The Global Language of Business

IMPLEMENTATION REALITY SESSION
Unique Device Identification (UDI)

Introductory Session – AIDC

30th GS1 Healthcare Conference – Beijing

Wednesday - 26 October 2016

UDI Implementation "Reality"…

Our Panel…

- GS1 AIDC UDI Basics
  - Chuck Biss - GS1 Global Office
  - Senior Director, AIDC Healthcare
- UDI Regulatory Considerations
  - Jackie Rae Elkin - Medtronic, Inc.
  - Global Process Owner - Standard Product Identification - Global Regulatory Operations …also our Q& A Moderator
- UDI AIDC Implementation Experiences
  - Tom Werthwine – Johnson & Johnson Supply Chain
  - Director, Industry Standards
- UDI AIDC Implementation Experiences
  - Stan Malinowski - Medtronic, Inc.
  - UDI Lead for GS1 Standards and Marking

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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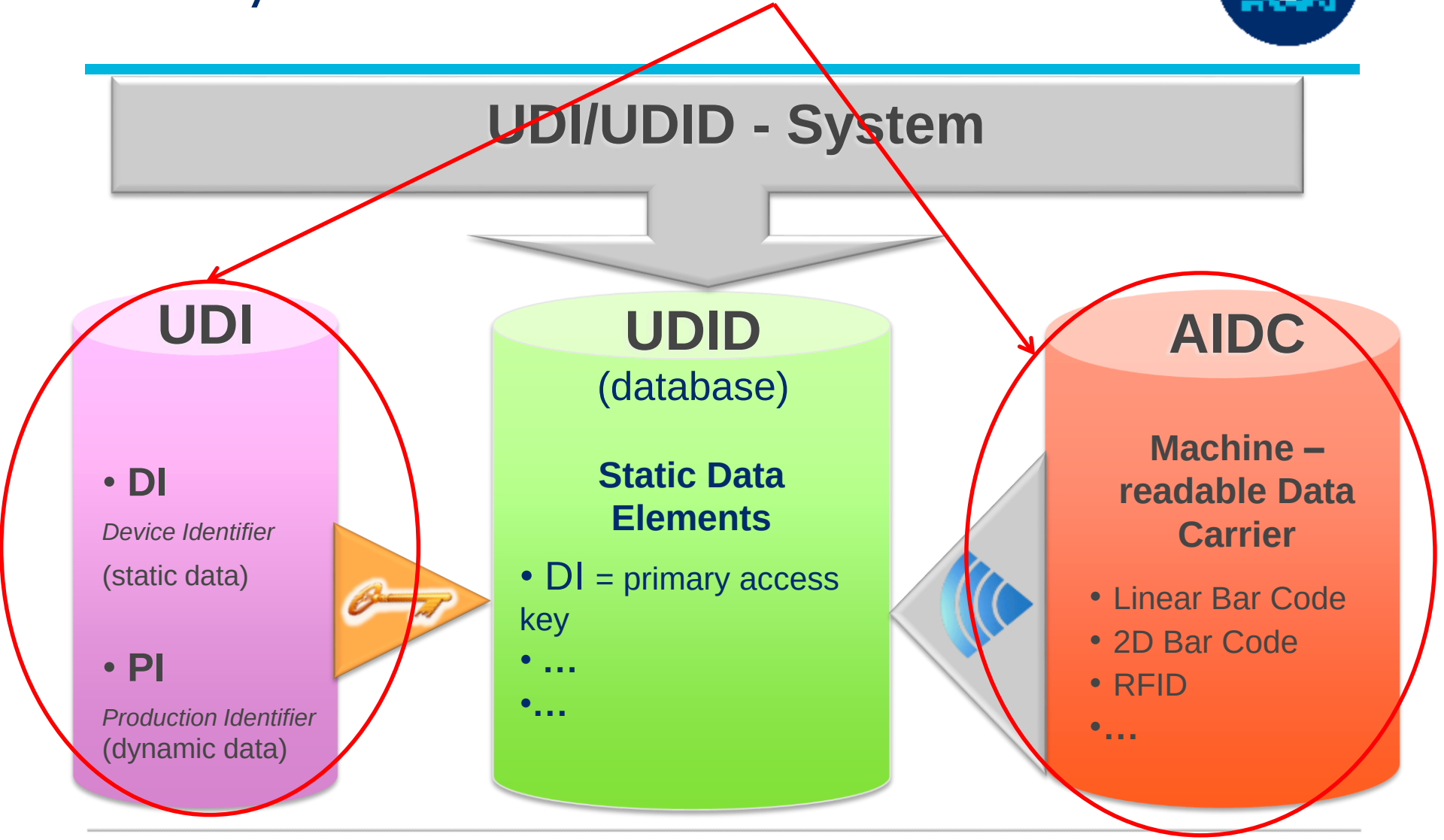
UDI purpose…

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**

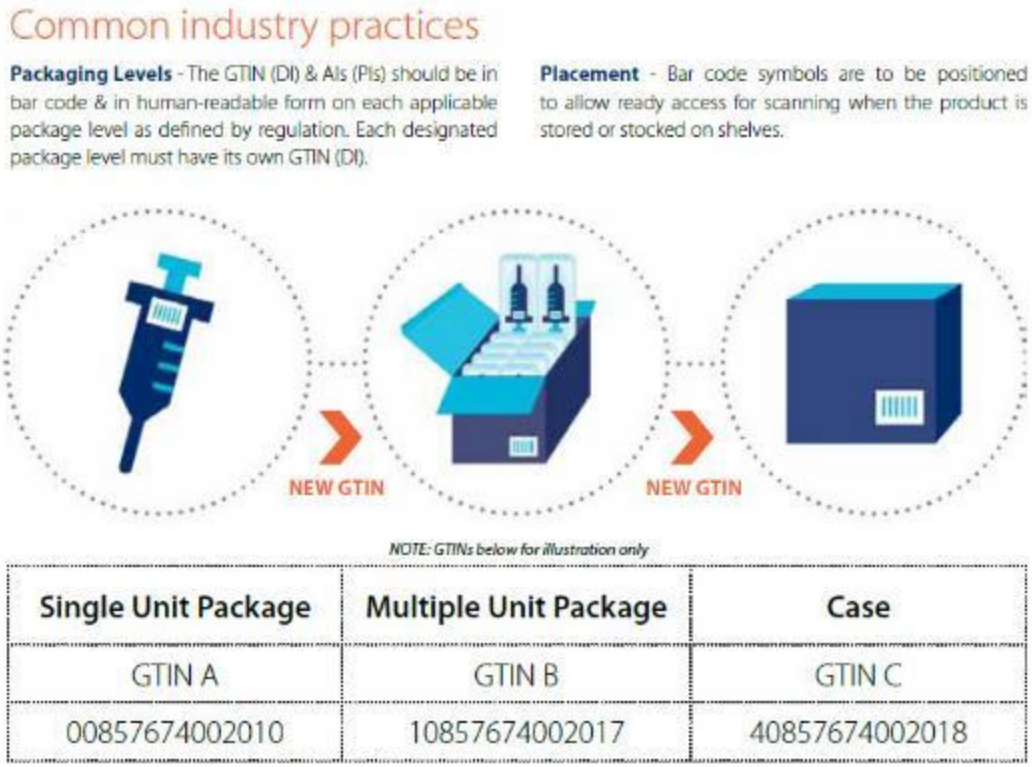
UDI & the GS1 system…

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.



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

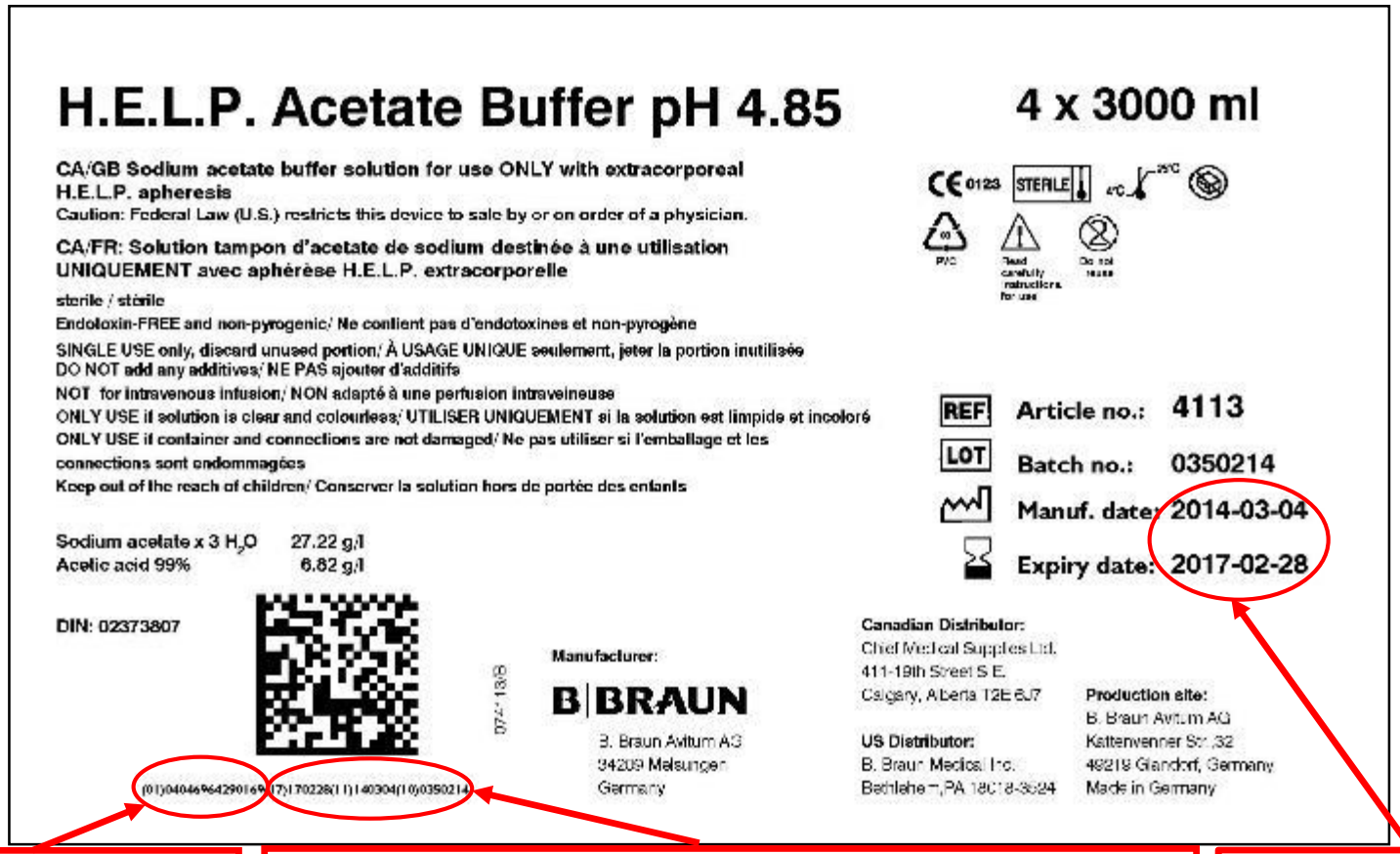
UDI & the GS1 system…

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…



H.E.L.P. Acetate Buffer pH 4.85

4 x 3000 ml

CA/GB Sodium acetate buffer solution for use ONLY with extracorporeal H.E.L.P. apheresis
Caution: Federal Law (U.S.) restricts this device to sale by or on order of a physician.

CA/FR: Solution tampon d'acetate de sodium destinée à une utilisation UNIQUEMENT avec aphérèse H.E.L.P. extracorporelle

sterile / stérile
Endotoxin-FREE and non-pyrogenic/ Ne contient pas d'endotoxines et non-pyrogène
SINGLE USE only, discard unused portion/ À USAGE UNIQUE seulement, jeter la portion inutilisée
DO NOT add any additives/ NE PAS ajouter d'additifs
NOT for intravenous infusion/ NON adapté à une perfusion intraveineuse
ONLY USE if solution is clear and colourless/ UTILISER UNIQUEMENT si la solution est limpide et incolore
ONLY USE if container and connections are not damaged/ Ne pas utiliser si l'emballage et les connections sont endommagées
Keep out of the reach of children/ Conserver la solution hors de portée des enfants

Sodium acetate x 3 H_2O 27.22 g/l
Acetic acid 99% 6.82 g/l

REF Article no.: 4113
LOT Batch no.: 0350214
Manuf. date: 2014-03-04
Expiry date: 2017-02-28

DIN: 02373807

(01)04046964290169(17)170228(11)140304(10)0350214

Manufacturer:
B. Braun Avitum AG
34209 Melsungen
Germany

Canadian Distributor:
Chief Medical Supplies Ltd.
411-19th Street S.E.
Calgary, Alberta T2E 6J7

US Distributor:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524

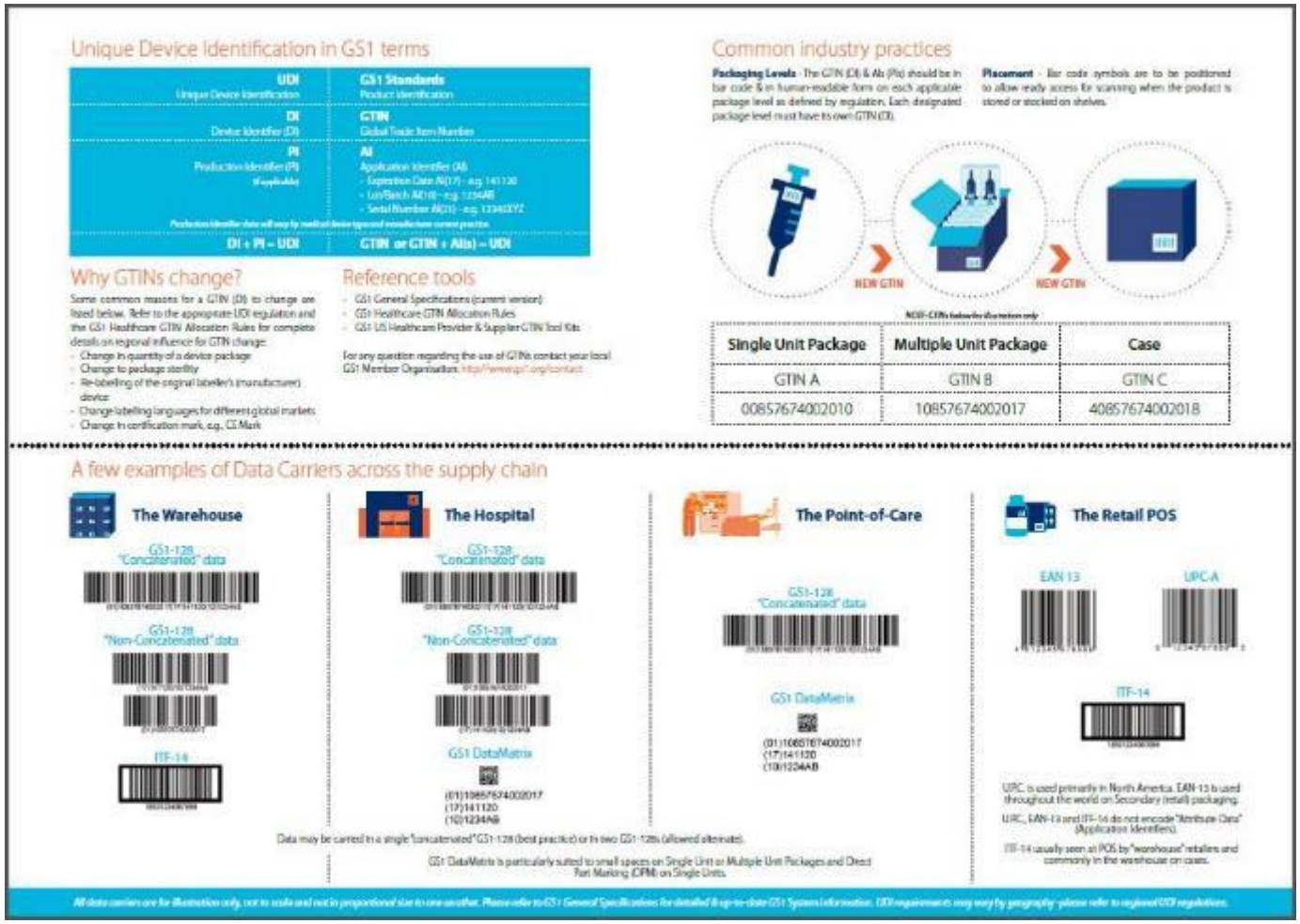
Production site:
B. Braun Avitum AG
Kattenvenner Str. 32
49219 Glandorf, Germany
Made in Germany

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, regulatory…

- UDI Regulatory Considerations
  - the principles, global considerations, the nuances…

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

PRINCIPLES OF UDI IMPLEMENTATION

October 26, 2016

JACKIE RAE ELKIN
MEDTRONIC GLOBAL REGULATORY AFFAIRS

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OUR THERAPIES IMPROVE THE LIVES OF MORE THAN

2 PEOPLE EVERY SECOND

EXTENSIVE SCOPE
PROVEN RESULTS

- **85,000+** EMPLOYEES
- **7,500+** SCIENTISTS AND ENGINEERS
- **$1.6B*** RESEARCH AND DEVELOPMENT INVESTMENT
- **53,000+** PATENTS
- **400+** CLINICAL TRIALS
- **62 MILLION+** LIVES IMPROVED

OUR REACH EXTENDS
AROUND THE WORLD

- **155+** COUNTRIES
- **460+** LOCATIONS
- **80+** MANUFACTURING FACILITIES
- **50+** RESEARCH AND INNOVATION CENTERS

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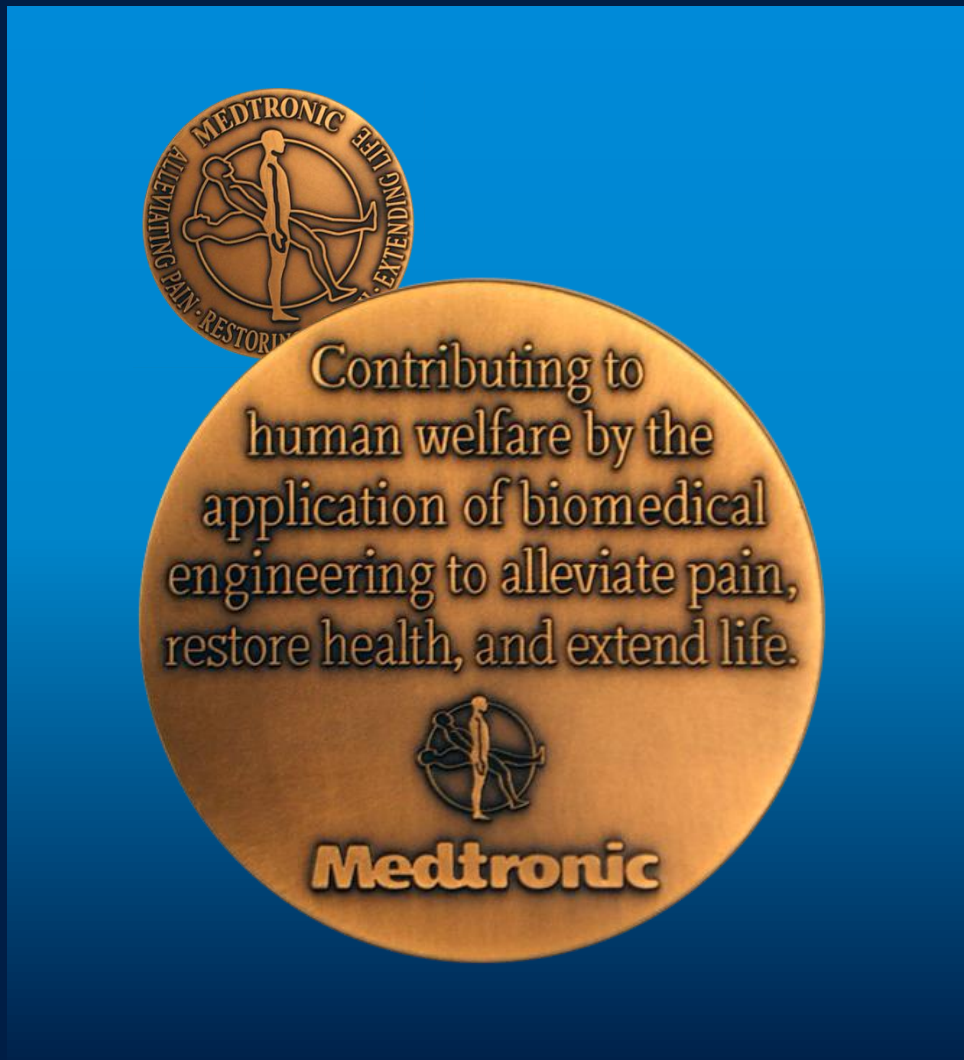
THE START OF AN **ENDURING** **MISSION**

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- To maintain good citizenship as a company.



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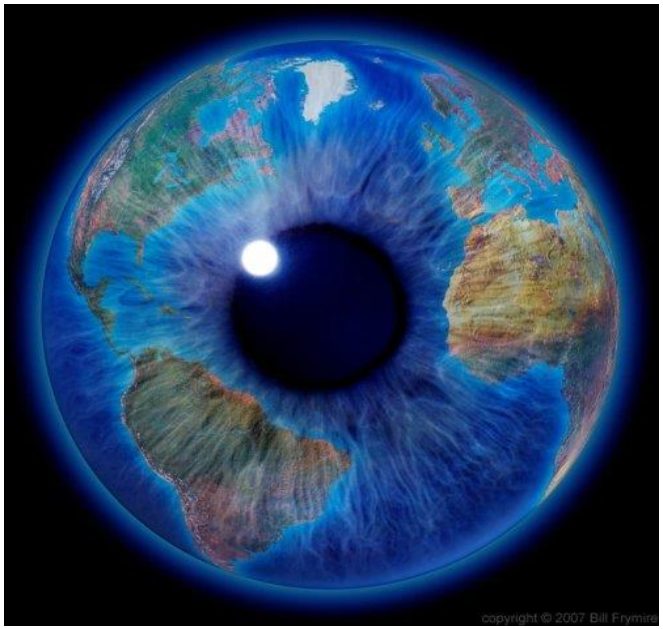
AGENDA

- IMDRF UDI Guidance
  - ➢UDI System Expectations
  - ➢UDI System Framework
- Comparison of UDI for US / EU/ IMDRF
  1) Develop a Standardize System of UDI
  2) Place UDI in HRI & AIDC on Package / Device

- Final Thoughts

UDI ……The Whole World is Watching



IMDRF
UDI SYSTEM
FRAMEWORK

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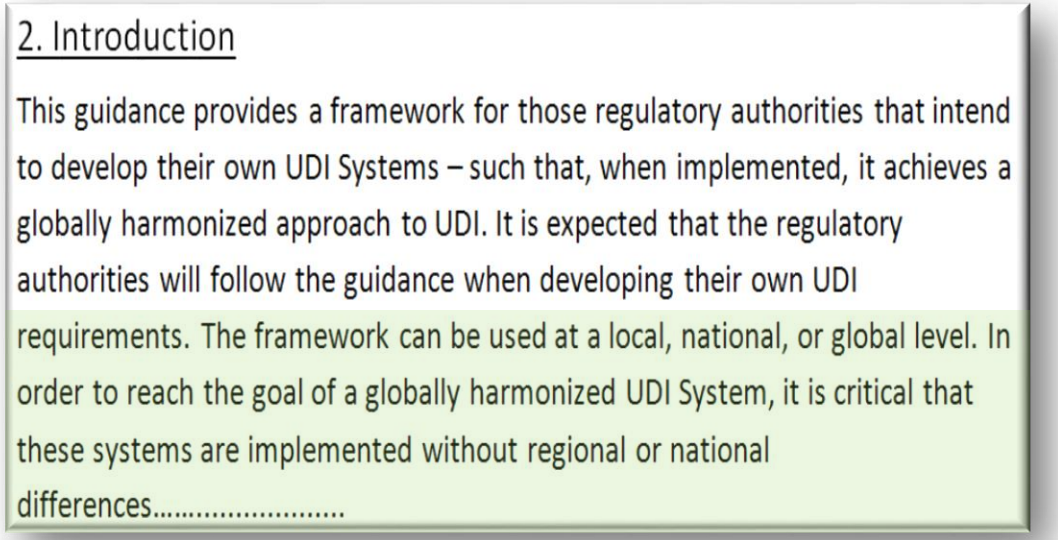
INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) UDI WORK GROUP

IMDRF International Medical Device Regulators Forum



2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences.....

UDI WG Established under Global Harmonization Task Force (GHTF) October, 2008.

IMDRF Guidance UDI for Medical Devices
Final Version, December 9, 2013

http://www.imdrf.org/documents/documents.asp

IMDRF
UDI SYSTEM EXPECTATIONS

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THE FUNDAMENTAL CONCEPTS OF A GLOBALLY HARMONIZED UDI SYSTEM INCLUDE:

- the UDI and UDI Carrier are based on **global standards**,
- a UDI applied to a medical device anywhere in the world should be able to be **used globally and to meet the UDI requirements** of its regulatory authority,
- national or local identification numbers should **NOT be a substitute for UDI**,
- regulatory authorities **should not specify the procedure for modifying** these UDI standards
- the UDI Database (UDID) **core elements should not be modifie**
- the UDID should use the Health Level Seven **International (HL7) Structured Product Label (SPL) and web based interface for data submission,**
- **every medical device needs to be identified by a UDI**, unless it is exempted

A GLOBALLY HARMONIZED AND CONSISTENT APPROACH TO UDI IS EXPECTED TO PROVIDE:

- **traceability of medical devices**, especially for field safety corrective actions,
- **adequate identification** of medical devices **through distribution and use**,
- **identification** of medical devices in **adverse events**,
- **reduction of medical errors**,
- documenting and longitudinal **capture of data** on medical devices.

COMPARISON OF UDI IMDRF / US / EU

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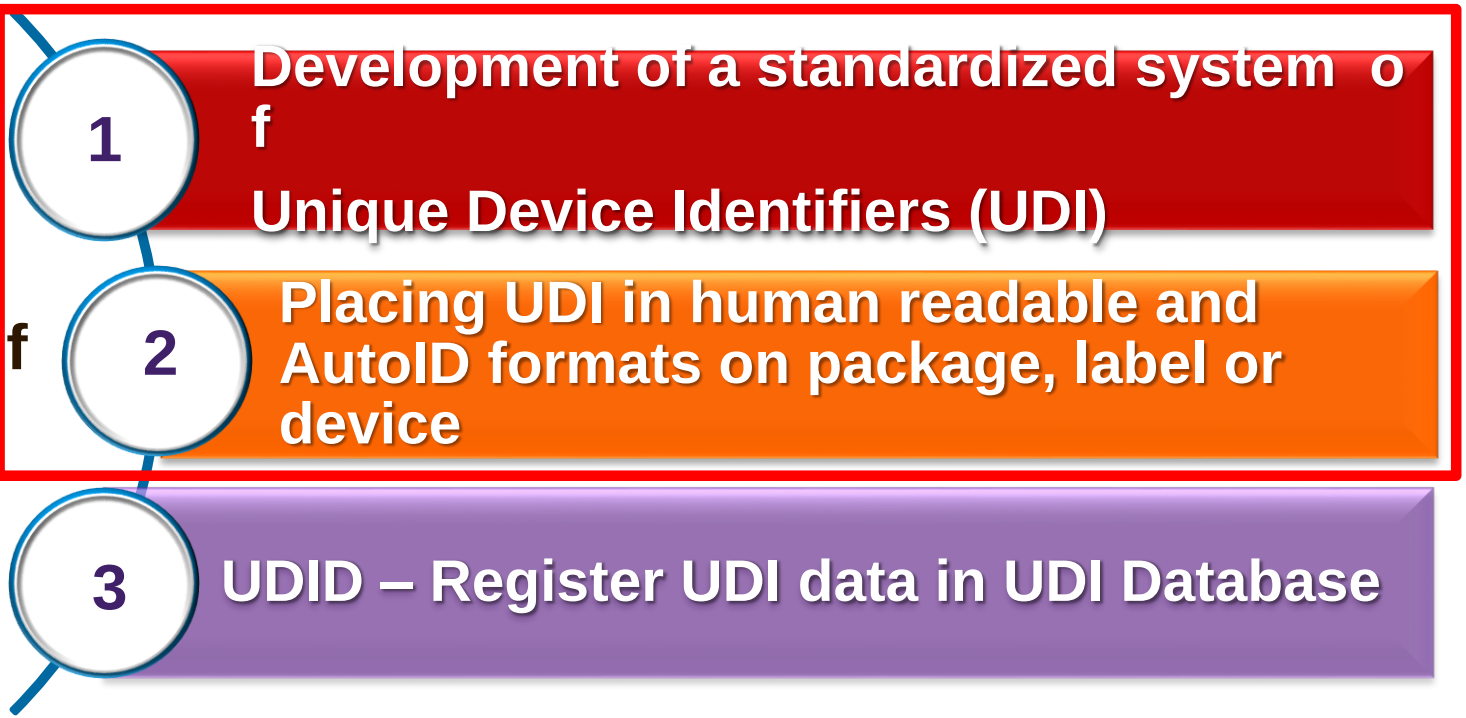
UNIQUE DEVICE IDENTIFICATION SYSTEM

Comprised of 3 Distinct Ideas



DEVELOP A STANDARDIZED SYSTEM OF UDI

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

- **Manufacturer should create and maintain** globally unique UDIs on medical devices
- **Only the Manufacturer can est** : UDI on the device or its packaging

- Globally accepted ISO/IEC coding standards implemented by global organizations such as **GS1, HIBCC and ICCBBA**, meet the criteria of the UDI and **manufacturers shall be permitted to choose** which system to use

- National or regional regulatory requirements **shall not restrict methods of AIDC** as this will hinder the establishment of a globally harmonized UDI Sy

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

- National/regional regulation for UDI System shall **include a robust and transparent mechanism for evaluating and adjudicating requests for UDI exemptions** and **alternative placements** of UDI and UDI-PI

- The employed UDI **must meet the requirements of the globally harmonized UDI System** to adequately identify a device **through its distribution and u**

- A **change of the label to** display or **modify a UDI-DI should not** (in and of itself) **require a premarket submission and/or re-registration**. Manufa may be requested to notify/inform the Regulator

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

- The UDI contains two parts: an **UDI-DI and UDI-PI.**

- If a **lot number, serial number, software version or expiration date** appears on the label, they **should be part of the UDI-PI**. If there also is a manufacturing date on the label, it does NOT need to be included in the UDI-PI (unless it is the only UDI-PI).
- A UDI shall be **assigned to the device itself or its package**. **Higher levels** of packaging **shall have their own UDI**. Shipping containers should be exempted.
- When a UDI is not assigned (and labelled) to a device at the level of its unit of use, **UoU UDI-DI should be assigned, to associate the use of a device with a patient**.

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

- Each **component, sub-system or accessory considered a medical device and is commercially available needs a separate UDI** unless the components are part of a convenience, medical procedure, IVD kit or configurable medical device system that is marked with its own UDI. **Kits should have their own UDI.**

- **Any change in the following Requires a New DI**:
  - ✓ Brand Name,
  - ✓ Device version or model,
  - ✓ Labelled as single use,
  - ✓ Clinical Size (Volume, Length, Diameter),
  - ✓ Packaged sterile / need sterilization before use,
  - ✓ Quantity of devices provided in a package,
  - ✓ Critical warnings or contraindications: e.g. containing Latex or DEHP.

PLACE UDI HRI & AIDC ON PACKAGE / DEVICE

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2 Placing UDI in human readable and AutoID formats on package, label or device

- The **UDI Carrier** (AIDC & HRI of the UDI) **shall be on the label or on the device itself and on all higher levels of device packaging**.

- In case of **significant space constraints** on the Unit of Use package the UDI carrier **may be placed on the next higher packa l**.

- The UDI Carrier for single use medical devices of risk class A and B packaged and labeled individually **does not need to be on its package but rather on higher level of packaging e.g. carton**.

2 Placing UDI in human readable and AutoID formats on package, label or device

- **No particular AIDC methods should be required by a regulatory authority**. Globally accepted AIDC methods based on ISO standards (GS1, HIBCC or ICCBBA) shall be used.

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

(01) 10222222333334(17) 091231(10) A1345B(21) 1234

- If linear bar codes are used, the UDI-DI and UDI-PI can be **concatenated** **non-concatenated** in two or more bar codes

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

(01)10857674002017

(17)141120(10)1234AB

- In case of RFID, a linear or 2D **bar code shall also be provided** on the lab

- The HRI format shall **follow the rules of the UDI code issuing organiza**

2 Placing UDI in human readable and AutoID formats on package, label or device

- If there are significant constraints limiting the use of both AIDC and HRI on the label, the **AIDC format shall be favored**.

- Medical devices that are reusable and require reprocessing between patients should have a **UDI Carrier on the device itself**.

FDA allows HRI

- A single finished medical device made up of multiple parts that have to be assembled **may have the UDI Carrier only on one part**.

- 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.

FINAL THOUGHTS .....

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UDI EVOLUTION AND CHALLENGES

Prerequisites

- **RIM – Regulatory data & systems**
- **Global Standards Adoption**
- **Regulatory Data Migration**

Compliance

- **Multi-year US implementation**
- **New regulations expected in several countries**

Efficiencies & Benefits

- **Supply Chain efficiencies**
- **Business opportunities**
- **Customer Offerings**

How do we …….. ?

Utilize RIM to full potential

- Adoption (enforcement) of principles and policy

Drive continuous improvement?

- Refine & improve UDI processes
- Extend submission capabilities
- Extend team structure to support Geographies

Formalize identification of benefits?

- Benchmarking
- Future state / benefit planning

THANK YOU!

Jackie Rae Elkin

Global Process Owner - Standard Product Identification | Corporate Regulatory Operations

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LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

UDI Implementation

To continue, implementation experiences…

- UDI AIDC Implementation
  - one company's implementation view to date, good and bad…

Tom Werthwine
Johnson & Johnson Supply Chain
Director, Industry Standards

Johnson & Johnson SUPPLY CHAIN

UDI AIDC Implementation Experience

Tom Werthwine
Director, Industry Standards
Johnson & Johnson Supply Chain

October 2016

Johnson & Johnson - A Global Presence

- Global Leader in Health Care
- More than 275 Operating Companies in 60 Countries
- Selling Products in more than 175 Countries
- Approximately 128,000 Employees Worldwide

The Johnson & Johnson Credo

- Created in 1943
- Drives deep commitment to ethical principles
- Common set of values unifying diverse business

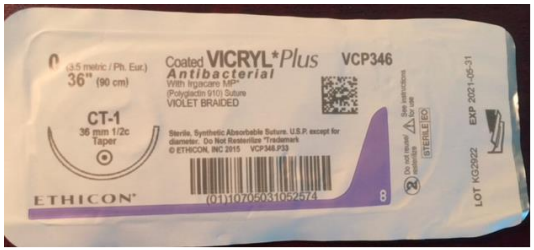
Johnson & Johnson Medical China

- Founded in 1994
- More than 3,500 employees
- Headquartered in Shanghai
- Offices in Beijing, Guangzhou, Wuhan, Nanjing, Jinan, Hangzhou, Chongqing, Chengdu, Shenyang, Xi'an, Tianjin
- Products for minimally invasive and open surgery, electrophysiology diabetes care, orthopedic & infection prevention
- Committed to technology, patient education and physician training

The Challenges

For Johnson & Johnson companies

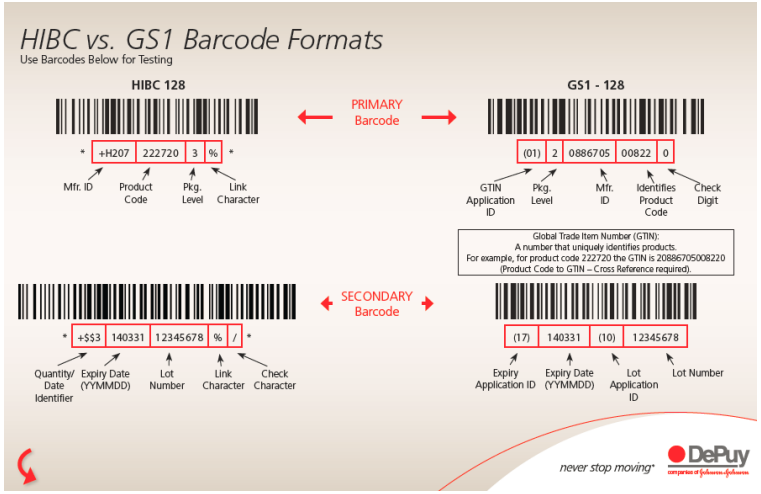
- A large portfolio of medical devices and in-vitro diagnostics
- A large and complex “make organization” relying on internal and external manufacturers
- Multiple ways to print labelling and a diverse packaging portfolio
- Products that need direct part marking
- A dynamic merger, acquisition, and divestiture program



The Challenges

For Customers

- Many companies adopted the HIBCC bar code standard and some customers use the bar codes
- Some customers use linear only bar code scanners
- Customers new to AIDC have issues with scanning
- Customers adopting UDI want to pre-load GTINs before they received UDI-compliant product



The Process

Build an Extraordinary team

- Find the Champions of UDI
- Engage all functions

Rely on external resources


AdvaMed
Advanced Medical Technology Association


Develop enterprise wide policies

- GS1 bar codes
- GTINS in one place
- Document specific decisions

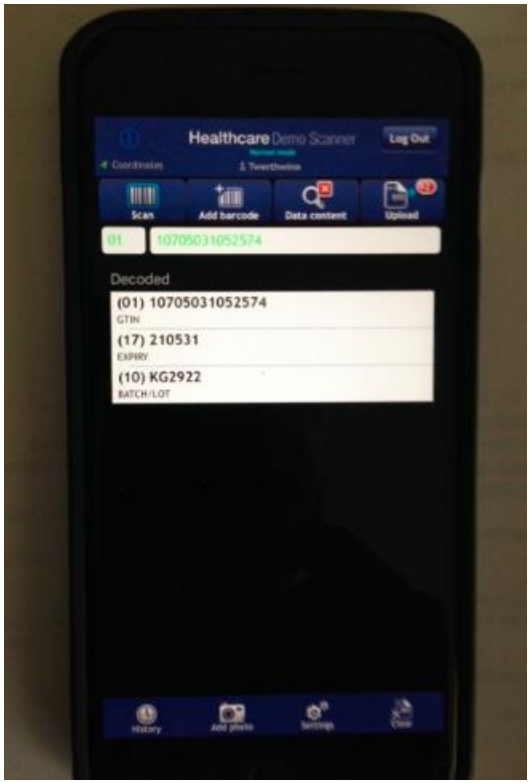
The Technology

Recognize that AIDC in healthcare is an open system

GS1 US Barcode Verification Report
Report Number: GS1USBV07064

Technical Analysis of the Symbol

GS1 Parameters	Assessed	Within Standard Range	Required	ISO Parameters	ISO Grade	Within Standard Range	Required
Symbol Structure	0	✓	Includes Check Digit, FNC1 in 1st position etc.	Overall ISO Grade	4.0/06/660 (A)	✓	≥ 1.5
X-dimension	10.0 mils 0.01"	✓	SST #6 .0067" To .0195"	Decode	PASS 248	✓	PASS
Bar Code Height Min	0.390" Manually Measured	C	.500"	Symbol Contrast	4.0 (A) 81%	✓	> 1.5
Quiet Zone (Left)	0.450" Manually Measured	✓	≥ 0.100" (10X)	Minimum Reflectance	PASS	✓	PASS
Quiet Zone (Right)	0.870" Manually Measured	✓	≥ 0.100" (10X)	Edge Contrast	PASS	✓	PASS
Human Readable	010081233702006 0	✓	One-to-one match with encoded data	Modulation	4.0 (A) 80%	✓	≥ 1.5
Bar Code Width	1.340" Manually Measured	✓	≤ 6.5" (Including Quiet Zones)	Defects	4.0 (A) 8%	✓	≥ 1.5



The Technology

Common mistakes in bar coding

New label designers often select EC200 Datamatrix and Code 128 and not the GS1 versions that use GS1 data carrier identifiers and group separators

2.2.1 Function 1 Symbol Character (FNC1)

By definition in ISO/IEC 16022 GS1 DataMatrix uses a special start sequence to differentiate GS1 DataMatrix from other ISO/IEC Data Matrix symbols. This is achieved by using the Function 1 Symbol Character (FNC1) in the first position of the data encoded. It enables scanners to process the information according to the GS1 System Rules.

The FNC1 (codeword 232) has two separate uses in GS1 DataMatrix:

- Start character: FNC1 is a special, non-printable, character. It is often inserted using a double-byte "Latch to extended ASCII" but this is system dependent.
- Field Separator to separate application identifiers that are not in the predefined list. (See table 2.2.3-1)

Important:

- In accordance with ISO/IEC 15424 - Data Carrier Identifiers (including Symbology Identifiers), the Symbology Identifier is the first three characters transmitted by the scanner indicating symbology type. For a GS1 DataMatrix the symbology identifier is]d2.

Why important?
Used to parse data.
Send GTIN to GTIN field.
Send LOT to LOT field, etc.

The Technology

Collaboration with actual clinical users

Geisinger staff scans new label in OR, warehouse and patient room.

GEISINGER

The Rewards

Patient Safety: A Credo Value

Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

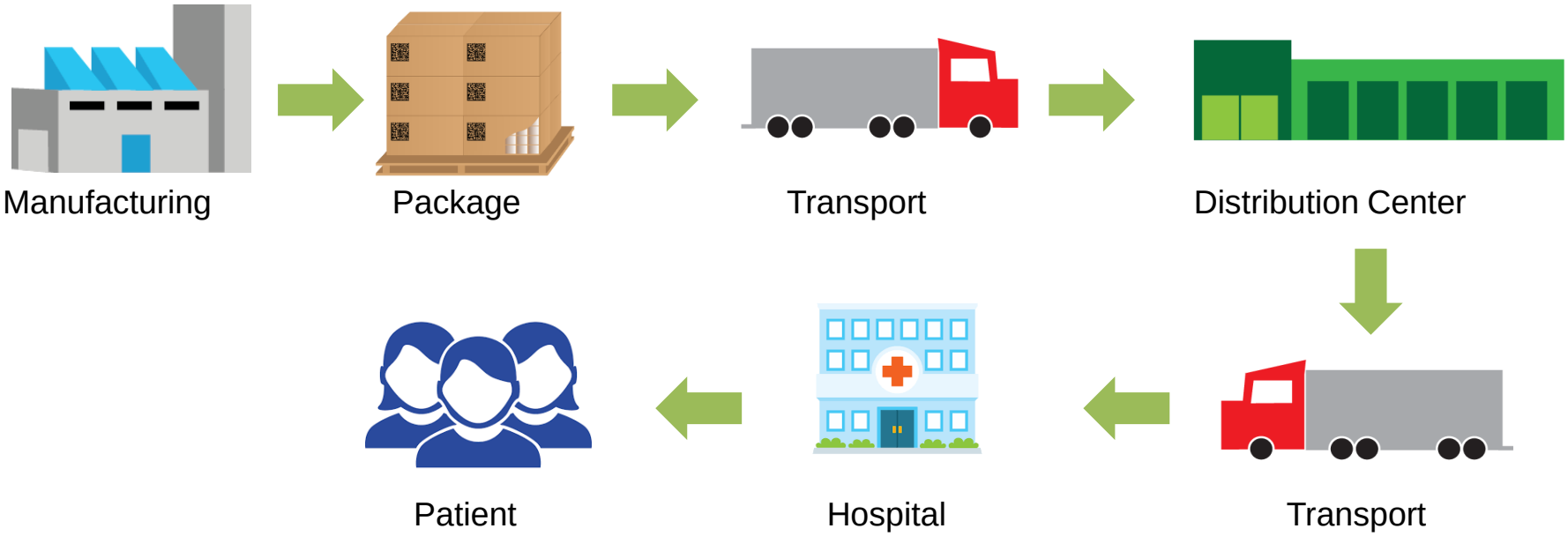
Johnson & Johnson

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

The Rewards

High Quality: A Credo Value

End-to-end visibility of our product through GS1 GTINS (UDI), GLNs and AIDC technology



The Rewards

Supply Chain Efficiency

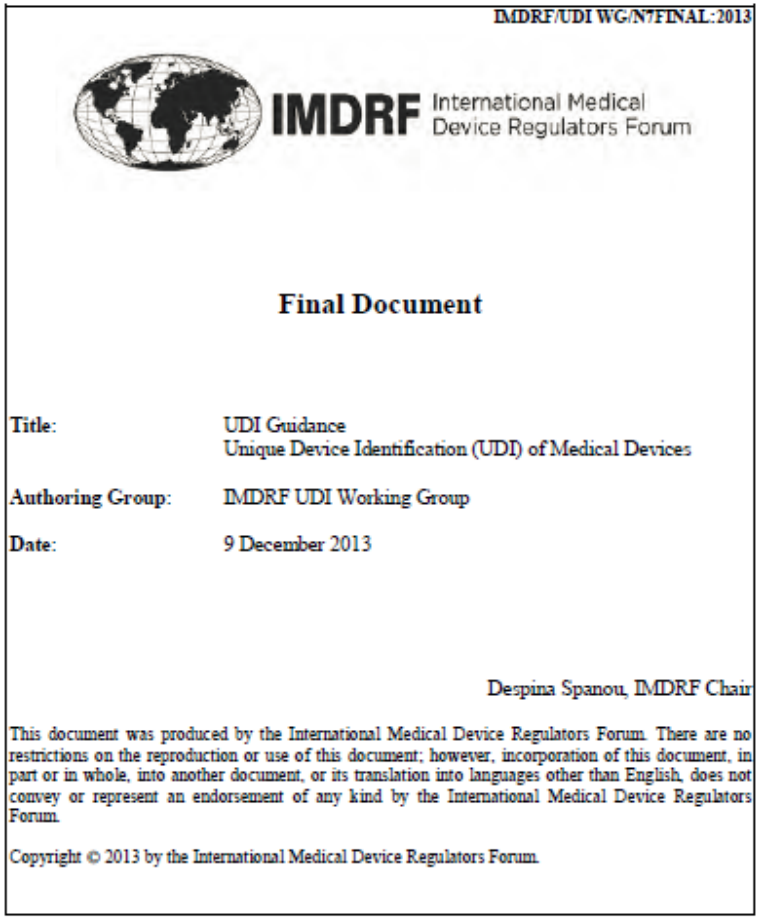
Process	Example	JNJ use
	Identify GTIN = Product GLN = Location	GTINs in product master data; on labels GLN in customer data
	Capture Bar Code RFID	Bar codes on some product directly; all packaging
	Share EDI GDSN	EDI and GDSN with major customers
	Use Traceability POS/POU RA submissions	Visibility for planning, track & trace and field action Market access

The Rewards

"It's not about the bar code, it's about the data. . ."

Karen Longe

The Rewards Gained through Cooperation



IMDRF/UDI WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	UDI Guidance Unique Device Identification (UDI) of Medical Devices
Authoring Group:	IMDRF UDI Working Group
Date:	9 December 2013

Despina Spanou, IMDRF Chair

Use the GS1 International Standards.
Manage Device in the same way
Share core data.

Healthcare is international!

谢谢

UDI Implementation

To continue, implementation experiences…

- UDI AIDC Implementation
  - one company's implementation view to date, good and bad…

Stan Malinowski
Medtronic, Inc.
UDI Lead for GS1 Standards and Marking

The Global Language of Business

UDI AIDC Implementation Experiences

28th Global GS1 Healthcare Conference

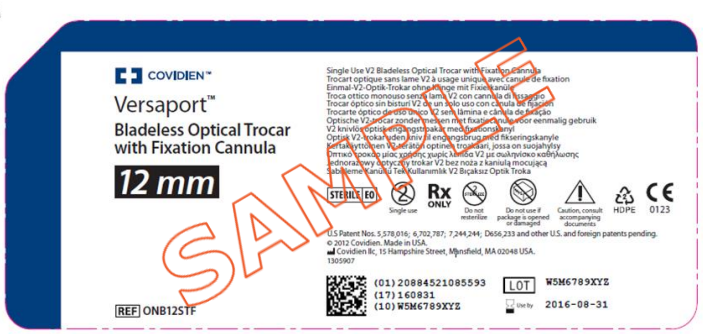
October 20, 2016

Stan Malinowski

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

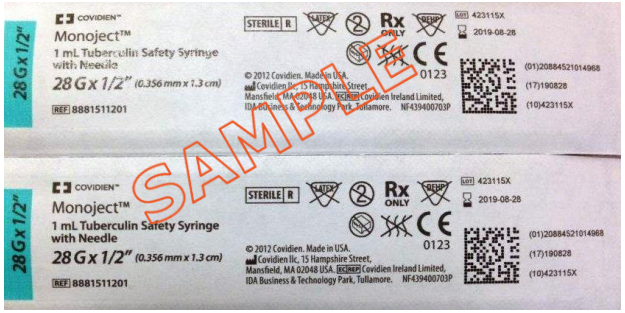
Business Process

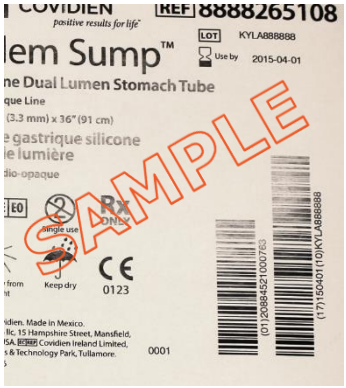
- Sustainable business processes will enable compliance
- Keeps focus after the project is over

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
- Label application for inner and outer boxes

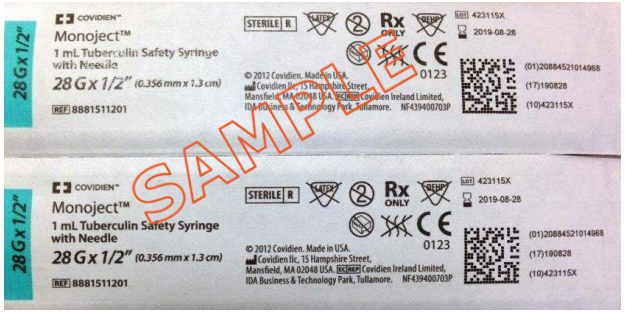


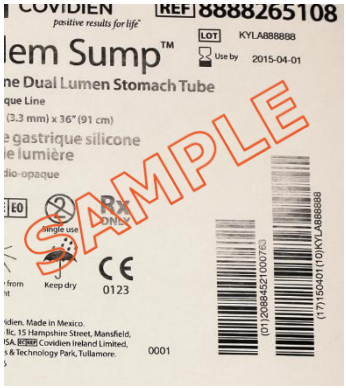


AIDC in Healthcare

Application of UDI (Details)

- Printing on primary packaging substrates: inkjet, thermal transfer
- Printing software inconsistencies
- Barcode **verification** for **AIDC quality**
  - Process Controls Variables & Process Capability
- Documentation in Device History Record

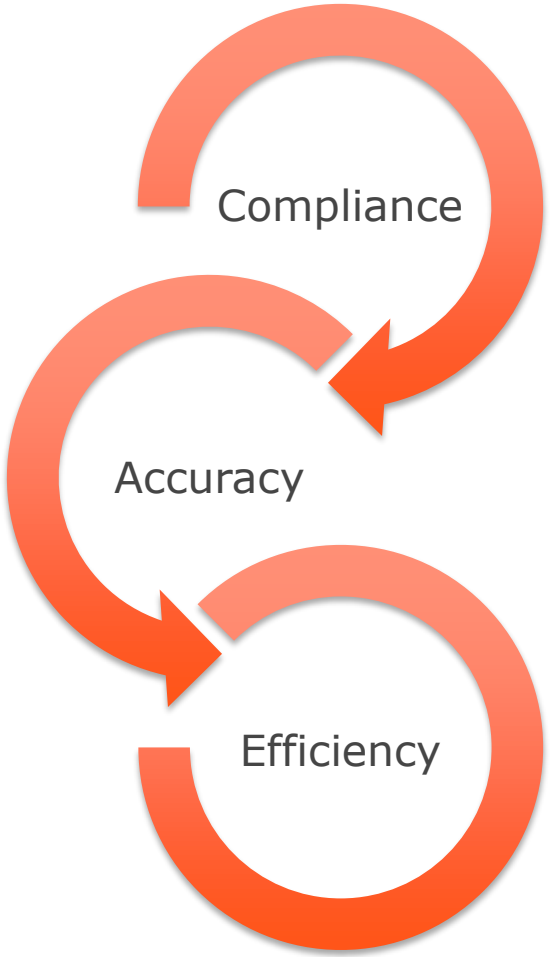




AIDC Structure is Important

- What's in our GS1 Barcodes?
- Correct Use of AIM Identifiers
  -]C1 for GS1-128
  -]d2 for GS1 DataMatrix
- Efficient Use of Application Identifiers - Order Matters
  - UDI application Identifiers
    - (01) GTIN the Device Identifier
    - 1 or more Production Identifiers
      - (17) YYMMDD Use By Date or (11) YYMMDD Manufacturing Date
      - (10) Batch Number and/or (21) Serial Number

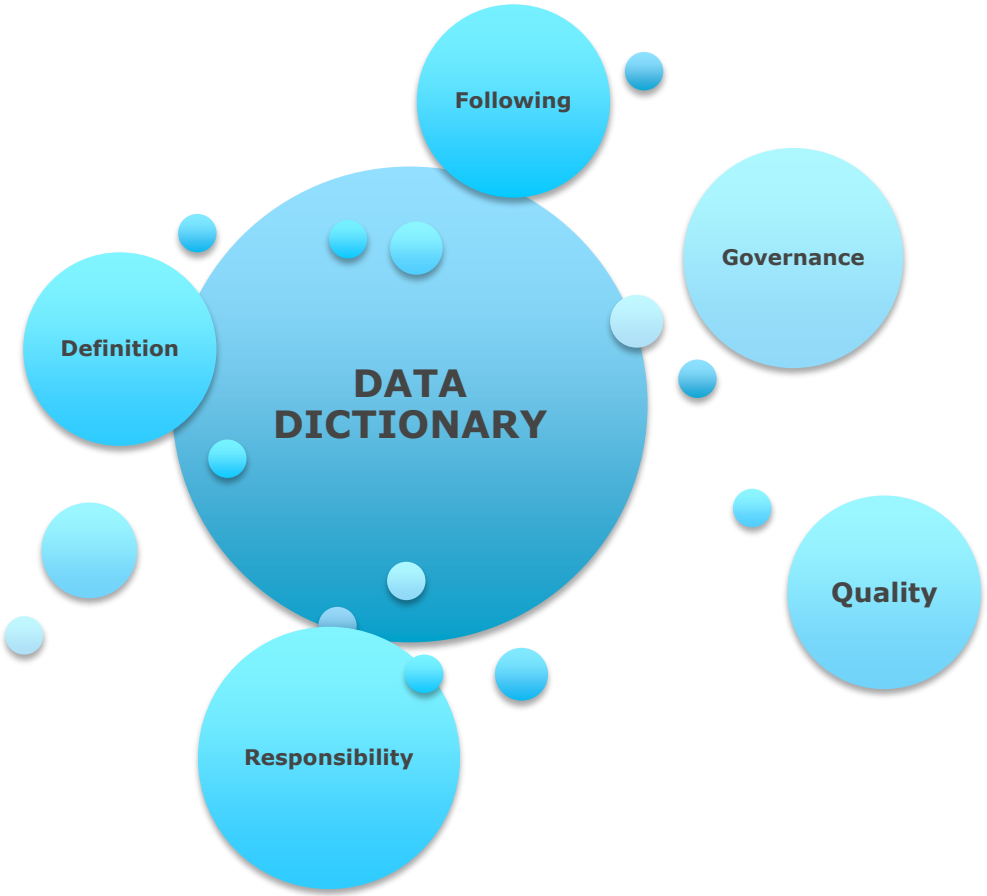
Why Data Quality?



Definition of Data

What is Product Data?

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



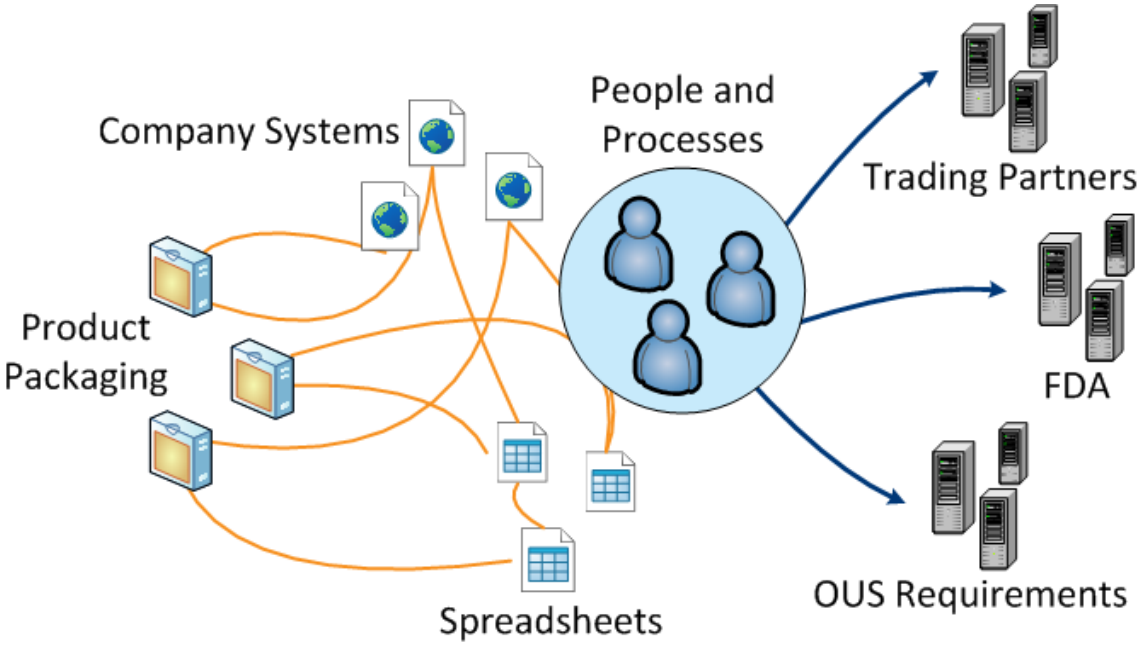
GTIN Hierarchy

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…

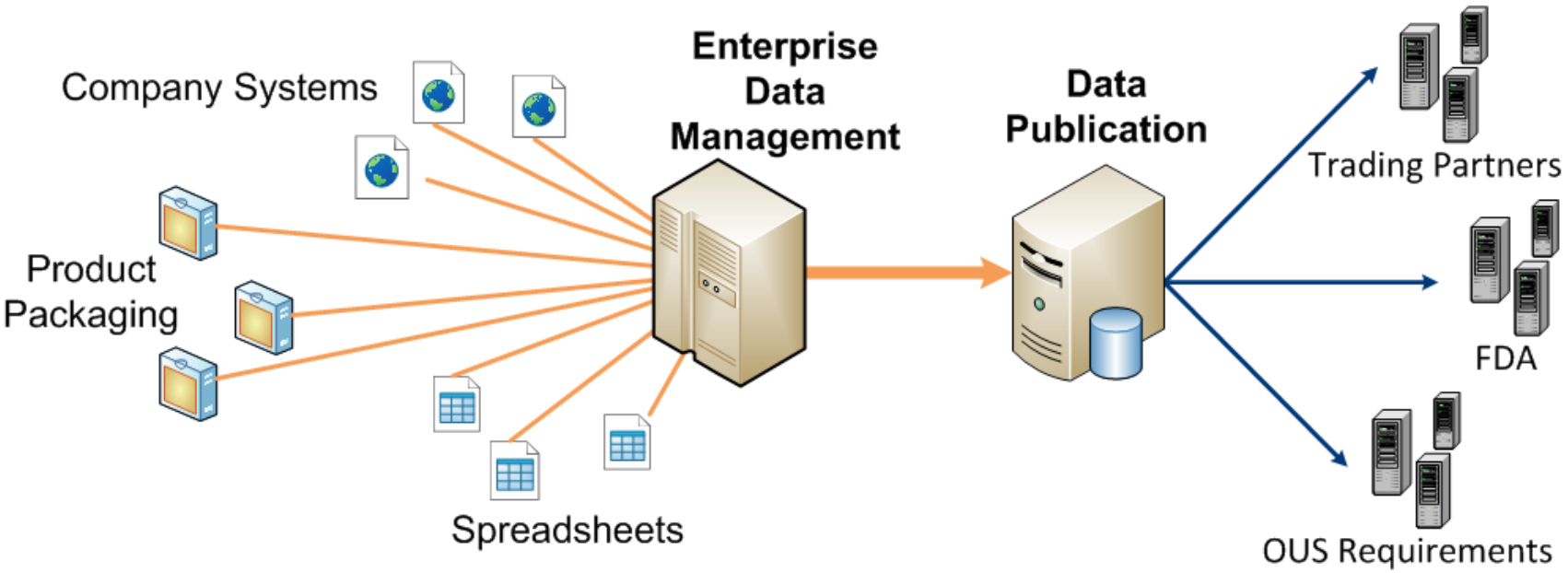
- Manual interactions
- Un-validated
- Lack of definition
- Disconnections
- Data degradation
- Multiple requirements



Future State

Strategic Approach…

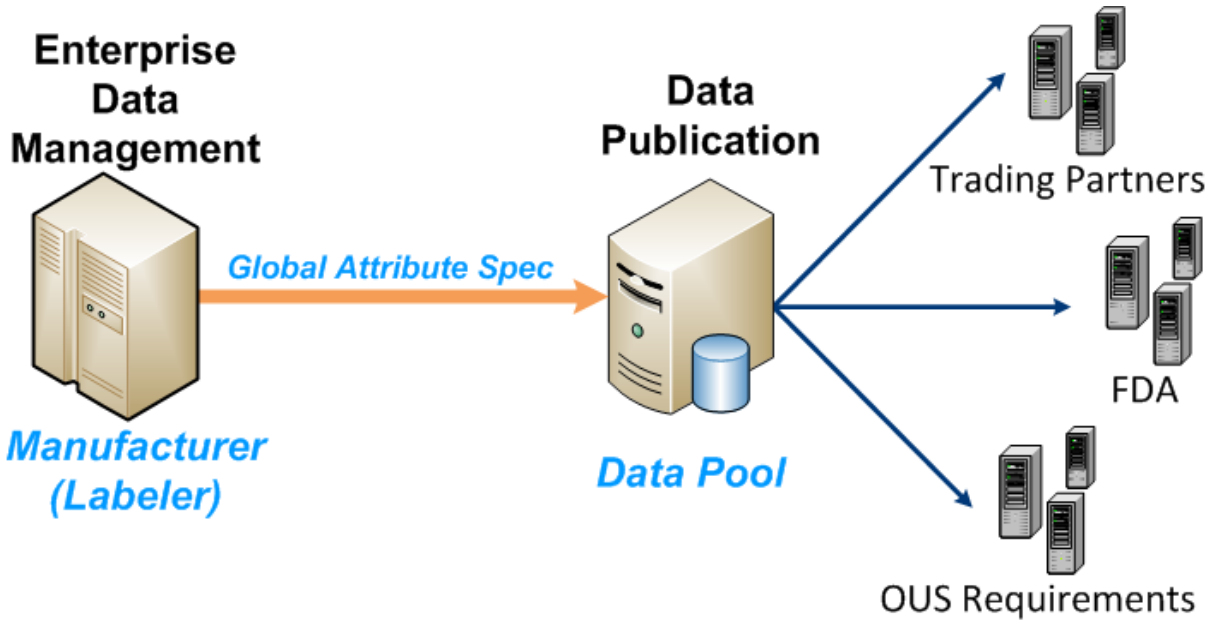
- Defined processes
- Data quality
- Validated interactions
- Model of publication and consumption



Data Publication

Best Practices…

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



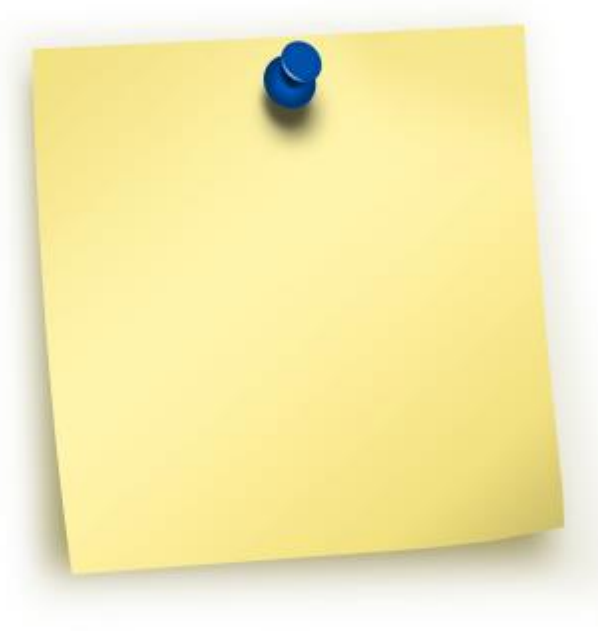
Why Data Pool / GDSN for UDI?

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-away

Key Points to Remember

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



To conclude… audience questions…