UDI Implementation Reality – AIDC

How to identify/mark my medical device products?

UDI Implementation Reality

…How to identify/mark my medical device products?…

Moderator

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

Panelists

Mr. Mark Hoyle
International R&D, Advanced Engineering
Teleflex Medical

Mr. Chuck Franz
Vice President and Chief Information Officer
Cook Group Incorporated

Mr. Bodo Winkler
Head of UDI Implementation, Sector Project Lead
Siemens AG - Healthcare Sector

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

...enabled by…

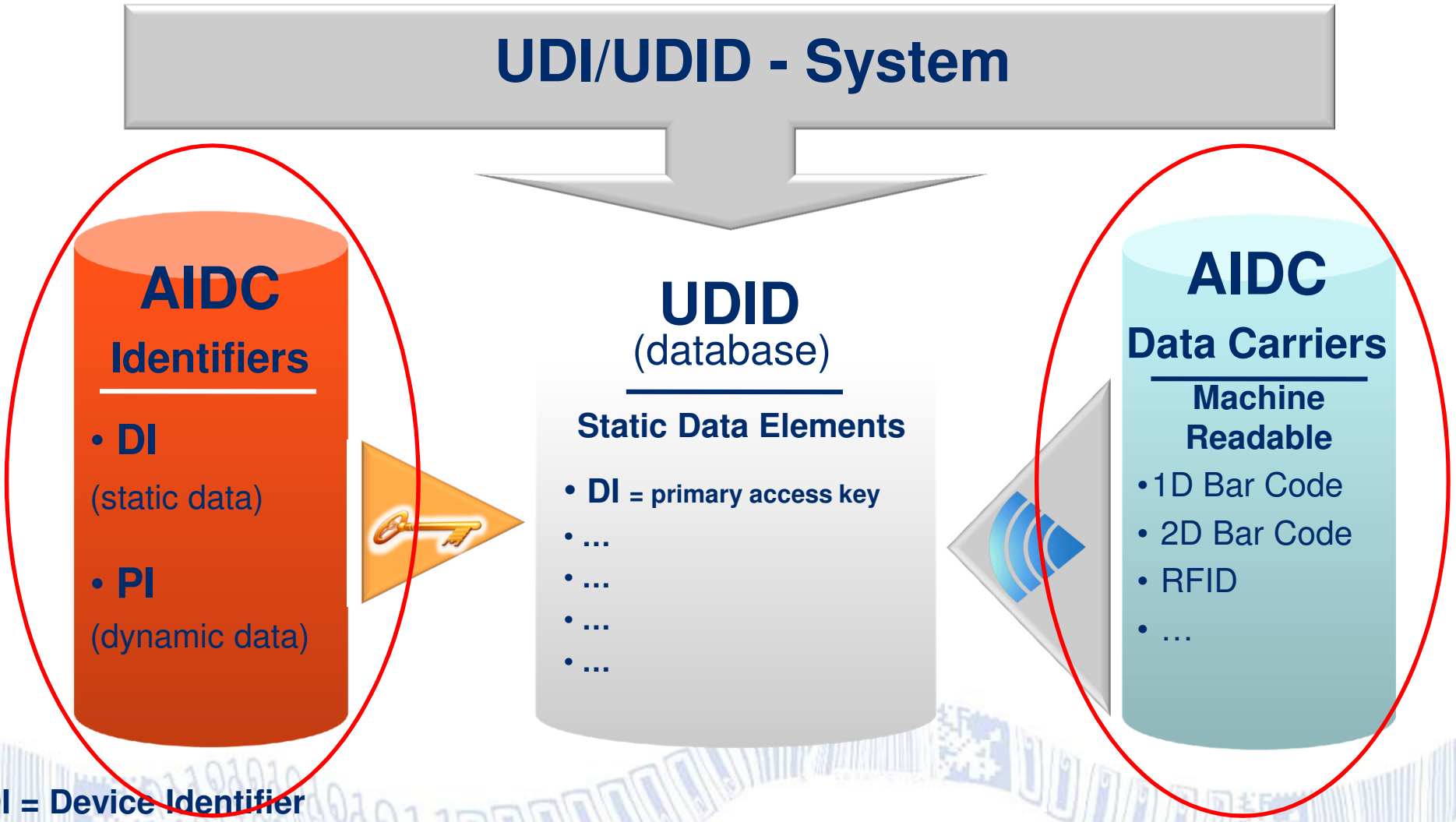
GS1 Standards !!

Unique Device Identification

1. A standardized system to develop **Unique Device Identification numbers** (UDI)
2. **UDI** in human readable and/or **bar code/RFID** on a device, its label, or both
3. **UDI Database** will be created and will need to be maintained
4. **Users** need your help to implement. FDA expects GS1 to play a major role

UDI system…

…AIDC components…



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…

AIDC – Unique Device Identification (UDI)

Goal to be unambiguous identification of a specific medical device. From an AIDC standpoint this identification has two (2) parts:

- **Device Identifier (DI)** – Meant to be the identification of the "generic" medical device – GS1 **GTIN** enables this.
- **Production Identifier (PI)** – Meant to be whatever "control" numbers or data a manufacturer uses in their process – GS1 **Application Identifiers** (**AI's** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

GTIN + AI(s) = UDI

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.

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…

Device Identifier / GTIN Allocation

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

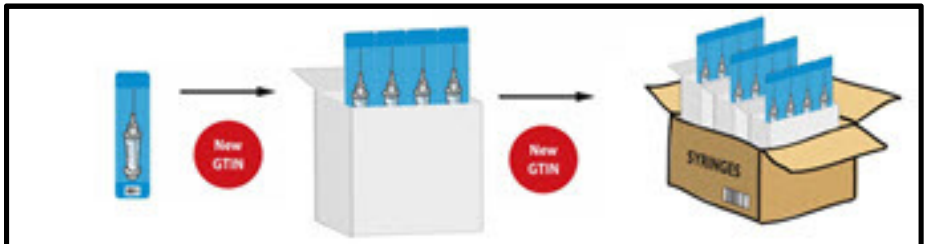
Refer to the appropriate UDI regulation in you area and the GS1 GTIN Allocation Rules for complete details on any regional influence for DI / GTIN change.

UDI in the GS1 system of standards

…UDI in GS1 terms…

Package Levels/Hierarchy, Kits & Placement

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



NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case or Shipper
GTIN A	GTIN B	GTIN C
10857674002017	00857674002010	00857674002027

Kits – Medical Device "kits" have there own UDI.
(NOTE: Refer to the FDA Rule for details. Additional definition & allocation rules for Healthcare kits are being clarified through the GS1 GSMP.)

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

UDI in the GS1 system of standards

…UDI in GS1 terms…

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

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.

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

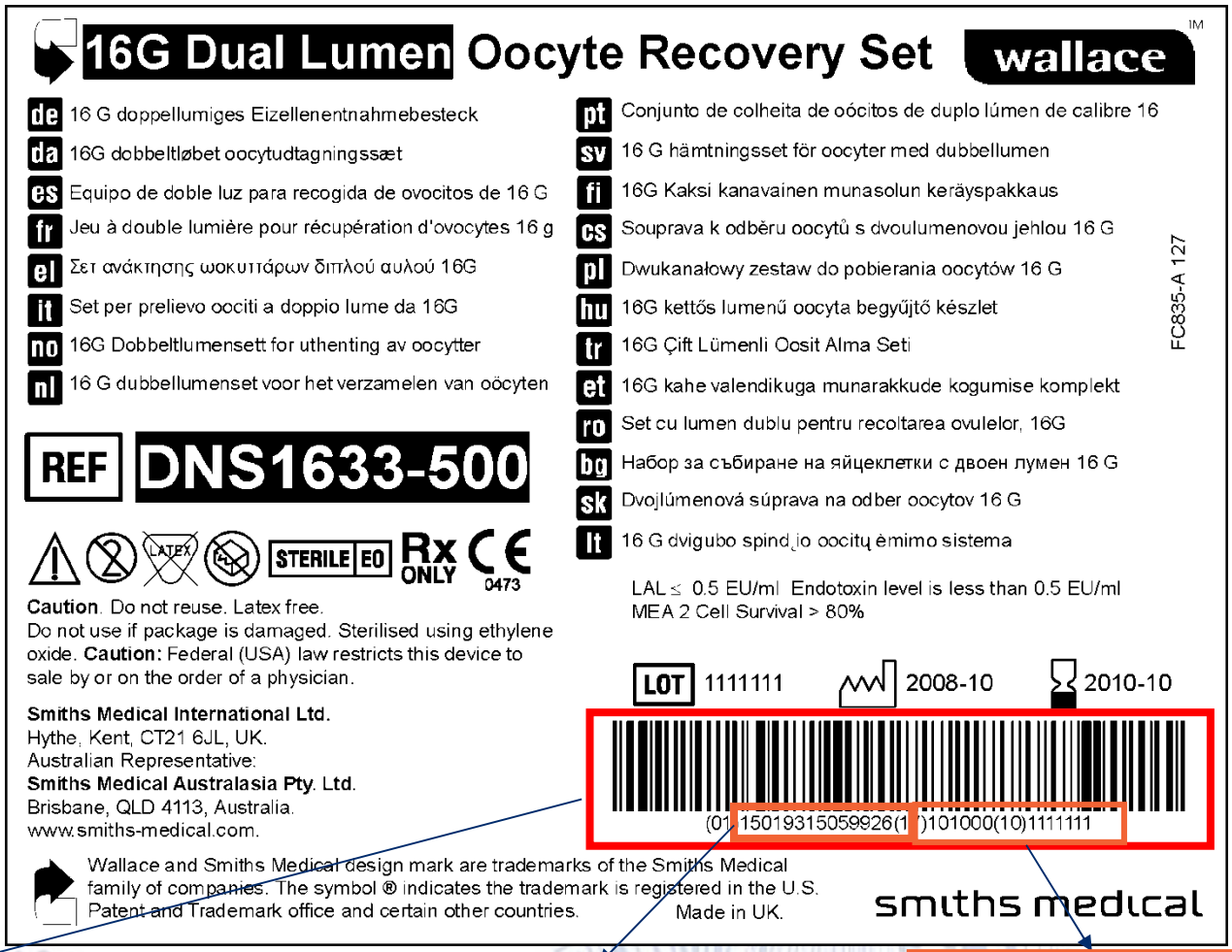
U.P.C. is used primarily in North America. EAN-13 is used throughout the world on Secondary (retail) packaging.

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.

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 example - #1



UDI Bar Code symbol

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

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

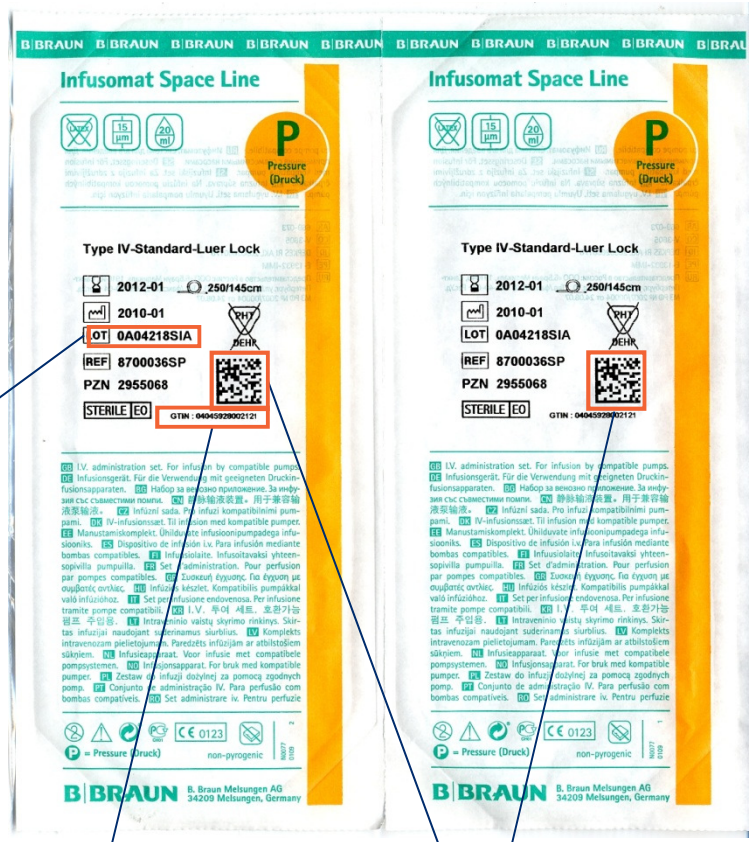
UDI example - #2

UDI Bar Code symbol

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

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

UDI example - #3



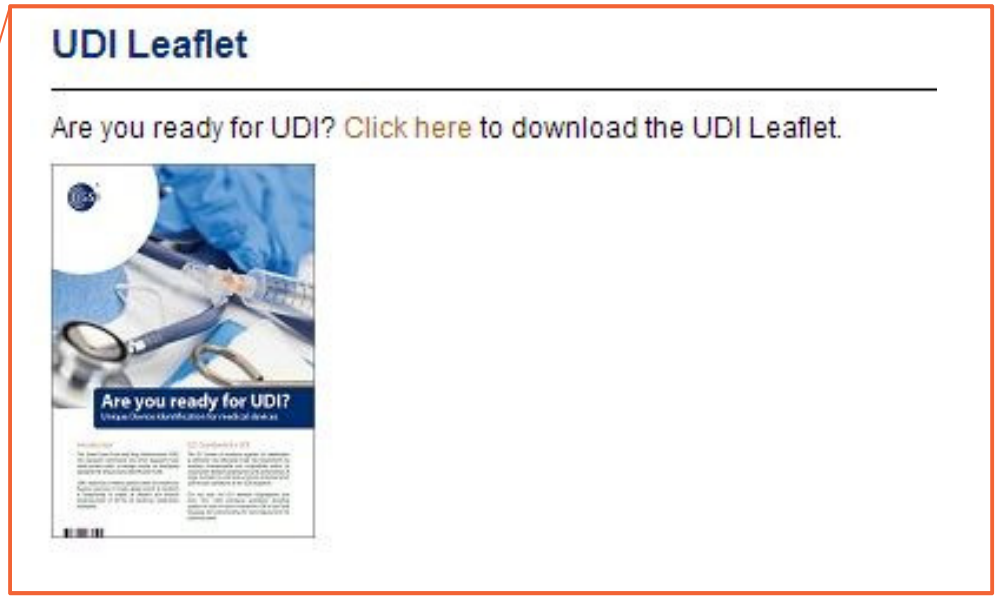
Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

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

UDI Bar Code symbol

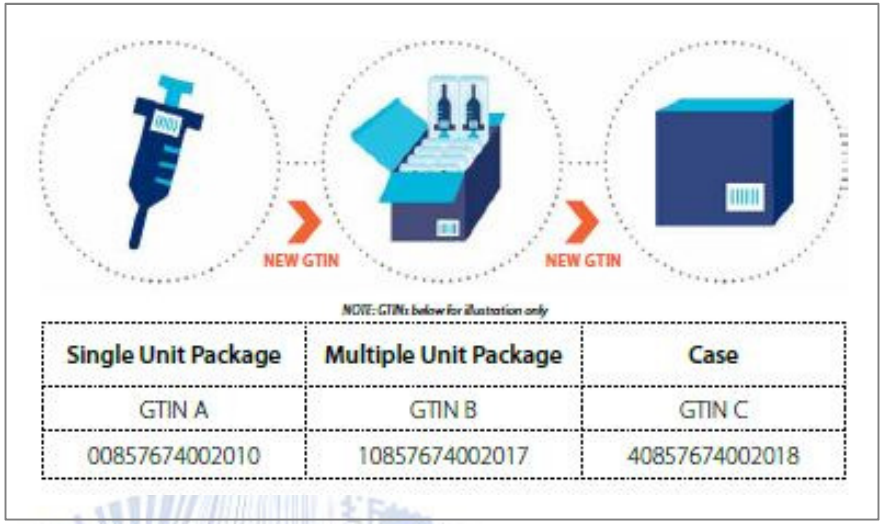
UDI webpage

www.gs1.org/healthcare/udi



UDI leaflet: “Are you ready for UDI?”

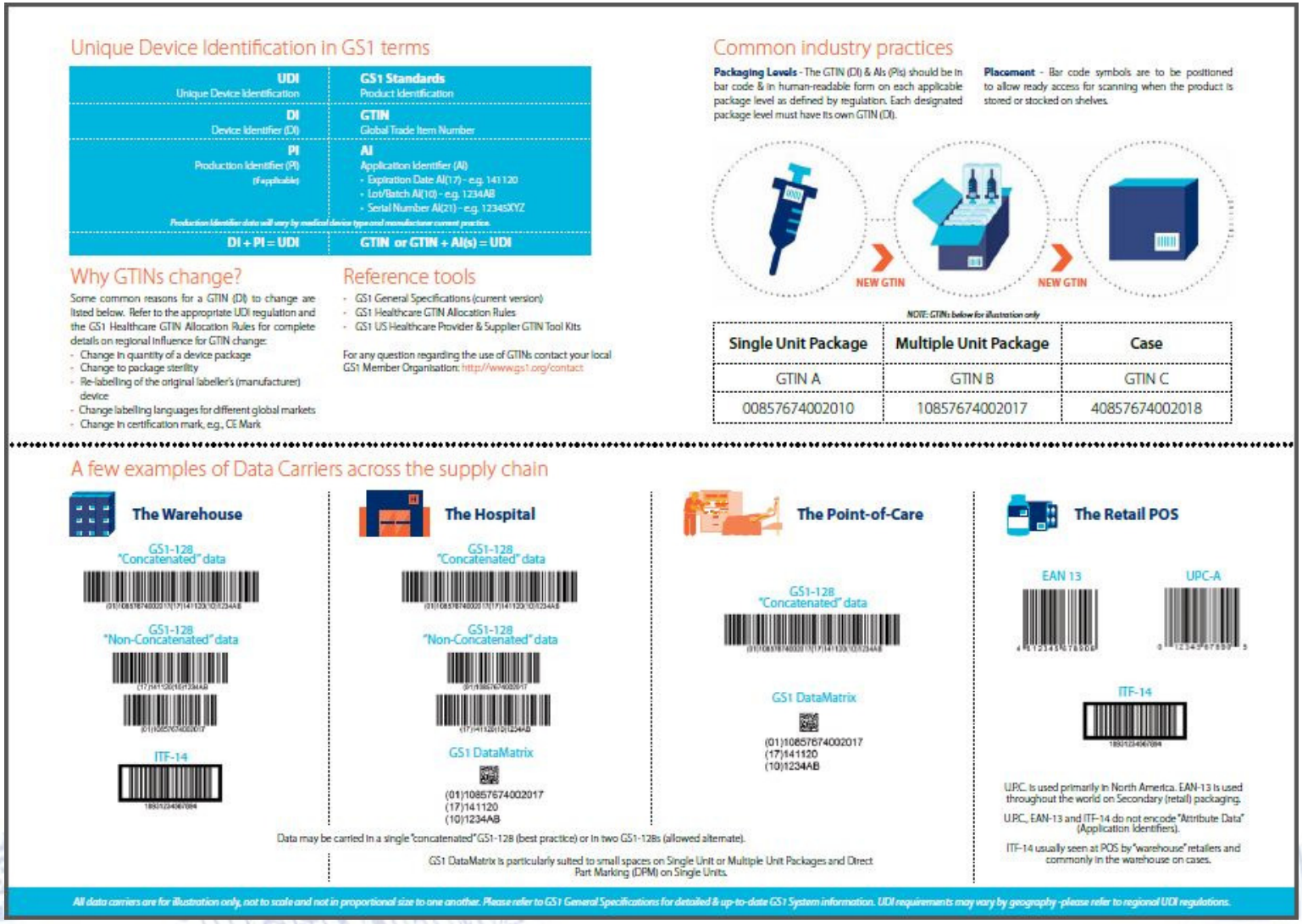
- Introduction to UDI
- UDI in GS1 terms
- Presentation of industry practices
- Benefits of UDI



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

www.gs1.org/healthcare/udi

UDI / GS1 AIDC - a 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. 1234SXYZ
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
00857674002010	10857674002017	40857674002018

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 Implementation Reality – AIDC

…our Panelists and the "reality"…

UDI Implementation Reality

…How to identify/mark my medical device products?…

Moderator

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

Panelists

Mr. Mark Hoyle
International R&D, Advanced Engineering
Teleflex Medical

Mr. Chuck Franz
Vice President and Chief Information Officer
Cook Group Incorporated

Mr. Bodo Winkler
Head of UDI Implementation, Sector Project Lead
Siemens AG - Healthcare Sector

The UDI (Unique Device Identification) Challenge

2013

Teleflex®

SUMMARY

Timing

- Presentation 10 minutes
- Plus Q&A

Discussion Points

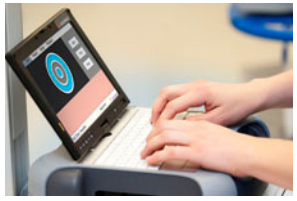
- Brief Teleflex Overview
- GS1 Specification & Rules
- AIDC Decision Process
- Symbology Format & Selection
- State of Readiness
- Quality Control

TELEFLEX AT A GLANCE

Leading global provider of medical devices with leading market positions

- Focused on critical care and surgical procedures
- Annual Revenues: $1.55 billion
- Serving healthcare providers in more than 140 countries
- Global operations: 25 countries
- Employees: ~ 11,500 organized into regions, divisions and global functions
- Established global sales and distribution network
- Well known brands in vascular access (including interventional access), anesthesia, respiratory care, urology, cardiac care and surgery
- Strong financial position
- NYSE: TFX

TELEFLEX TODAY…

Vascular Access	Surgical	Specialty Markets	Cardiac Care	Anesthesia / Respiratory	OEM
					
▪ Central, Peripheral and Arterial Vascular Access Catheters ▪ Catheter Tip Positioning Systems ▪ Sheath Introducers ▪ Vascular Access Accessories	▪ Ligation Systems ▪ Closure Devices ▪ Laparoscopic Access Ports/Trocars ▪ General & Specialty Instruments ▪ Chest Drainage Systems ▪ CV Sutures	▪ Foley Catheters ▪ Intermittent Catheters ▪ Dialysis Catheters ▪ PTA Balloons ▪ Interventional Access	▪ Intra Aortic Balloon Pumps ▪ IAB Catheters ▪ TransRadial Access ▪ Right Heart Products ▪ Percutaneous Sheath Introducers	▪ Supraglottic Airways ▪ Atomization ▪ Epidurals ▪ Peripheral Nerve Blocks ▪ Airway Management ▪ Respiratory Therapy	▪ Specialty Sutures ▪ Catheter Fabrication ▪ Performance Fibers ▪ Custom Engineered Precision Extrusion
~$375 million	**~$291 million**	**~$260 million**	**~$79 million**	**~$406 million**	**~$140 million**

Note: Figures represent 2012 revenues per Form 10K.

Teleflex®

SYMBOLOGY, ALLOCATION RULES & INDICATOR DIGITS

Version 13

Version 8

Teleflex®

AIDC DECISION PROCESS

Artwork Required
- New Product
- Revised Product

GTIN Allocation Rules – Applied

Market / Regulatory Req.?

Space Limitation
Determines Symbology

Home Care
Determines HRI Priority

Production Ready

(DI + PI)

Data integrity is the light at the end of the tunnel, this will partly determine your company success!

FORMAT AND SELECTION – ROUTE TO MARKET - RETAIL?

(01) – GTIN

Indicator Digit

Check Digit

GS1 Company Prefix

Item Reference

Can be shorter based on your GS1 Agreement

A	3	0	0	1	2	3	4	5	6	1	1	1	1	8
B	0	0	0	1	2	3	4	5	6	1	1	1	1	7
C	1	0	0	1	2	3	4	5	6	1	1	1	1	4
D	2	0	0	1	2	3	4	5	6	1	1	1	1	1

Retail Barcode Compatibility EAN / UPC

Note: A, B, C & D Represent different levels of packaging in the hierarchy

Indicator Digits do **NOT** have any meaning, other than specific use cases for 0 and 9. Indicator Digits are **NOT** package level indicators.

YOUR COMPANY's ABILITY TO APPLY THE ENTIRE UDI

The UDI for a large number of devices incorporates two parts, DI (Device Identification) & PI (Production Information)

- DI = GTIN (Global Trade Item Number)
- PI = Expiry Date, Lot Number, Serial Number, Manufacturing Date (or some part thereof).
  - Not all PI components apply to all Classes of Device, or all Levels of Packaging within the Hierarchy for a Product.

Teleflex®

MANUFACTURING ABILITY TO APPLY THE ENTIRE UDI

The variable component (PI) of the UDI may have huge impact on your manufacturing facility and their ability to apply.

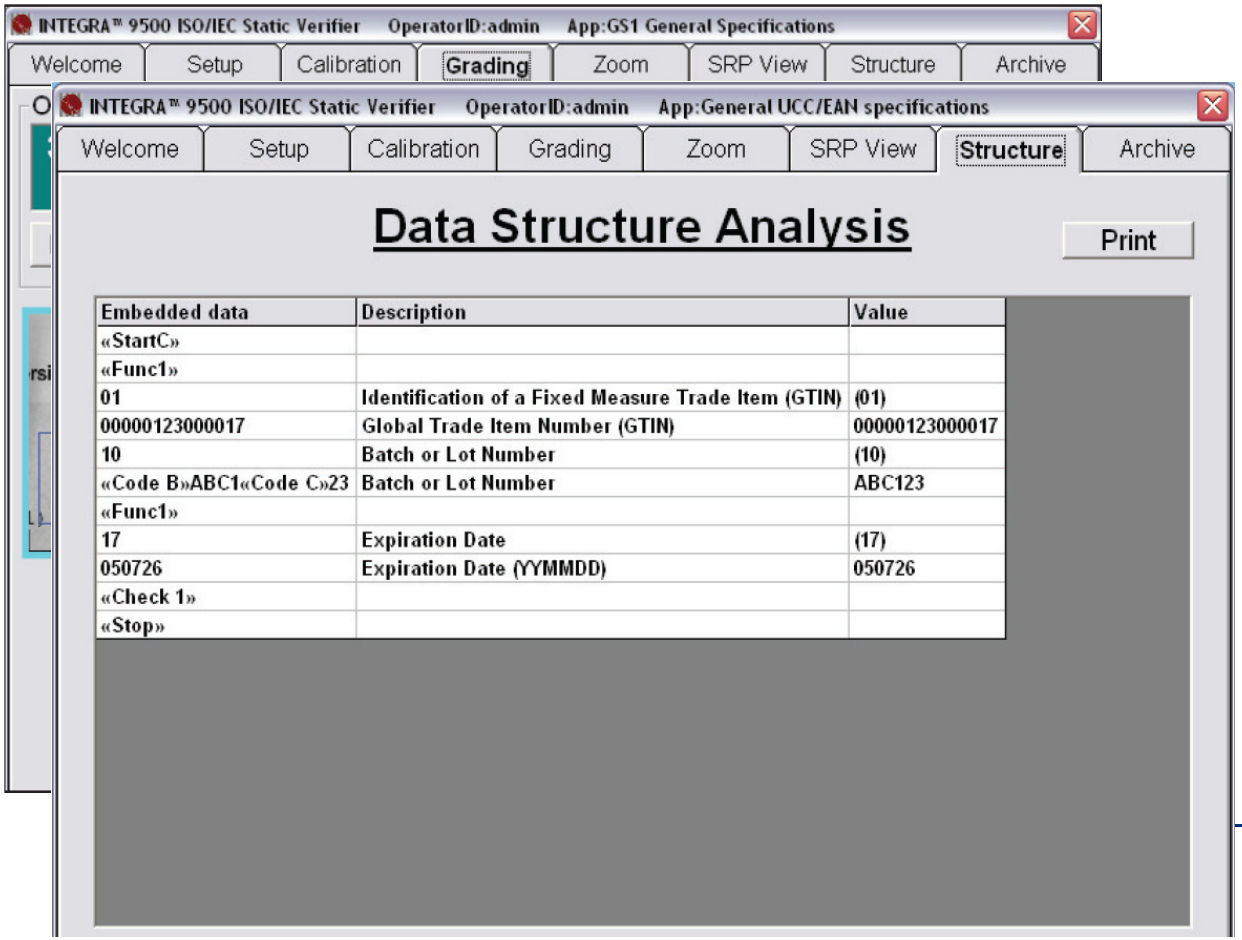
Production speeds, print processes, in-line marking processes, data integration and validation all pose challenges and investment to enable.

Timelines could be significant for implementation.

QC must be managed, that is not the ability to read a code but the ability to measure the quality of the code to ISO / ANSI Standards.

It Beeped, it Must Be Good!

Unfortunately Not….



Standards to Meet

- ISO-15417
- ISO-15420
- ISO-16022

Teleflex®

Contact Details

Mark Hoyle
Packaging Technology Manager
International R&D, Advanced Engineering

Teleflex Medical
Athlone, Co.Westmeath
Ireland

mark.hoyle@teleflex.com

THANK YOU

Teleflex®

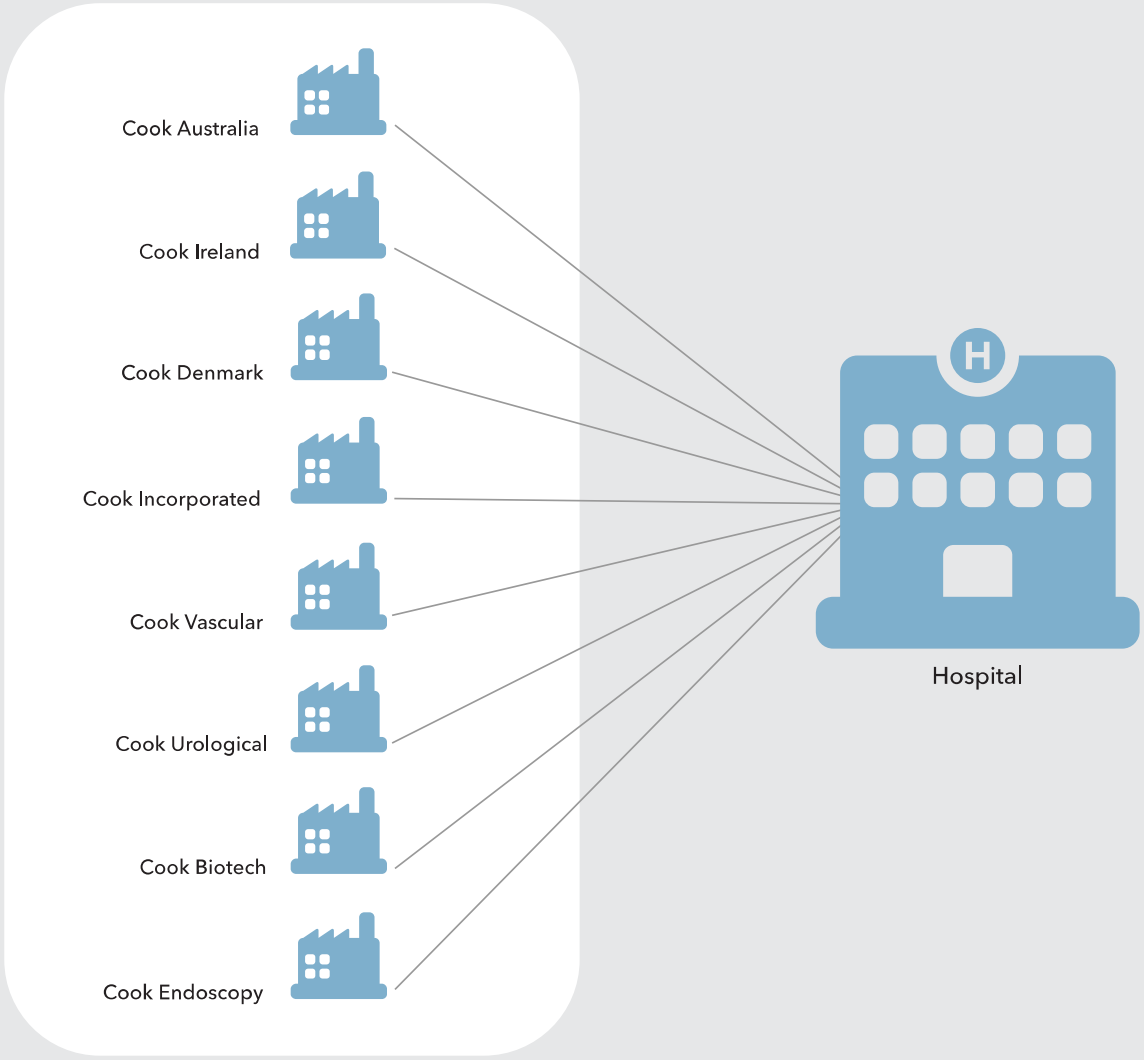
Data Standards Implementation

Chuck Franz
Vice President & Chief Information Officer
Global GS1 Healthcare Conference
San Francisco, October 1, 2013

Cook Medical Overview

- Celebrating 50 years in business
- 8 manufacturing companies
- 10 clinical divisions
- Coverage in 135 countries
- 16,000 SKUs

Cook Medical Circa 1999



How We Got To a Global Standard

1999

376,000 SKUs representing 20,000 parts

2001

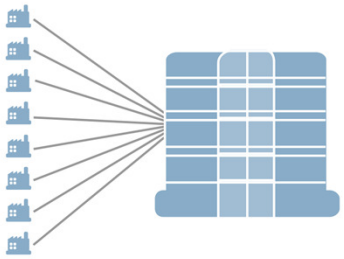
Created global Cook product database

2003

Implemented GS1 standards on labels (GTIN-14 and other AI's)

2005

Created Cook Americas customer service center (CMI)

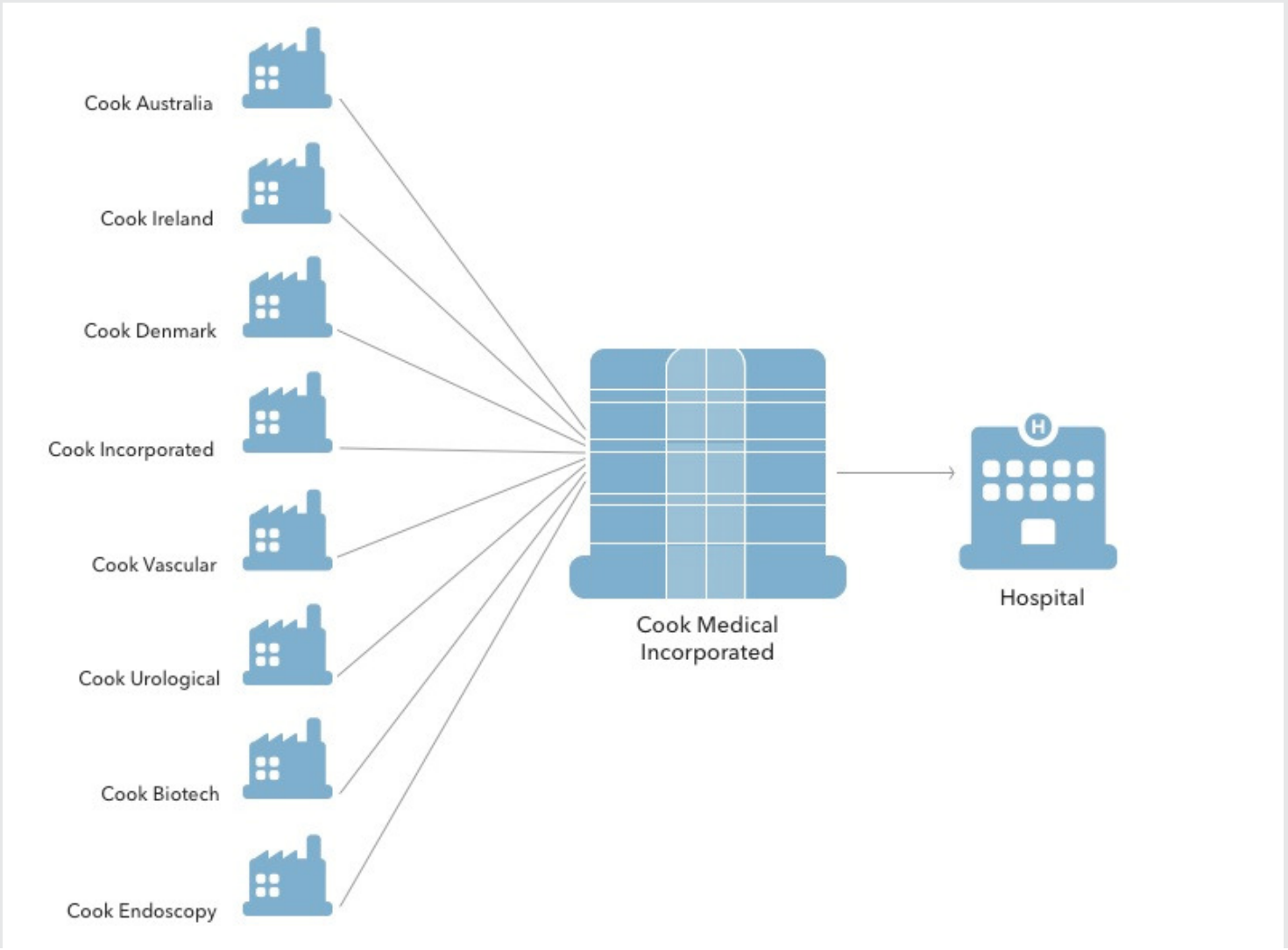


Allows for one customer interface to do business with Cook

2012

- Validated and aligned packaging level indicators on labels
- Published attributes to GDSN
- Transacting with GTINs

Cook Medical Today



SIEMENS

GS1 Conference , October 1-3

Unique Device Identification – What are the Consequences for Manufacturers?

San Francisco, CA, USA

Answers for life.

Unique Device Identification for Medical Devices – The rationale behind…

SIEMENS

MORE
PATIENT SAFETY
THROUGH ENHANCED
DEVICE TRACEABILITY
IN POSTMARKET
SURVEILLANCE

What does UDI stand for?

Unique Device Identifier

Truly unique, manufacturer-independent identifier for listed medical devices

Device Identifier (DI) + **Production Identifier (PI)**

Type/Model-specific
Human-readable on label
Captured in AIDC (Optical Data Carrier)
Transmitted to UDID

Device-specific (unit)
Human-readable on label
Captured in AIDC (Optical Data Carrier)
NOT transmitted to UDID

Situation on UDI
Drivers, Consequences & Outlook

SIEMENS

Drivers

Regulators see UDI as the core element for postmarket surveillance
Customers see in UDI prerequisite for optimizing procurement & inventory management

Situation

The deployment of UDIs will become mandatory in all major markets (USA, EU, CN, JAP etc.), **starting in September 2014 with class III in USA**.
Non-compliance will result in a lock-out from these markets.

No UDI – no business!

Goal & Challenge of a large medical device manufacturer

Create one UDI standard for the whole organization and in parallel accomplish UDI-compliance for Class III-Products by SEP 2014.

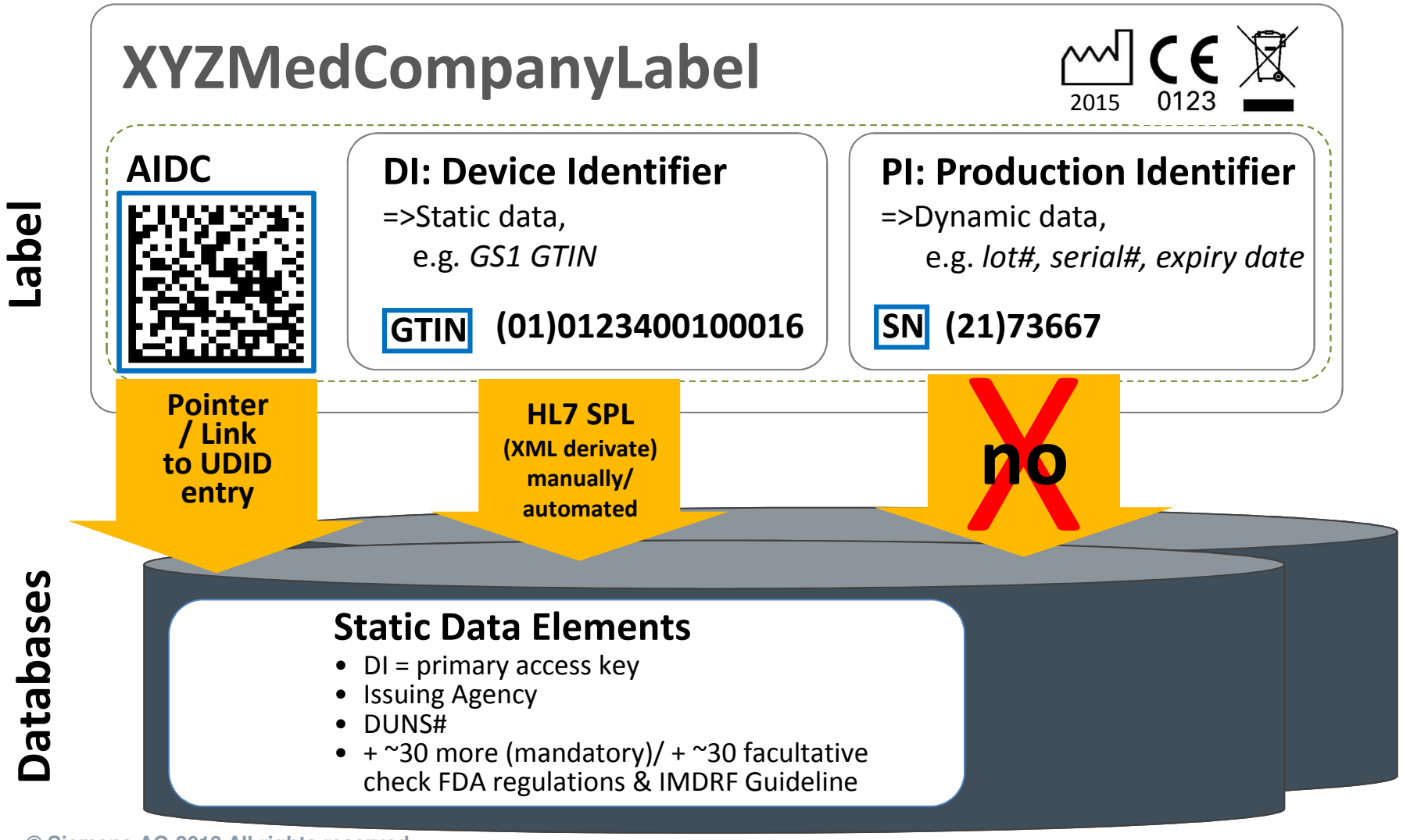
Outlook: This is just the starting point – UDI will open a new dimension of post market surveillance (EHR), hospital logistics/inventory management and performance controlling

Devices - Where to Apply UDI

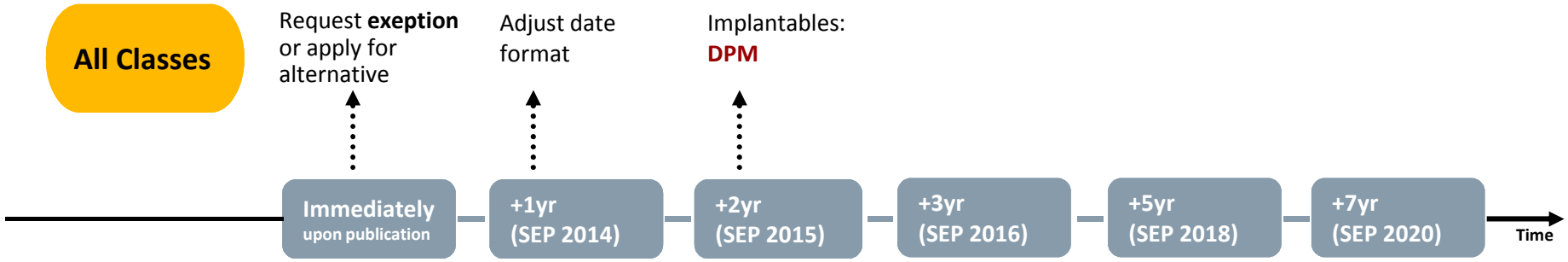
- All **registered medical devices** must carry a UDI
- The **UDI on systems** must be placed in a position that is **accessible during routine use**
- **Components/ Service parts** do not require UDI's *unless they are registered medical devices in their own right*

Core Elements of the UDI System

SIEMENS



UDI-Timelines (FDA)



Class III → UDI on label and package; Data in UDID → DPM if 1) used >1x and sterilized before use 2) stand-alone SW

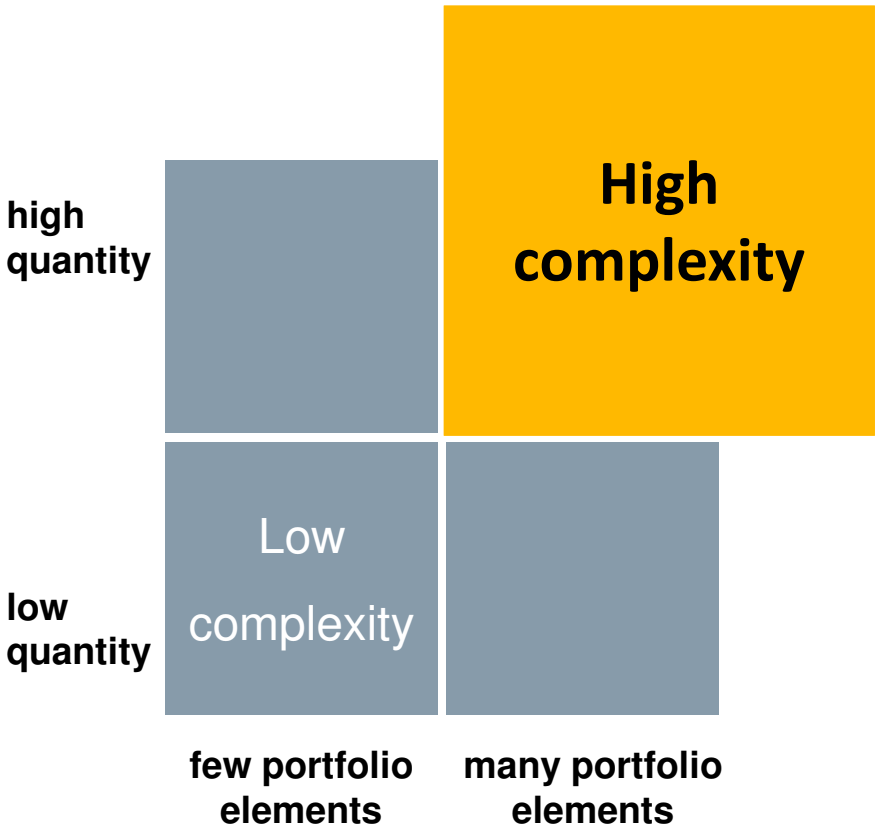
Class II & I – Life-supporting, life-sustaining devices → UDI on label and package; Data in UDID

Class II → UDI on label and package; Data in UDID → DPM if 1) used >1x and sterilized before use 2) stand-alone SW

Class I & devices that have not been classified into class I, class II, or class III → UDI on label and package; Data in GUDID → DPM if 1) used >1x and sterilized before use 2) stand-alone SW

DPM – Direct Part Marking
UDID - UDI Data Base

Challenges in UDI Implementation for Manufacturers



Heterogeneity of upcoming UDI regulations?

Risk classes in portfolio elements?

Existence of OEM business in/out?

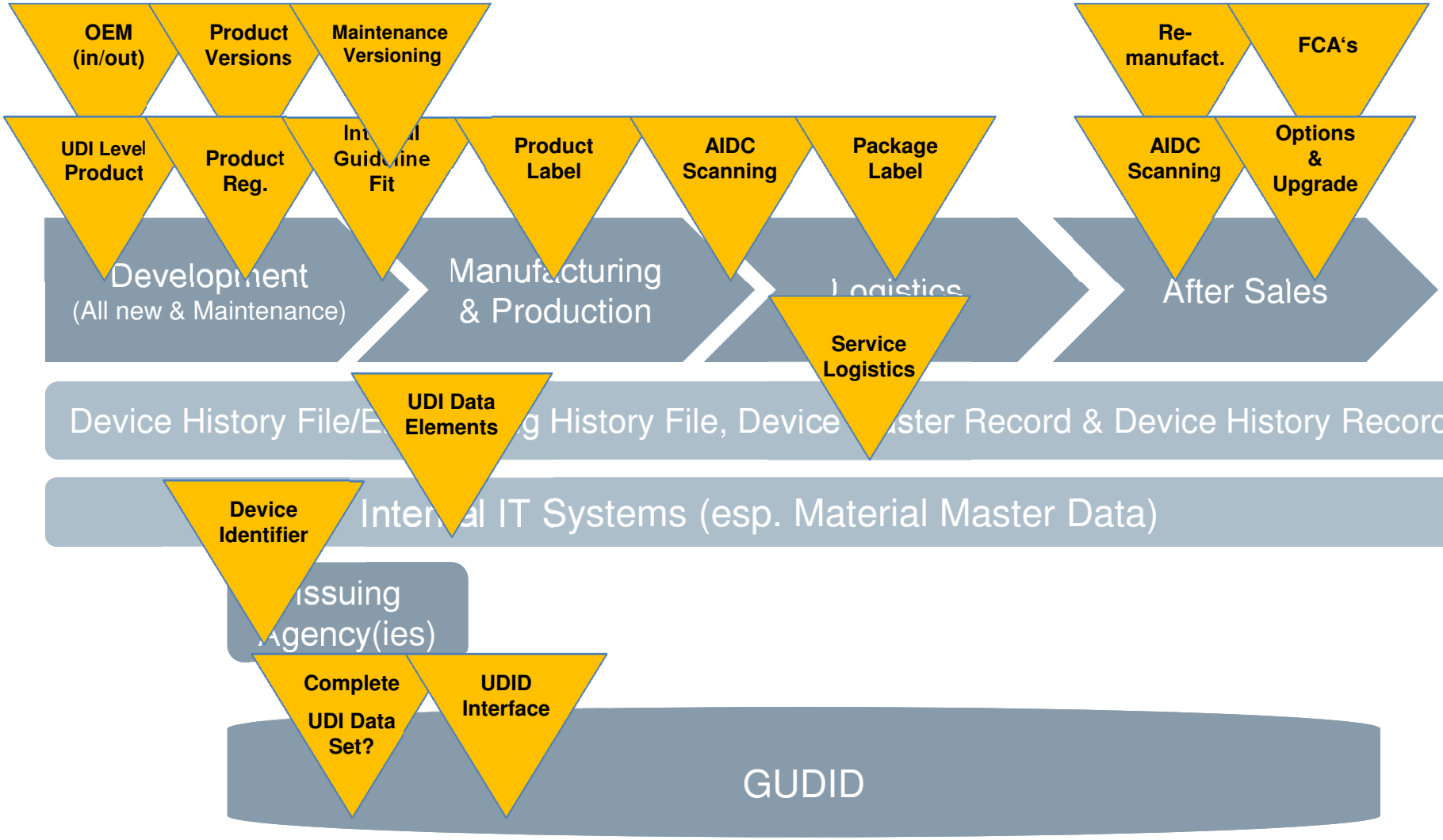
Availability of mandatory data elements?

Regional distribution of customers & service?

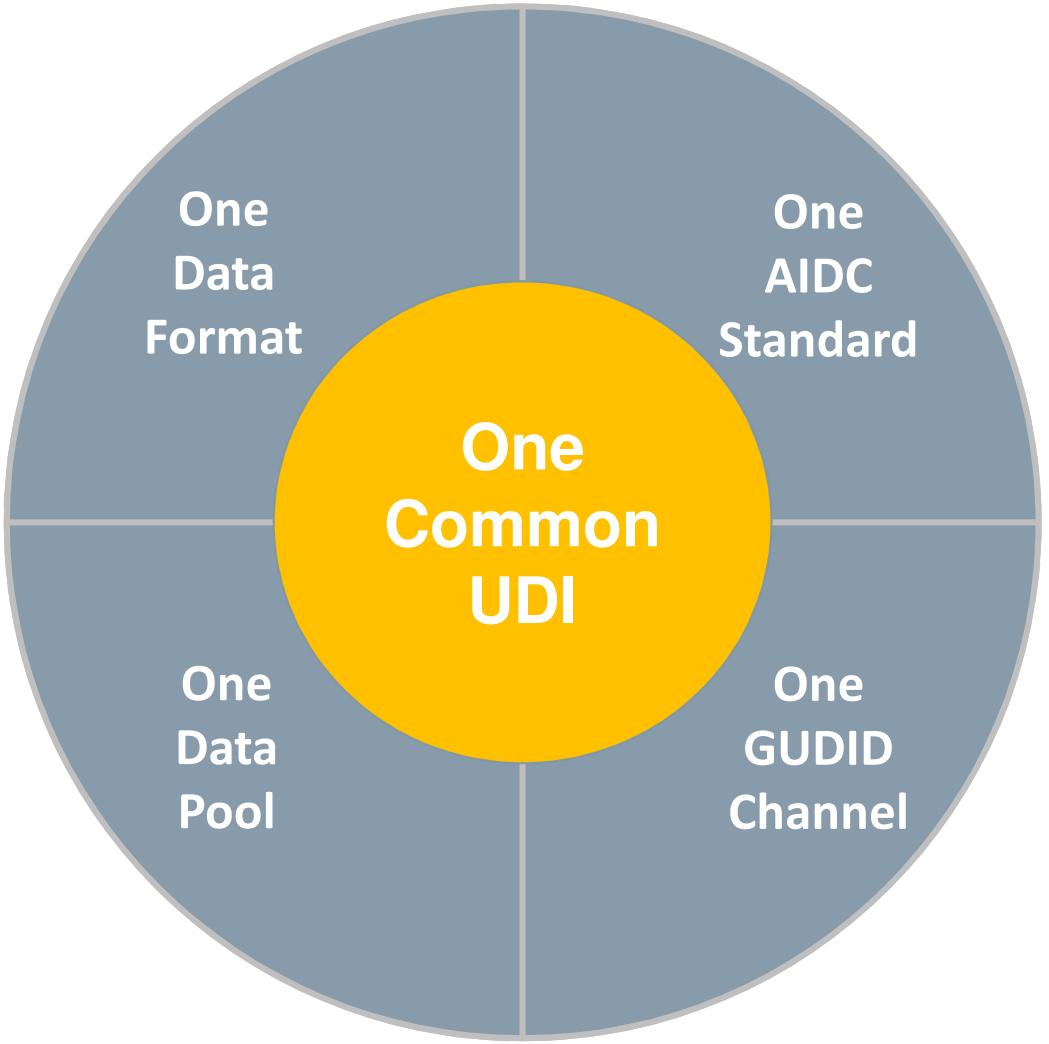
Regional distribution of manufacturing?

Regional Warehousing and distribution?

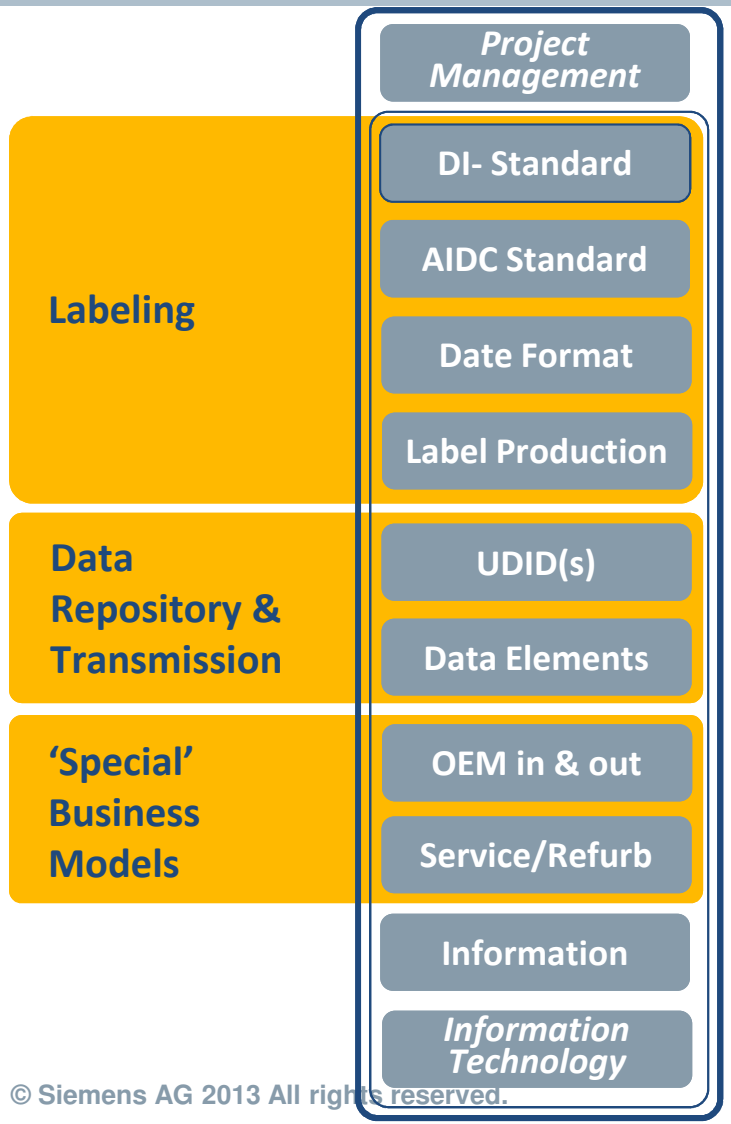
Process Impact Assessment



Keep it simple: One common UDI Standard



UDI Project Workstreams



Project Set-up, government affairs, regulatory guidance corporate governance, implementation control

GS1 GTIN, HBICC

1D stacked Barcode, GS1 2D-Data Matrix, RFID?

CCYYMMDD

Label printers & scanners, design adaptions

Regulators side, centralization/standardization

Data Elements, Data Pool, Data Transmission & UDI in Regulatory Documentation along core processes

OEM in & out

Customer Services, Refurbishing Business

Information Privacy

Any IT related aspects of UDI

Contact Information

Bodo Winkler
Head of UDI Implementation,
Sector Project Lead

Siemens AG

Healthcare Sector

H QT PMO UDI

Henkestr. 127
91052 Erlangen

Germany

Phone: +49-9131-84-6909
Mobile: +49-170-6329368

E-mail:
bodo.winkler@siemens.com

UDI Glossary & Acronyms

- UDI – Unique Device Identifier
- DI – Device Identifier, e.g. GTIN, HBICC…
- PI – Production Identifier, e.g. serial#, lot#...
- HIBC - Health Industry Bar Code
- GTIN – Global Trade Item Number
- GLN – Global Location Number
- AIDC – Automatic Identification and Data Capture, e.g. 2D Data Matrix
- DPM – Direct Part Marking, e.g. laser, etch, engrave
- (G)UDIDs – (Global) UDI Data Base(s) with mandatory & facultative data elements
- Sellable Unit – Units intended to be sold, down to the lowest available level
- Unit of Use – Unit as applied by end user; 1 lancet; 1 test mixed from different bottles
- Configurable Medical Device - Group of Configurations represented by common DI
- Risk-based Approach – Start with highest Risk Class
- IMDRF – International Medical Device Regulators Forum, formerly GHTF
- EHR – Electronic Health Record
- …

Legal Disclaimer

The information contained in this presentation is based on the FDA draft UDI regulations of July 2012, the EU Commission UDI Harmonised Framework of April 2013 and the IMDRF (formerly GHTF) UDI Guidance document published September 2011.

It is not intended to be used as a UDI implementation guide but only as a general information on what might be practical considerations when implementing UDI.

The reader must take the responsibility for the correct interpretation of the published final legislation, application and implementation of UDI in their own organisation.

Please note that some information in this document might become obsolete after the publication of the final legislation, Siemens AG can accept no responsibility for the validity of the information after the final legislation is published.

FDA Unique Device Identification (UDI)…….. a Global Opportunity

Jackie Rae Elkin

Medtronic, Inc. Global Regulatory Affairs

Maximizing the UDI Investment

A strategic approach is necessary (vs. project) for an effective implementation

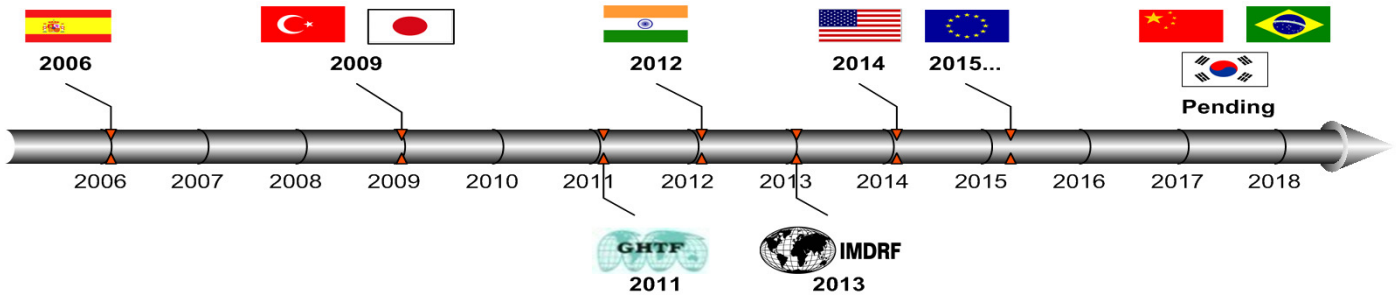
Consider holistic view of how this information **will** be used externally, and how industry can capitalize on the investment internally

- ✓Supply Chain Efficiency
- ✓Clinical Use Data Capture
- ✓Regulatory Compliance
- ✓Regulatory Master Data Foundation

Regulatory Benefits

- Enables healthcare providers to auto-capture device information consistently and accurately in systems and electronic medical records
- Provides for more efficiency, accuracy and automation of capturing product information in the global supply chain, i.e., traceability
- Provides better visibility of device supply and movement through the healthcare supply chain to the patient
- Provides better visibility to device adverse events
- Provides better global visibility to recalled devices
- Provides a better means to perform postmarket surveillance

Global Device Identification Monitoring



Country	Timeline	STD	AIDC / HRI Label Requirements	Data Reporting
Spain	*2006*	*GS1*	*Device Identifier, Production Identifiers to Unit of Use Level*	*Reimbursement* *SAS - Department of Health Andaluz*
Turkey	*2009*	*GS1* *HIBC*	*Device Identifier, Production Identifiers to Unit of Use Level*	*TITUBB: Reimbursement* *SGK – Social Security Institute*
Japan	*2009 - Guideline*	*GS1*	*Device Identifier, Production Identifiers to Unit of Use Level*	*MEDIS: Reimbursement* *Ministry of Health, Labor and Welfare*
India	*2012*	*GS1*	*Device Identifier, Production Identifiers to Unit of Use Level*	*Procurement* *Ministry of Health and Family Welfare*
IMDRF	Release 2013	GS1 HIBC	Device Identifier, Production Identifiers to Unit of Use Level	**UDI -** International Medical Device Regulators Forum (IMDRF)
USA	Implementation Timeline Class III: 2014 Life Sustaining: 2015 (all) Class II: 2016 Class I: 2018	GS1 HIBC ISBT	Device Identifier, Production Identifiers to Unit of Use Level Class II & III	**UDI** Database – US FDA
EU	Release 2013	GS1 HIBC	Will Align with IMDRF	**EUDAMED -** European Commission
China	TBD	TBD	TBD	**TBD - CFDA**
Brazil	TBD	GS1	Will Align with IMDRF	**TBD - ANVISA**
S. Korea	TBD	GS1	TBD	**TBD - KFDA**

Future of UDI

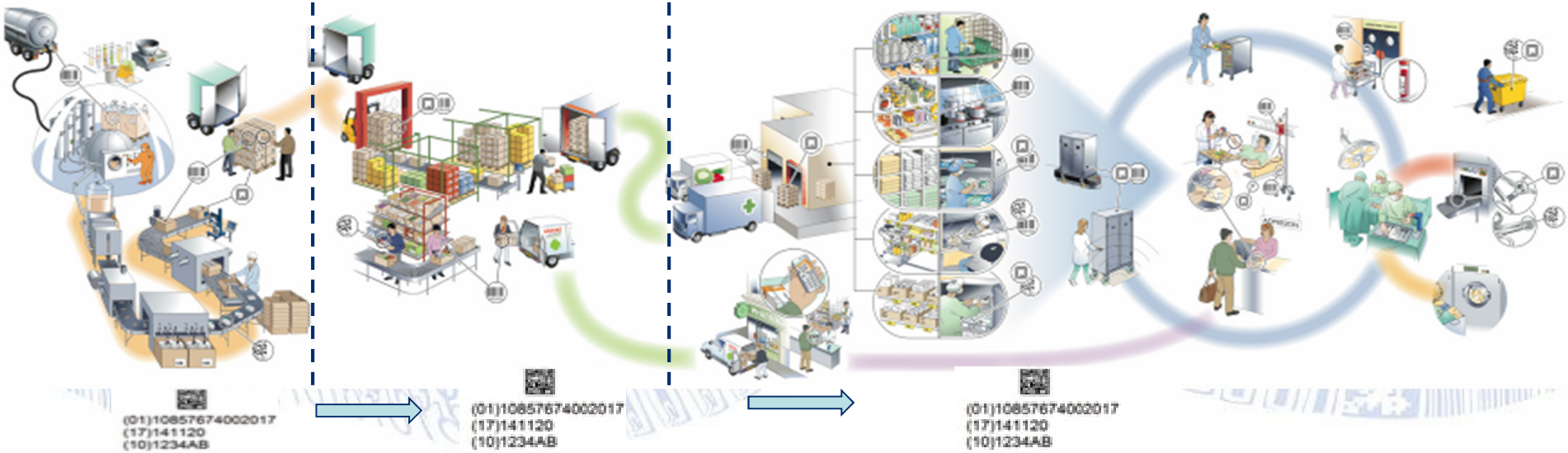
"The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices"

- IMDRF UDI System for Medical Devices

UDI requires ***All*** Healthcare Supply Chain Stakeholders to use the same identifier

(01)00643169001763(17)160712(21)21A11F4855

Manufacturer → *Distributor* → *Hospital or Healthcare Provider* → *Regulator*



Contact Details

Jackie Rae Elkin

Global Process Owner - Standard Product Identification |
Medtronic, Inc.

Global Regulatory Operations

710 Medtronic Parkway, LS 330 | Minneapolis, MN 55432 USA

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

jackie.elkin@medtronic.com

Medtronic

Contact Details

Chuck Biss

Senior Director, AIDC Healthcare
GS1 Global Office Healthcare
Email: chuck.biss@gs1.org