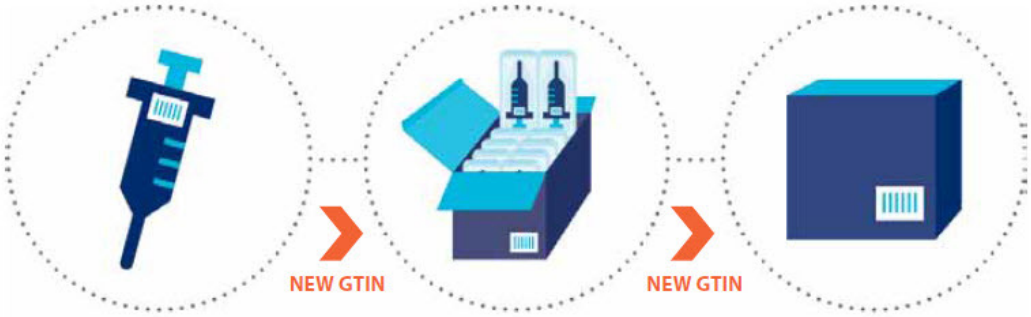
Allocation - Package Levels/Hierarchy

Packaging Levels –The UDI (a DI, i.e. GTIN and PIs i.e. AIs) should be in the AIDC data carriers (i.e. bar code symbol) and also in human-readable form on each applicable packaging level as defined by regulation. Each designated packaging level that is a trade item must have its own DI (GTIN). Logistics items are exempt.

Common industry practices

Packaging Levels - The GTIN (DI) & AIs (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

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



NOTE: GTINs below for illustration only

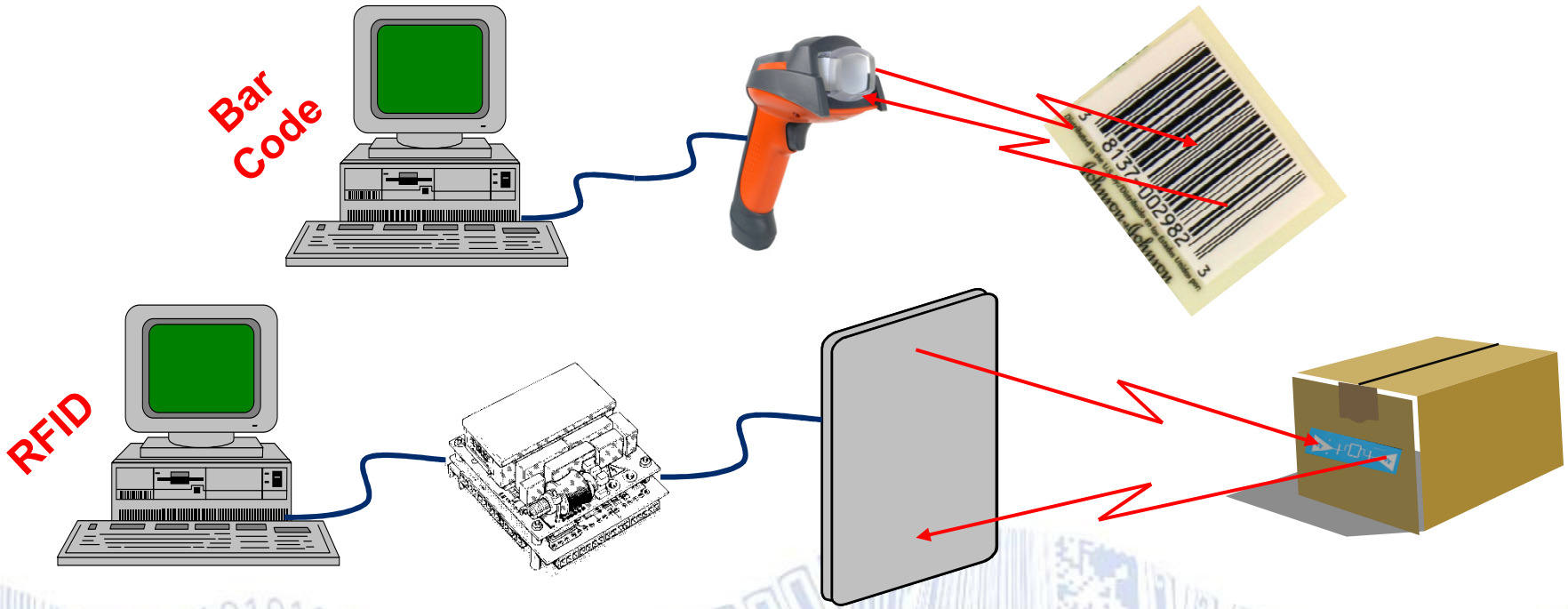
Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

UDI in the GS1 system of standards

…UDI in GS1 terms…

AIDC - Data Carriers

ISO compliant machine-readable **Data Carriers** on the product (via label or DPM… Direct Part Marking) or it's packaging, which contain the UDI – 1D / Linear & 2D / Matrix bar code symbols, RFID.



NOTE: Though "any" ISO compliant machine-readable Data Carrier is applicable… GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers…

UDI / GS1 AIDC - the “snapshot”…

Unique Device Identification in GS1 terms

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

Why GTINs change?

Some common reasons for a GTIN (DI) to change are listed below. Refer to the appropriate UDI regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional influence for GTIN change:

- Change in quantity of a device package
- Change to package sterility
- Re-labelling of the original labeller's (manufacturer) device
- Change labelling languages for different global markets
- Change in certification mark, e.g., CE Mark

Reference tools

- GS1 General Specifications (current version)
- GS1 Healthcare GTIN Allocation Rules
- GS1 US Healthcare Provider & Supplier GTIN Tool Kits

For any question regarding the use of GTINs contact your local GS1 Member Organisation: http://www.gs1.org/contact

Common industry practices

Packaging Levels - The GTIN (DI) & AIs (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

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

NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
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A few examples of Data Carriers across the supply chain

The Warehouse

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

ITF-14

The Hospital

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

The Point-of-Care

GS1-128 "Concatenated" data

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

The Retail POS

EAN 13

UPC-A

ITF-14

U.P.C. is used primarily in North America. EAN-13 is used throughout the world on Secondary (retail) packaging.

U.P.C., EAN-13 and ITF-14 do not encode "Attribute Data" (Application Identifiers).

ITF-14 usually seen at POS by "warehouse" retailers and commonly in the warehouse on cases.

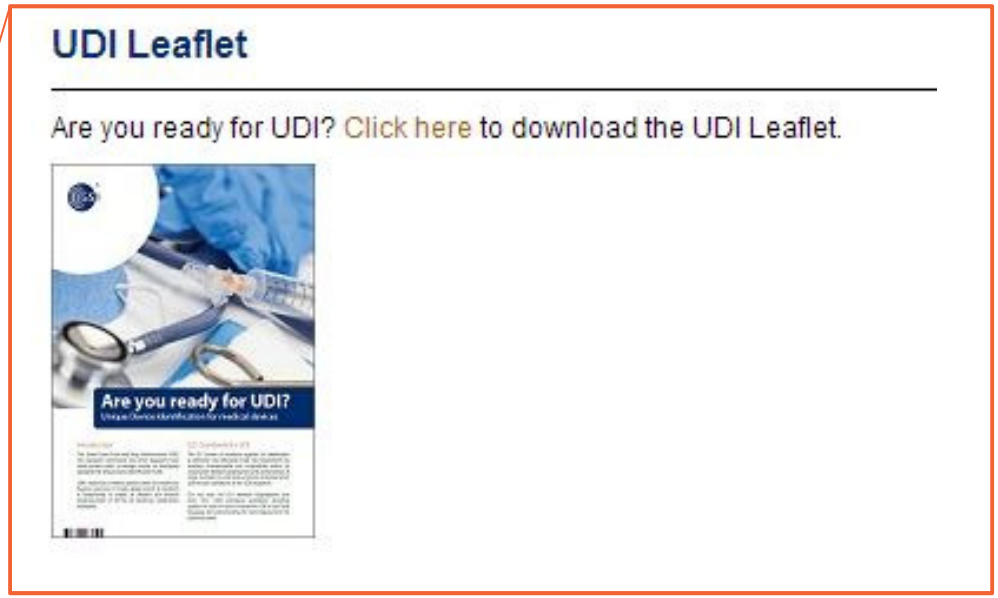
Data may be carried in a single "concatenated" GS1-128 (best practice) or in two GS1-128s (allowed alternate).

GS1 DataMatrix is particularly suited to small spaces on Single Unit or Multiple Unit Packages and Direct Part Marking (DPM) on Single Units.

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.

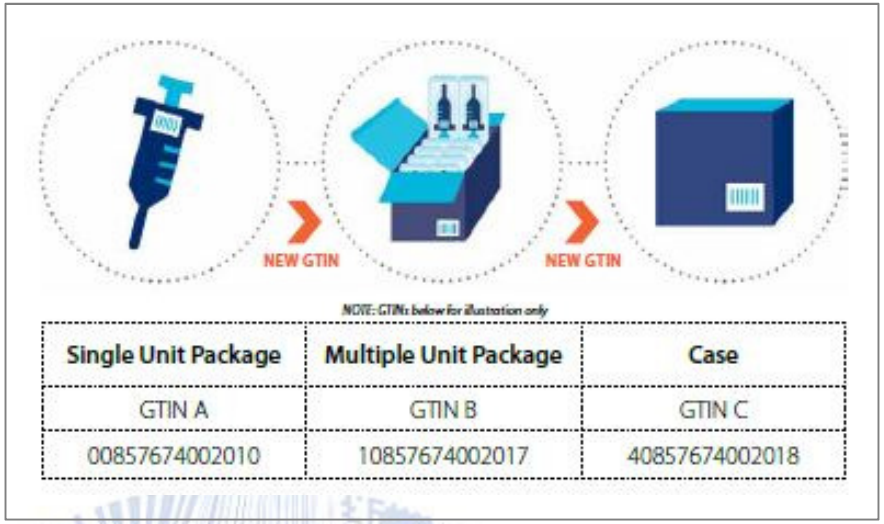
UDI webpage

www.gs1.org/healthcare/udi



UDI Support: “Are you ready for UDI?”

- Introduction to UDI
- UDI in GS1 terms
- Presentation of industry practices
- Benefits of UDI



Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
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www.gs1.org/healthcare/udi

UDI Implementation Reality – AIDC

…our Panelists and the "reality"…

UDI Implementation Reality

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USDM Life Sciences

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

Jackie Rae Elkin
Global Regulatory Affairs
Medtronic, Inc.

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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UDI AIDC Requirements are Regulation

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

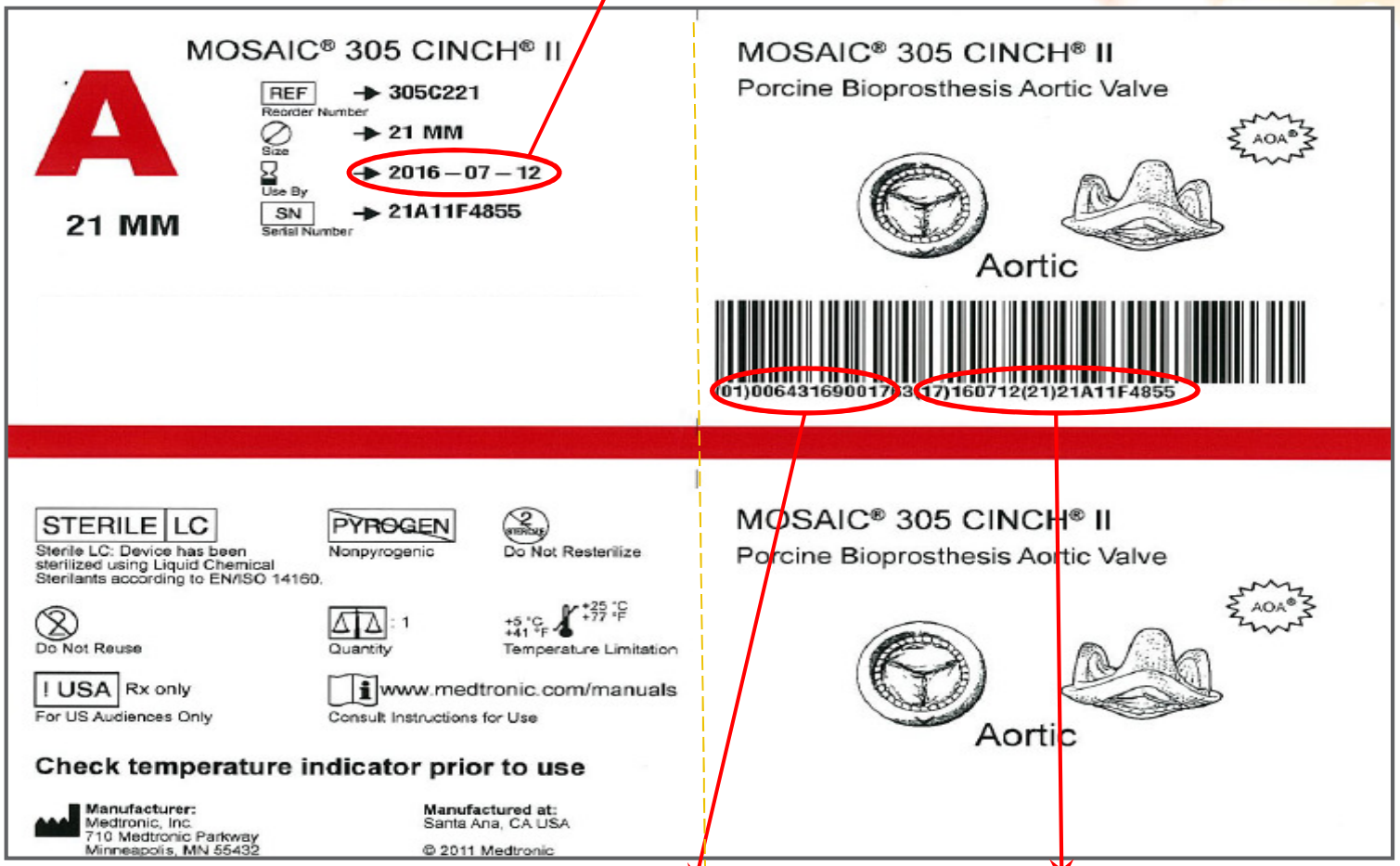
- Who will be responsible for maintaining **Interchangeability** rules and **change** records?
- **Remember UDI is required in the Device History record under 820.184 along with the labeling inspection and verification in 820.120.**
- All UDI data for a medical devices must be submitted to the GUDID **before commercialization** of the product – where is product 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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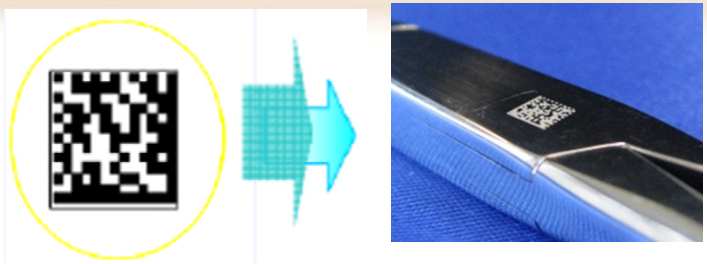
Direct Marking UDI on the Device



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

- 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.**
- Follow the issuing agency AIDC format and symbology (GS1/ HIBC)

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 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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4 Implementation

UDI Rule leaves a lot of opportunity for interpretation – Use It!

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

Global Process Owner - Standard Product Identification

Medtronic, Inc. - Global Regulatory Operations

710 Medtronic Parkway | Minneapolis, MN 55432 USA

Office: 1-763-505-2575 Mobile: 1-612-801-6615

jackie.elkin@medtronic.com

Medtronic

Medical Devices

How to identify/mark my product

Georg Keller
Regulatory Affairs/Labeling Coordinator
Aesculap AG

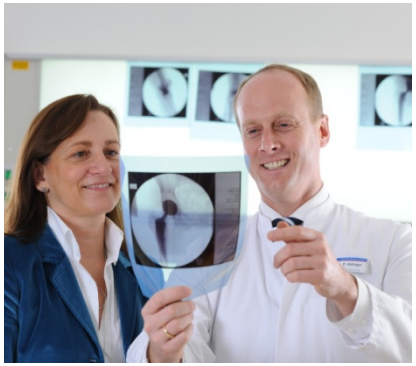
Copenhagen, 22 October 2014

B BRAUN
SHARING EXPERTISE

B BRAUN
SHARING EXPERTISE

We are organized in four divisions.

Hospital Care



Aesculap

OPM
(Out Patient Market)

B. Braun Avitum

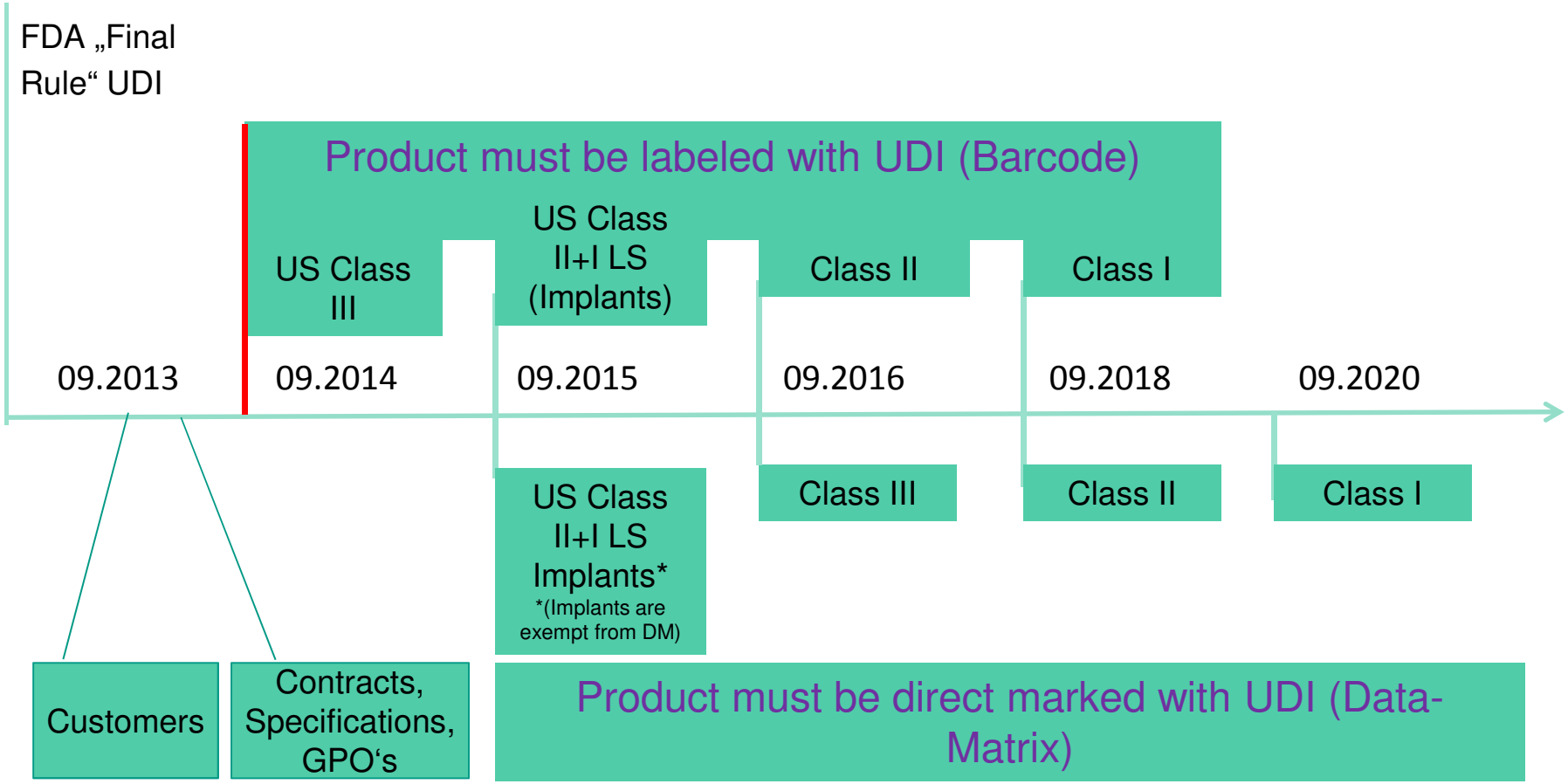
The Aesculap division focuses on products and services for all surgical processes and interventional cardiology – from surgical instruments and implants to suture materials.

Surgical Technologies
Innovation, Quality und Efficiency

- Surgical Instruments
- Endoscopic Technology
- Instrument Management Services
- Sterile Technology

- AIDC UDI Compliance Timeline
- Labeling AIDC Use
- Direct Marking/
- Technical Limits and Solutions

AIDC UDI Compliance Timelines



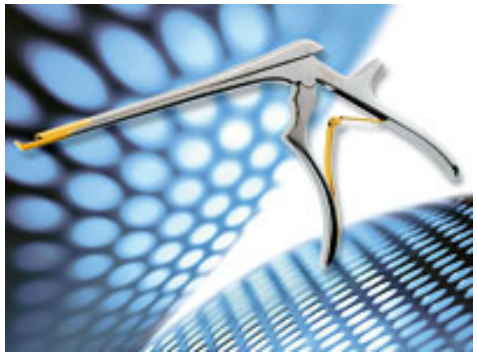
AIDC : Label Samples (DI + PI included)

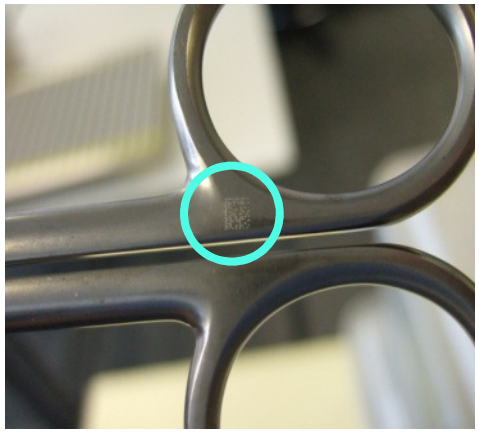
- avoid multiple barcode on the same level
- barcode on patient stickers

  to serve
- Implant Registries
- Documentation (Health Records)
- Inventory Control

Reusable Devices …

… requiring sterilization or high-level disinfection between uses
e.g. surgical instruments





- UDI must be on the device
- UDI must be readable after each sterilization or high-level disinfection
- UDI Production Identifier be defined by the manufacturer according the QM system
  e.g. lot or serial no

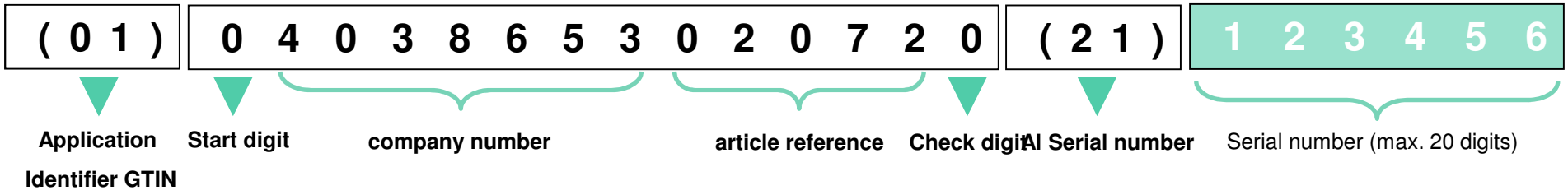
Exceptions possible

- DM interferes with the safety or effectiveness of the device
- DM technically not feasible

Direct Part Marking (DM) or
other permanent marking method !

DM Possible Solution

sGTIN in *Data Matrix*:



- Data carrier: GS1 DataMatrix
  - for a safe reading a min. plane surface of 3x3mm needed
- Identification key: GTIN
  - GTIN (Global Trade Item Number) – preferred option- GTIN-13
- Attribute: Serial number
  - AI(21) (Application Identifier) serial number
- high-quality DM technology required
  - (laser, dot peen, etc.)

Changing to sGTIN

BC579R-17G9C

AESCULAP Artikelnummer | Individueller Anteil

12-13 Digits, alpha numeric

2.5 mm

x-module 0.15 mm

symbol size 16 (row/column)

2.5 mm

FNC1 (01) 04038653020720 (21) 123456

sGTIN with minimum 25 Digits
→ Size of Data Matrix is changing

Size of a Data Matrix in a square form as a function of the data encoded

Symbol Size (without Quiet Zone)		Maximum data capacity	
		Numeric	Alphanumeric
Row	Column	Capacity	Capacity
10	10	6	3
12	12	10	6
14	14	16	10
16	16	24	16
18	18	36	25
20	20	44	31
22	22	60	43
24	24	72	52
26	26	88	64
32	32	124	91

x-module 0.15 mm

symbol size 18 (row/column)

Technical Limits and Solutions

Limit

- marking over edges
- alterating marking (out of focus)
- not visibly enough marked
- corrosion

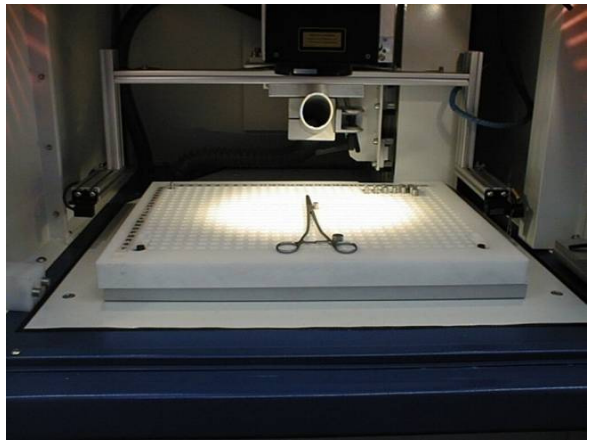
Solution

- valididated parameters
- optimized Code
- contineously control of equipment
- use of stable marking processes
- fixed attachements
- optimized samples for comparison

Technical Limits and Solutions

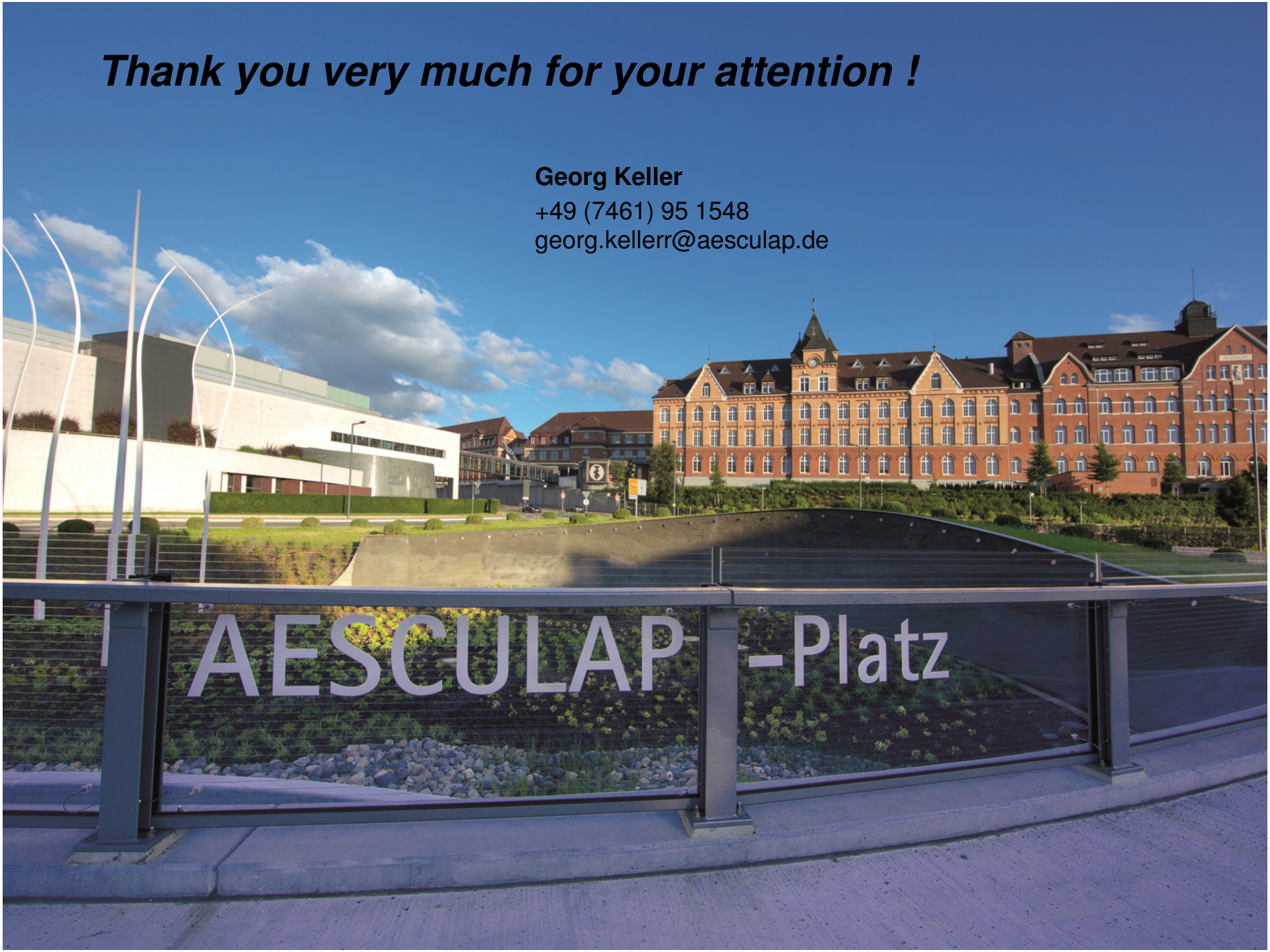
Shelf-Life

- fading by chemicals in the re-processing process
- destroyed by scretches
- reduced readability due of wear



Conclusion

- If the Data Matrix is marked on the instrument according to the specifications a long-term function is guaranteed.
- Only the deterioration of the surface by scretches can not be influenced



Thank you very much for your attention !

Georg Keller
+49 (7461) 95 1548
georg.kellerr@aesculap.de

UDI AIDC Challenges, Experiences and Considerations

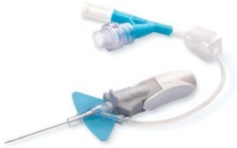
GS1 Healthcare Forum

2014-10-22

BD

BD (Becton, Dickinson and Company)

- FORTUNE 500 company (#332)
- Locations in more than 50 countries
- Approximately 29,000 associates worldwide
- Serves healthcare institutions, life science researchers, clinical laboratories and the general public
- Sells a broad range of medical supplies and services, devices, laboratory equipment and diagnostic products



BD Nexiva™ Closed IV Catheter System

BD Viper™ System with XTR Technology

BD Influx™ Flow Cytometry System

BD™ Insulin Syringes

BD PosiFlush™ Flush Syringe

BD Rx

BD Vacutainer® Push Button Blood Collection Set & Blood Collection Tubes

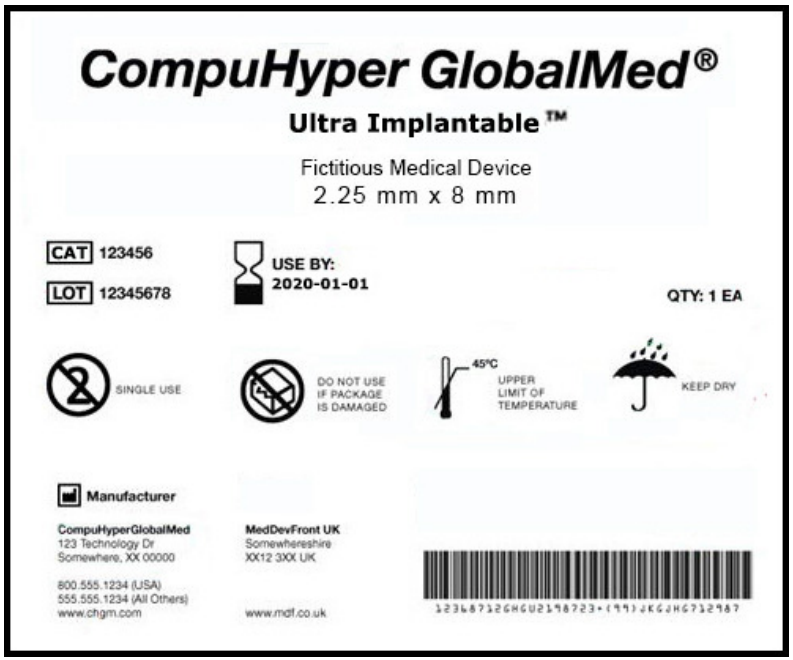
BD SurePath™ PAP Collection System

Challenges Include:

- **Market Preferences for AIDC Markings**
  - Geographical Preferences
  - Specific Market Needs (Retail)
  - Customer Specific Requirements
  - Myths
- **Further Harmonizing Variances/Nuances within the GS1 Specifications**
  - Requests for AI (02) in some markets
  - AI (30) in the U.S. Pharmaceutical Supply Chain
  - Level below Base Unit!
- **Internal Education and Alignment**
  - Developing consensus on UDI requirements
  - 6 digits in the bar code vs. 8 digits in Human Readable
  - Defining Base Unit for some products
  - Consistency of GTIN Allocation Practices
- **Eliminating NHRIC Codes**
- **Eliminating barcodes that are integrated with Laboratory Equipment**
- **Lack of Label Space**

BD

Label Space



Label space is a challenge for some products

Experiences Include:

- Expect to find some errors in your “pre-UDI” bar codes
- Don’t expect internal consensus on AIDC selection
- Know which decisions should be centralized/localized
- Determine when external input should be ignored
- Identify your true system of record for GTINs
- Determine your true printing capabilities before investing in new equipment or processes
- AIDC Placement (Location, Location, Location)

BD

Considerations Include:

- Assemble the necessary skill sets on your UDI team
- Know which of the GS1 rules are “etched in stone”
- Decide who will arbitrate questions on the regulation or implementation matters
- Implement a QA process to check AIDC accuracy
- Share best practices amongst various product groups
- Hope that future UDI regulations are aligned with IMDRF Guidelines, GS1 Standards and the FDA UDI rule

BD

Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)

USDM Simplify, Unify, Optimize
Life Science Compliance for Regulated Systems

UDI Compliance Challenges (… and opportunities?)

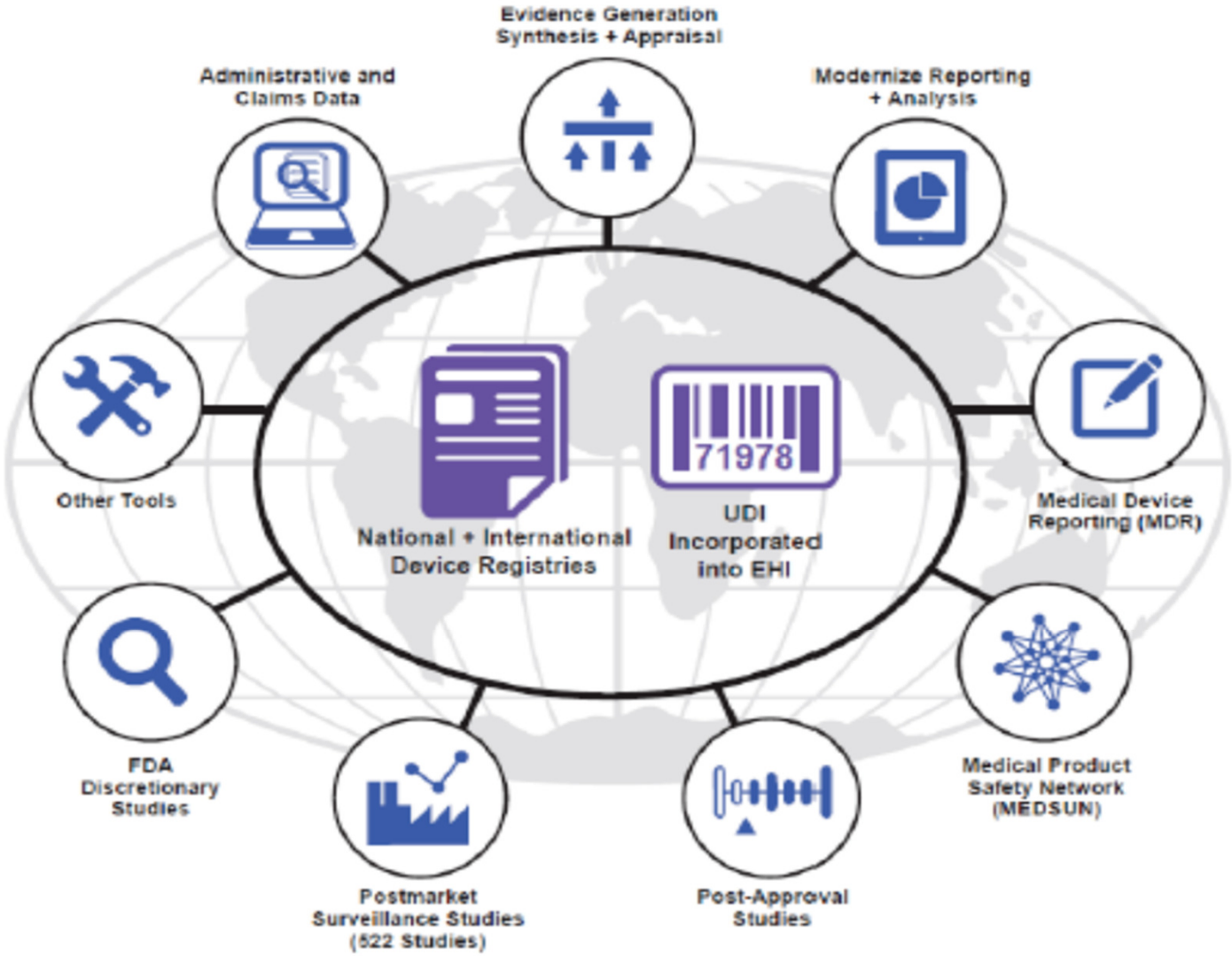
Jay Crowley, VP and UDI Practice Lead
jcrowley@usdm.com
Tel: 850-880-2591
Cell: 443-438-0608

USDM Life Sciences

US FDA UDI Rule Intent/Objective

- Provide standardized granular identification of medical devices and associated meta-data to support various public-health initiatives
- Most notably FDA's postmarket surveillance activities – including:
  - adverse event reporting/aggregation
  - recalls
  - device and disease specific registries
  - EHRs
  - large population-based data sets, e.g., claims data
- Understand stakeholders/users needs and use

US FDA UDI Rule Intent/Objective



Issues and Challenges

- Is product a regulated medical device – and what is the risk class – both vary globally
- “Label” – regulatory concept – where is it?
- Labeler – private label – both for you and for others – decide and document who is doing what
- UDI Label vs Direct Mark
- UDI on level below orderable/shippable unit
- Barcode verifiers/grading – grade C or better
- Non-sterile implants/kits
- Packaging hierarchy
- Accessories vs spare/service parts
- Classification vs premarket path

UDI “Compliance” is Really Hard

But not for obvious reasons:

- Many manufactures have grown by acquisition (silos, multiple SOPs, ERPs/PLMs) – different approaches which need to be centralized
- Using UDI to make all sorts of other label changes
- A lot of uncertainty about UDI use
- Uncertainty about global UDI
- UDI rule is tried to balance costs/risks – but there is a lot of (too much?) flexibility and ambiguity
- FDA – and not the “user” – is the arbiter of correct
- UDI is (primarily) a regulatory activity

UDI has uncovered…

1. Many business practices that are no longer sustainable (e.g., orthopedic trays/sets, private label)
2. Opportunities to leverage UDI to solve business problems – asset management, loaners
3. Rule provides flexibility for individual manufacturers – is leading to inconsistency across market
4. Many exceptions are not aligned/do not support downstream business practice (e.g., SUD exception)
5. That different country's/regulator's needs are going to create significant implementation issues (e.g., what is a device, device class, meta-data needs, actors)

Conforming Amendments

Adds to each the requirement to use UDI:

- Part 803 – Medical Device Reporting
- Part 806 – Reports of Corrections And Removals
- Part 810 – Medical Device Recall Authority
- Part 814 – Premarket Approvals
- Part 820 – Quality System Regulation
- Part 821 – Medical Device Tracking Requirements
- Part 822 – Postmarket Surveillance

Conforming Amendments

803.32 User facilities must include the UDI on the device label or on the device package in individual adverse event report submissions.

803.33 User facility must submit in annual reports the UDI that appears on the device label or device package.

803.42 Importers must include the UDI on the device label or on the device package in individual adverse event report submissions.

803.52 Manufacturers must include the UDI on the device label or on the device package in individual adverse event report submissions.

806.10 The manufacturer or importer must include on reports of corrections and removals: the UDI that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

806.20 Records of corrections and removals not required to be reported to FDA shall contain the UDI, or the device identifier, UPC, model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

Conforming Amendments

810.10 FDA will include the UDI that appears on the device label or on the device package in its cease distribution and notification order.

814.84 The holder of an approved pre-market approval shall identify in its periodic report each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report.

820.120 Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct UDI or UPC, expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.

820.184 Device history records must include any UDI or UPC, and any other device identification(s) and control number(s) used.

820.198 Manufacturers must include in their complaint files any UDI or UPC, and any other device identification(s) and control number(s) used.

820.200 Service reports that represent an event that must be reported to FDA must include any UDI or UPC and any other device identification(s) and control number(s) used.

Conforming Amendments

821.25 A manufacturer of a tracked device must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of these devices.

821.30 Persons other than device manufacturers and distributors must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device.

822.9 Class II and III device manufacturers required to conduct postmarket surveillance must include both premarket application/submission number and device identifiers in the postmarket surveillance plan submission.

IMDRF and US FDA Differences (1/3)

- Manufacturing date exemption – IMDRF yes, FDA no.
- Significant label space constraint exemption – UDI on next higher package level – IMDRF yes, FDA no.
- IMDRF limits the single use device packaging exemption to risk class A and B devices – FDA has no limitations (though narrower definition of how it can be used).
- IMDRF allows any “non-prescription medical devices exclusively for retail Point of Sale (POS) do not need to encode Production Identifiers in AIDC on the point of sale package.” – FDA limits this to class I devices.
- For RFID, IMDRF also requires linear or 2D barcode on the label.” – FDA does not.

IMDRF and US FDA Differences (2/3)

- IMDRF states that if constraints limiting both AIDC and HRI on the label – the AIDC format shall be favored (certain environments, such as home care, may warrant the use of HRI over AIDC) – FDA always requires both.
- IMDRF allows GMDN to be optional – FDA requires it.
- IMDRF requires “serial numbers for active implantable devices” – FDA does not.
- IMDRF requires the UDI of the implantable device must be identifiable prior to implantation (e.g., tear-away tag, peel-off label) – FDA has no such requirement.
- IMDRF exempts orthopedic trays whose contents are configured for a specific order – FDA has no exemption.

IMDRF and US FDA Differences (3/3)

- IMDRF requires medical devices within a kit to have a UDI – FDA exempts all contents of the kit from UDI.
- IMDRF has “rules” for how UDI is applied to configurable medical device systems – FDA has no rules (at least yet).
- IMDRF has “rules” for how UDI is applied to stand-alone software (IMDRF uses the term Software as a Medical Device (SaMD)) – more detail than FDA currently has.
- FDA has exempted completely from UDI all GMP-exempt Class I devices – IMDRF does not have anything similar.
- FDA has an “existing inventory” exemption – IMDRF does not.

Ask where you are relative to…

A. Analysis, Strategy and Planning

1. Determine FDA UDI requirements impact by device and organize products by:
   Class, Market, Production Location, CPO, Label and Packaging Components
2. Analyze gaps between FDA requirements and current labeling/packaging for each product.
3. Determine your FDA-accredited organization for assignment of UDIs and auto ID barcode
4. Analyze gaps between current PLM, connectivity to GUDID, labeling/packaging/inspection and supply chain systems and requirements for UDI.
5. Establish the Strategy and Plan (Activities, Schedule, Budgets, Responsibilities, Partners) to:
   a) Remediate gaps in Labels and Packaging
   b) Develop the interface to GUDID
   c) Remediate PLM and Supply Chain Systems, labeling/packaging equipment and Processes
   d) Establish validation and compliance strategy and plan

B. Build and Execute

6. Update Product Label/Packaging design and materials – sequence by compliance date
7. Design, Develop, Implement and Validate IT system changes and interfaces
8. Purchase or enhance printing, labeling, packaging equipment and validate
9. Execute dry runs to update GUDID and confirm capability of equipment, systems, and processes
10. Develop production SOPs and execute process validation

C. Commercialization

11. Manage the cutover to production for the first run of each product
12. Incorporate UDI requirements into new products and new versions of existing products
13. Registration of new products and new versions of existing products with the GUDID

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Life Science Compliance for Regulated Systems

Thank you!

Jay Crowley
VP and UDI Practice Lead
jcrowley@usdm.com
Tel: +1-850-880-2591
Cell: +1-443-438-0608

More questions afterwards… ??

Check out more FAQ's at:

http://helpdesk.gs1.org/ArticlesBySubject.aspx?UDI%20-%20Unique%20Device%20Identifier&id=3a55268a-c05a-e311-ba24-00155d644240

Or if you have additional questions:

UDI Regulations / Public Policy
Géraldine Lissalde-Bonnet g.lissalde@gs1.org
UDI AIDC
Chuck Biss chuck.biss@gs1.org
UDI GUDID
Pete Alvarez peter.alvarez@gs1.org
UDI Marketing & Collateral
Anouk Chavel anouk.chavel@gs1.org
GS1 Healthcare UDI web page at:
http://www.gs1.org/healthcare/udi
GS1 US Healthcare UDI web page:
http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
FDA Helpdesk Direct
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm

Contact Details

Chuck Biss
Senior Director, AIDC Healthcare
GS1 Global Office
T +1 (315) 252-5941
M +1 (315) 480-2034
Email: chuck.biss@gs1.org

REMEMBER TO CHECK OUT:

…GS1 Healthcare UDI web page at: http://www.gs1.org/healthcare/udi
…GS1 US Healthcare UDI web page at: http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
…U.S. FDA UDI general web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm