



Implementation Reality: GDSN Success Story and Preparation for the U.S. FDA GUDID

Seoul

Tuesday, 1 April 2014

2:00 and 4:00 p.m.





Panelists:

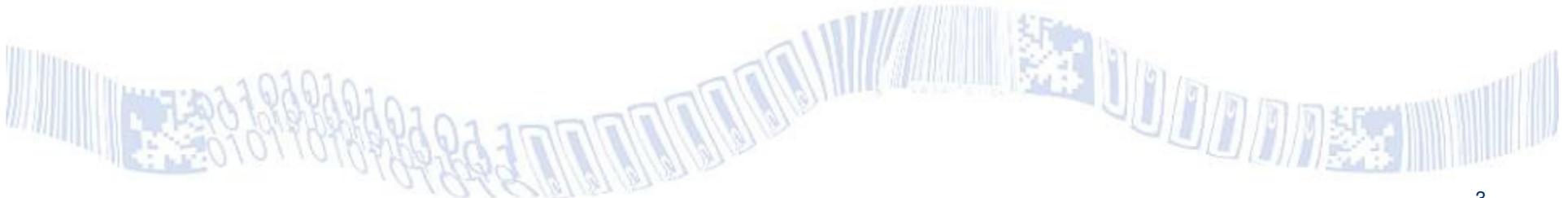
- **Mike Wallace – Abbott**
- **Dan Wilkinson – 1WorldSYNC**
- **Margot Drees – GHX**
- **Mark Wasmuth – GMDN**
- **Robert Webb – Cook Medical**





Agenda

- **Manufacturers Perspectives**
 - High-level overview
 - Key steps to load data, key choices, key questions
 - Lessons learned and challenges ahead
- **Data Pools Perspective**
 - Overview
 - Benefits of the GDSN for the FDA GUDID
- **GMDN, GTIN and UDI**
- **Q & A**

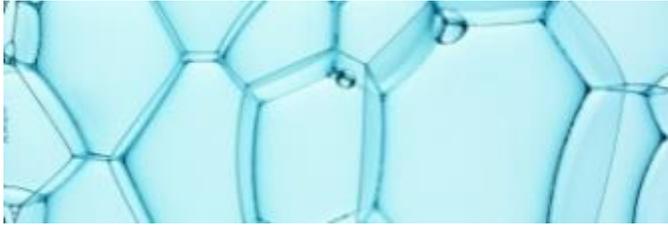




Preparing to meet the U.S. FDA Unique Device Identification (UDI) Regulation

Mike Wallace, Abbott

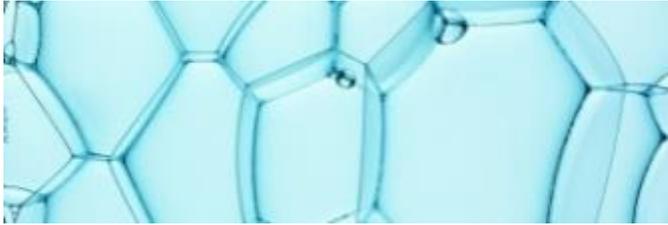




Our Work

- Advanced diagnostics
- Innovative medical devices
- Trusted nutritional products
- Established pharmaceuticals





Our Work

Our Promise for Life

We are here for the people we serve in their pursuit of healthy lives. This has been the way of Abbott for more than a century – **passionately and thoughtfully translating science into lasting contributions to health.**

Our products encircle life, from newborns to aging adults, from nutrition and diagnostics through medical care and pharmaceutical therapy...

...the promise of our company is in the promise our work holds for health and life



US FDA UDI Major Component Summary

QS Doc / Systems

QS Documents:

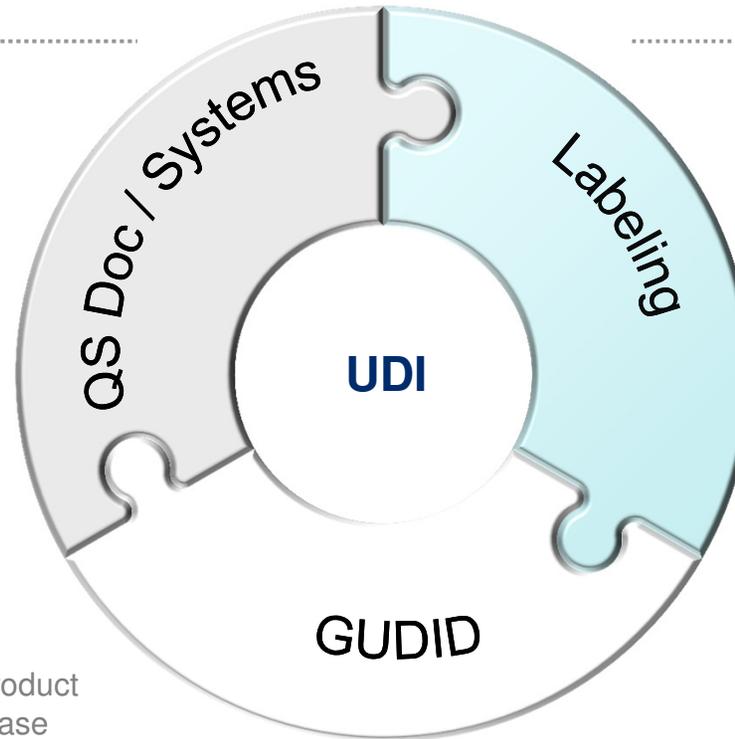
- MDR
- Correction
- Recall
- DHR
- Complaints
- Service
- Post Market Surveillance
- PMA Annual Report

IT Systems:

- GDSN
- LANSAs
- IQ
- Various Divisions Systems

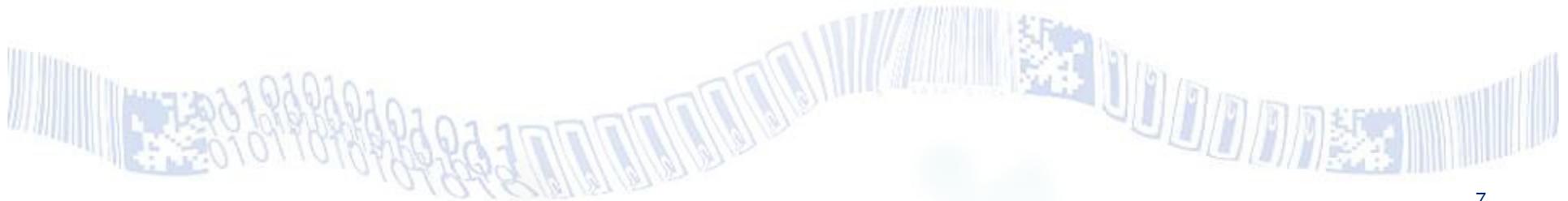
GUDID

- 60+ Data attributes per unique product
- Publication to FDA GUDID database



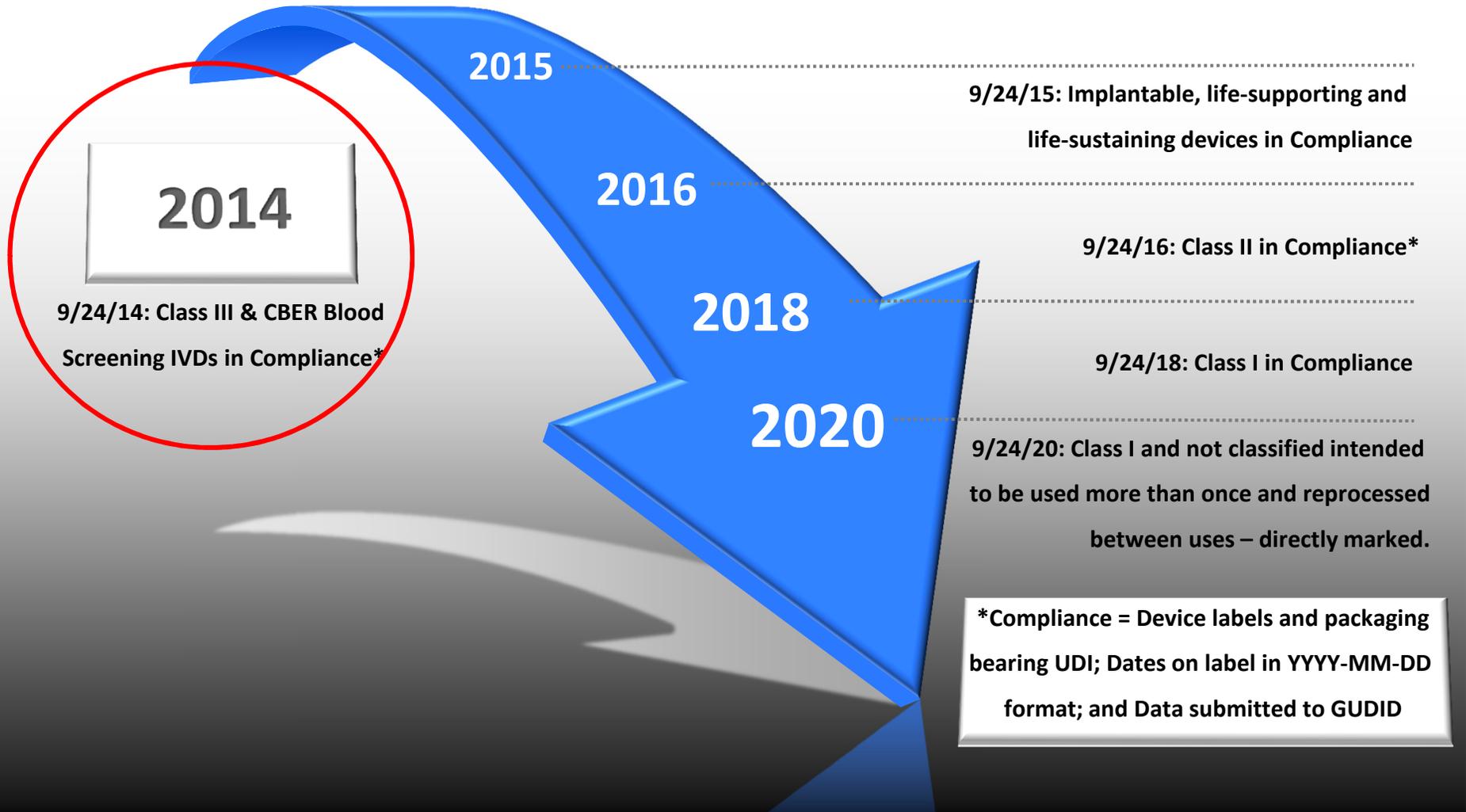
Labeling - Barcodes

LN's impacted for Class III/BLA





US UDI Compliance Timeline





The clock is ticking.....



SEPTEMBER 2104

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				





Key Steps – FDA Model

Standard Project Management

- Obtain sponsor, funding, prioritization
- Understand the requirements, education
- Assemble the multi-functional team, leader(s)

UDI Project Management

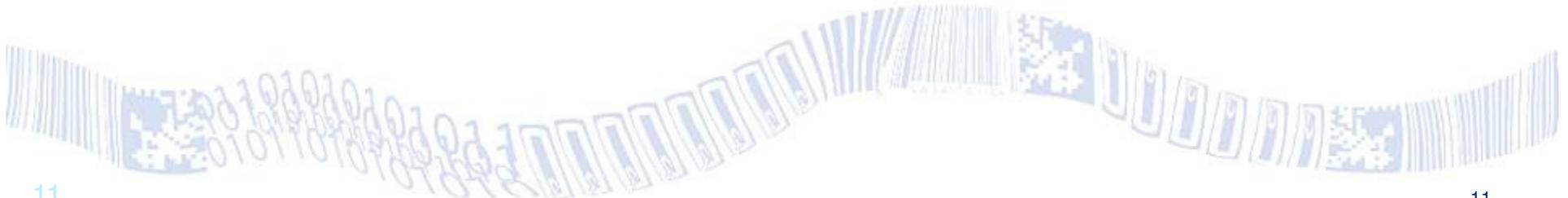
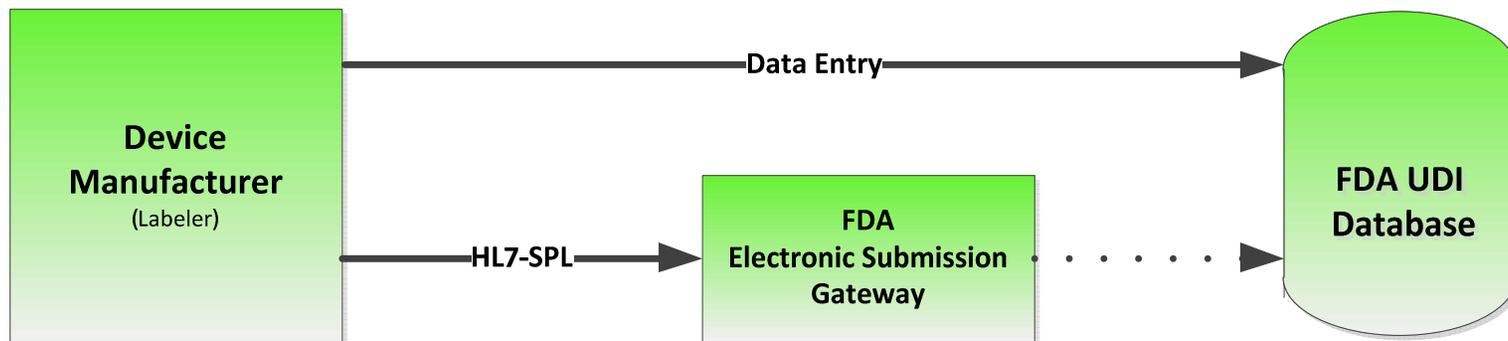
- Determine solution path
- Understand your Validation approach
- Select solution providers (if applicable)
- **Find, collect, clean, store data attributes**
- Publish data attributes to the FDA GLN “1100001017041”
- Address any error messages
- Create ongoing operational procedures





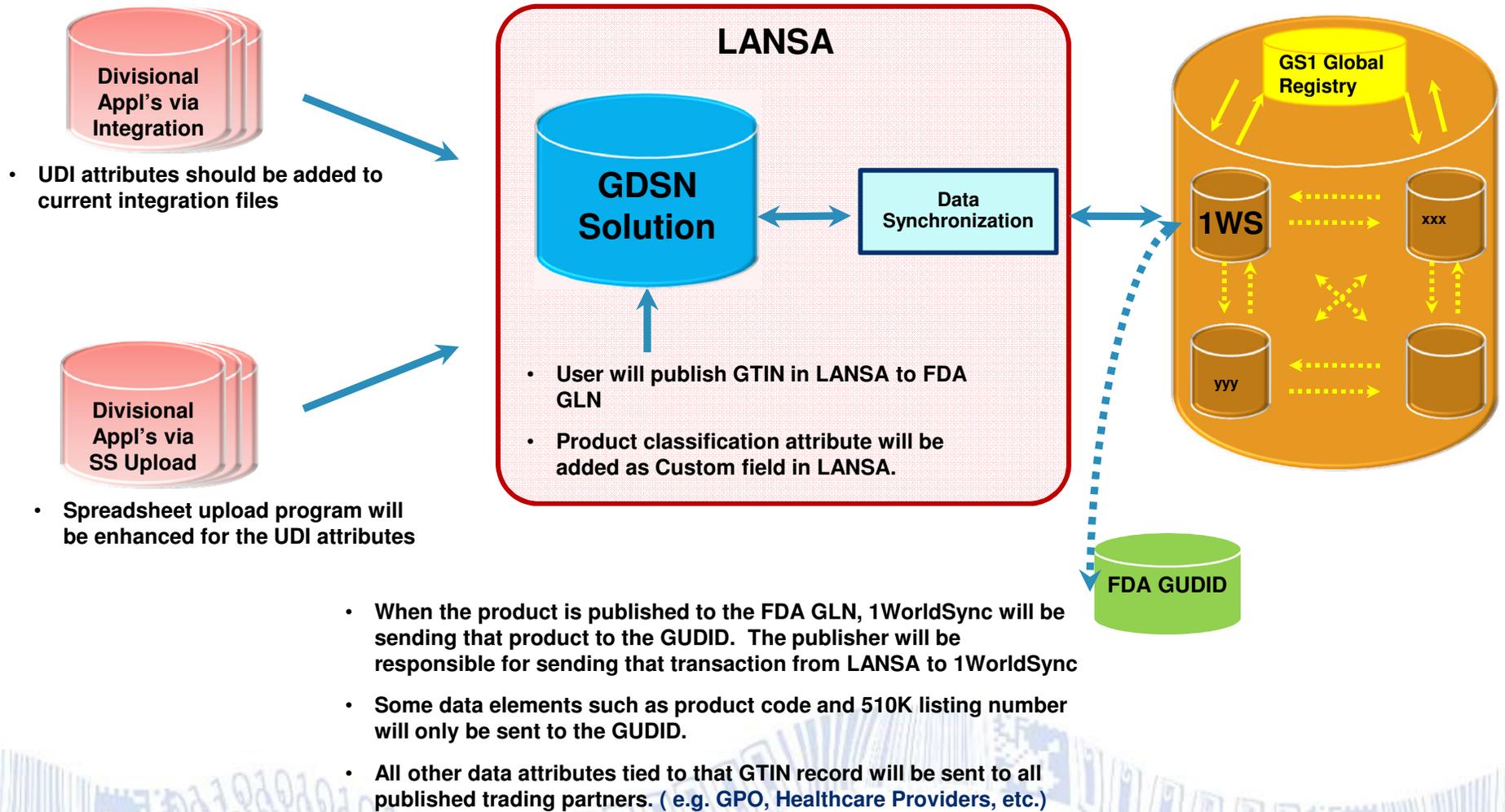
Loading Data into the FDA GUDID

- Manual Data Entry
- Electronic Data Submission (HL7 SPL)
 - Direct Labeler Submission
 - Via Third Party



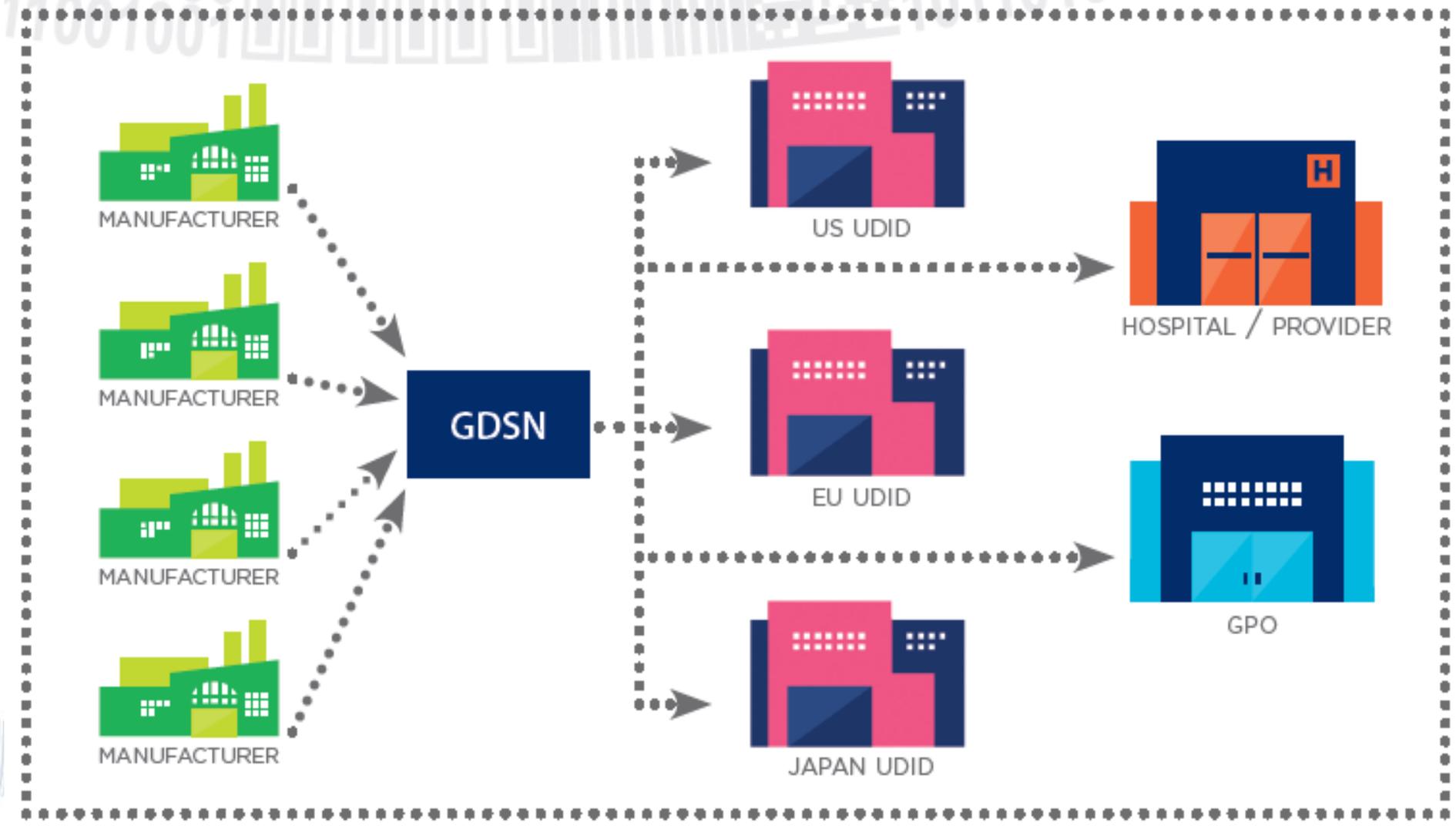


Using a GDSN Solution to Populate the GUDID





Why GDSN? One connection to UDI databases





Manufacturer Lessons Learned

- *The requirement is real, it is no longer just a concept*
- *UDI is not a “project”, it is an ongoing effort*
- *A clear owner is not always evident. Data governance can be multi-faceted*
- *Some GUDID attributes are more complex than others*





Manufacturer Lessons Learned

- *Takes longer than you expect*
- *It's BIGGER than you think*
- *Not simply assigning a unique number*



You are here



GDSN & UDI Readiness

Dan Wilkinson, 1WorldSYNC





Our vision is to be the trusted, global source of authentic, enriched data to support regulatory compliance, improvements in patient safety, and increased supply chain efficiencies within the healthcare industry.



Our Solution



A trusted product information network for global manufacturers and brand owners.



Our Solutions & Platform



Product information For
**Supply Chain
Enablement**

Enabling sales, supply chain, B2B and IT services teams to setup and exchange quality, trusted product master data with trading partners, via a single global connection point.



Product Information For
**Product Risk &
Compliance**

Enabling product safety, quality, legal and regulatory, procurement and marketing teams to manage product safety and compliance programs across global trading networks.

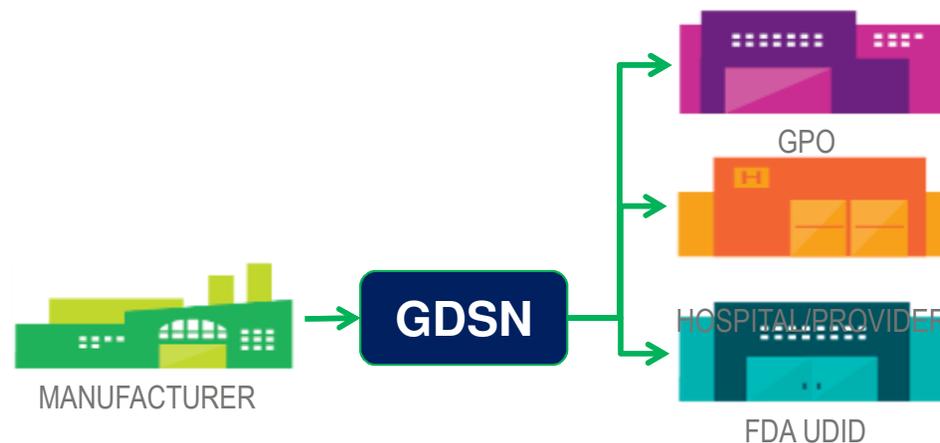


Product Information For
**Marketing & Multi-
channel Commerce**

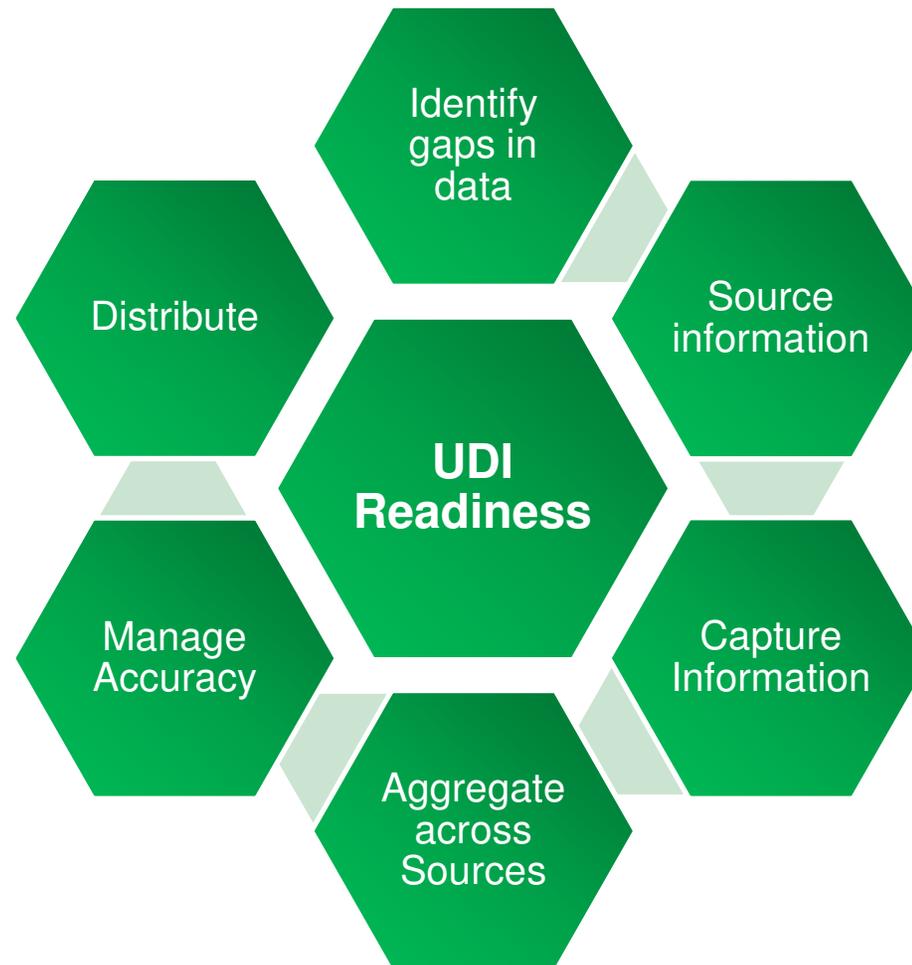
Enabling marketing , eCommerce & Application Developers to acquire trusted product images, assets, information and more – sourced directly from and approved by its original owner.

Benefits of Using GDSN for the GUDID

- GPOs and Providers receive public UDID data elements
- UDID data to the FDA and other similar UDI databases globally
- The electronic transfer of standardized product and location information
- Continuous synchronization of that data over time between two or more parties as part of an ongoing standards based business process
- One to Any Distribution of data through a Global Network



Preparing your Data for Compliance



Preparing your Organization for Compliance

Business Process Design

- Establish and document business processes incorporating data synchronization
- Include item set-up and on-going changes

Attribute Preparation

- Understand the requirements
- Determine data to populate
- Perform gap analysis
- Consult User/Implementation Guides

Data Quality

- Adhere to GS1 Standards
- Align with Data Governance policies
- Design control mechanisms
- Include measurement practices

What to do next...

- **PERFORM**

- *a Readiness Assessment* for your Class III, II and Class I medical devices

- **IDENTIFY**

- *Areas of Impact* within your company

- **CREATE**

- *Improved long-term data management processes* to meet regulatory and consumer information demands

- **ADOPT**

- *GS1 Standards* and comply with business requirements put forth by the Healthcare Transformation Group

- **LEVERAGE**

- Successful work done with other industry Best Practices
- Education
- Data Quality Framework





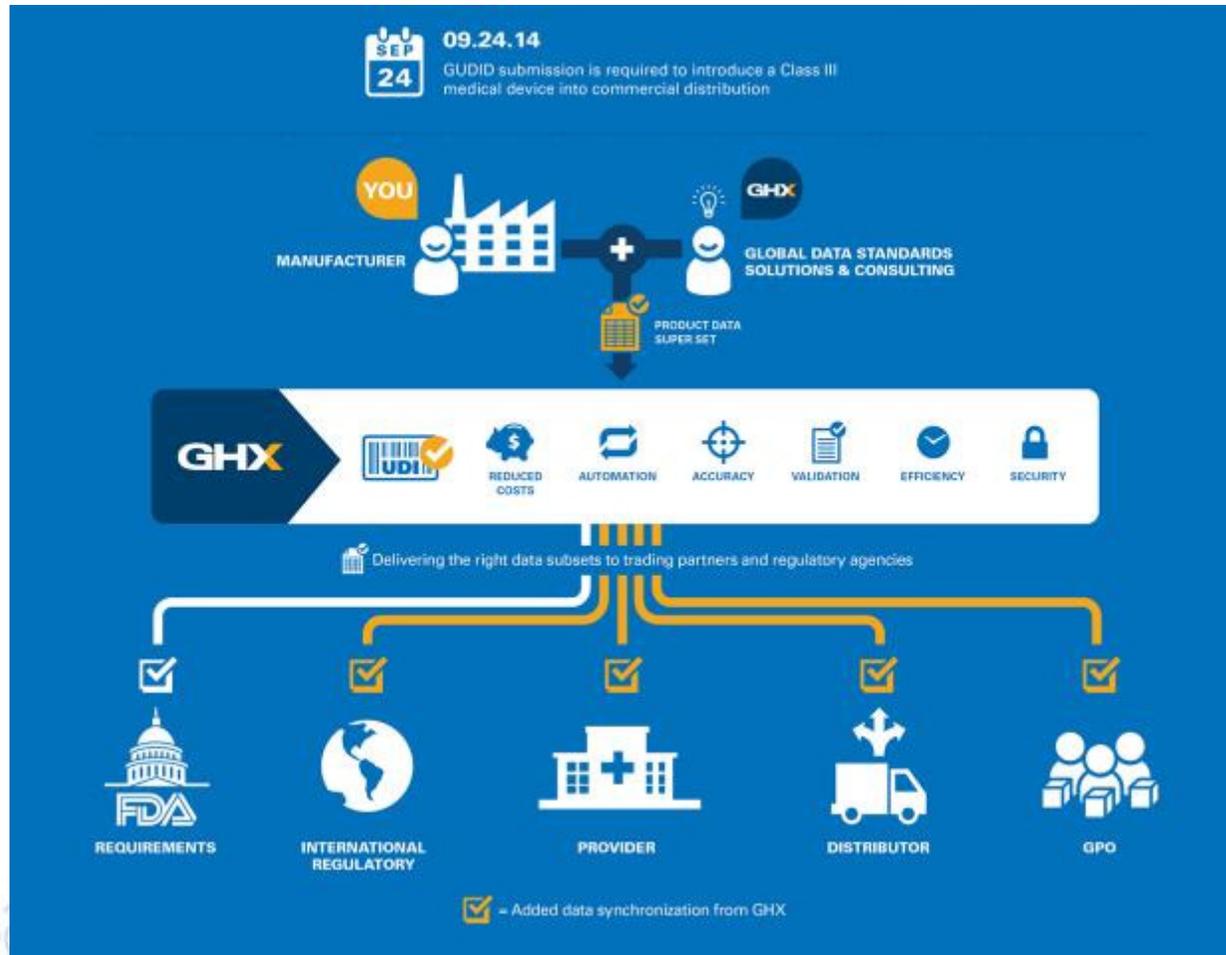
UDI Implementation & Healthcare System Value

Margot Drees, GHX





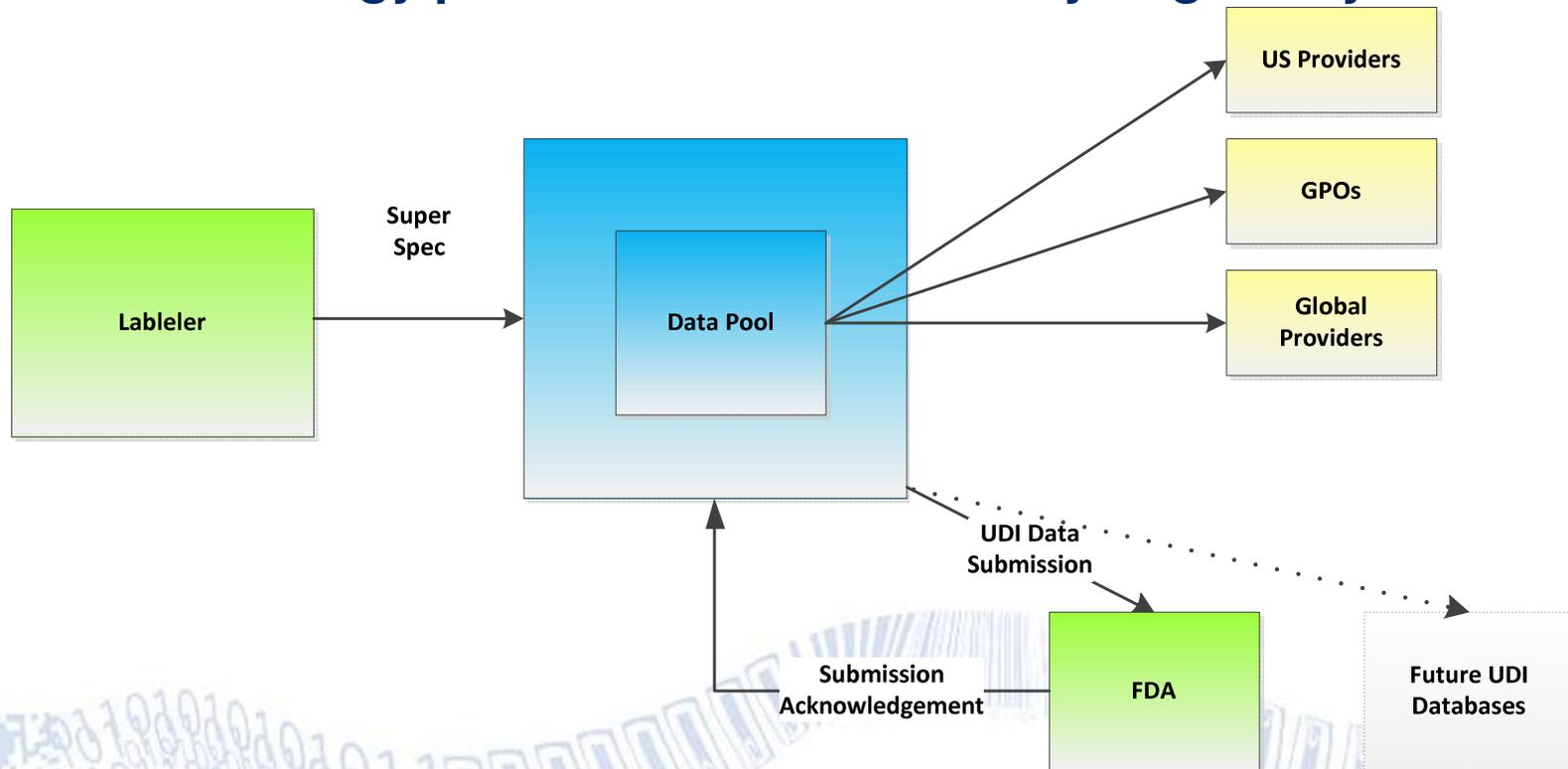
More than FDA Regulatory Compliance





Find a Single Solution

- **Build a Global Master Data Management Strategy**
- **Define ALL regulatory and commercial attributes (Super Spec)**
- **Find a technology partner that can connect you globally**





Value of the UDI Data

ADDED VALUE

- › ONE PROCESS FOR DELIVERING DEVICE DATA TO REGULATORY AND INDUSTRY
- › RAPID PATH TO GUDID SUBMISSION LEVERAGING GHX UDI EXPERTISE AND DATA
- › PARTNERSHIP WITH *THE* TRUSTED NAME IN HEALTHCARE DATA MANAGEMENT



ADDED VALUE IN YOUR RELATIONSHIPS WITH:

FUTURE READY



INTERNATIONAL REGULATORY

- › Reduced integration costs with global regulatory agencies' UDI
- › Reduced development, maintenance, and support costs
- › Future-ready product identification methodology



PROVIDERS

- › Improved DSO, cash collection
- › Reduced invoice discrepancies
- › Automated, efficient ordering
- › Greater visibility into demand and product usage; timely ordering; right-size inventory, fewer stock outs and rush shipments
- › Reduced lost, wasted and expired products
- › Improved scorecard and reporting
- › Improved staff productivity
- › Achieve preferred vendor status; allow customers to demonstrate meaningful use



DISTRIBUTORS

- › Eliminate need for cross reference with distributors
- › Reduced order and price discrepancies
- › Reduced UOM exceptions; reduced stock outs and additional orders/rush orders
- › Consistent, efficient transactions with distributor partners



GPOS

- › Simplified generation of sales tracing report
- › Streamlined contract execution
- › Single product reference in contracts and orders
- › Fewer discrepancies



From Regulation to Value

It's All About Visibility

- Medical device recalls
- Adverse event reporting
- Traceability
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Point of Use Capture
- Demand Signals
- Supply Chain Efficiencies
- Comparative Effectiveness
- Value Analysis



A Holistic Approach to UDI

“This is not about just being able to identify devices. We (FDA) are talking about a holistic approach to integrating medical device identification throughout the entire healthcare system. UDI will be a fundamental piece of everything we do going forward.”

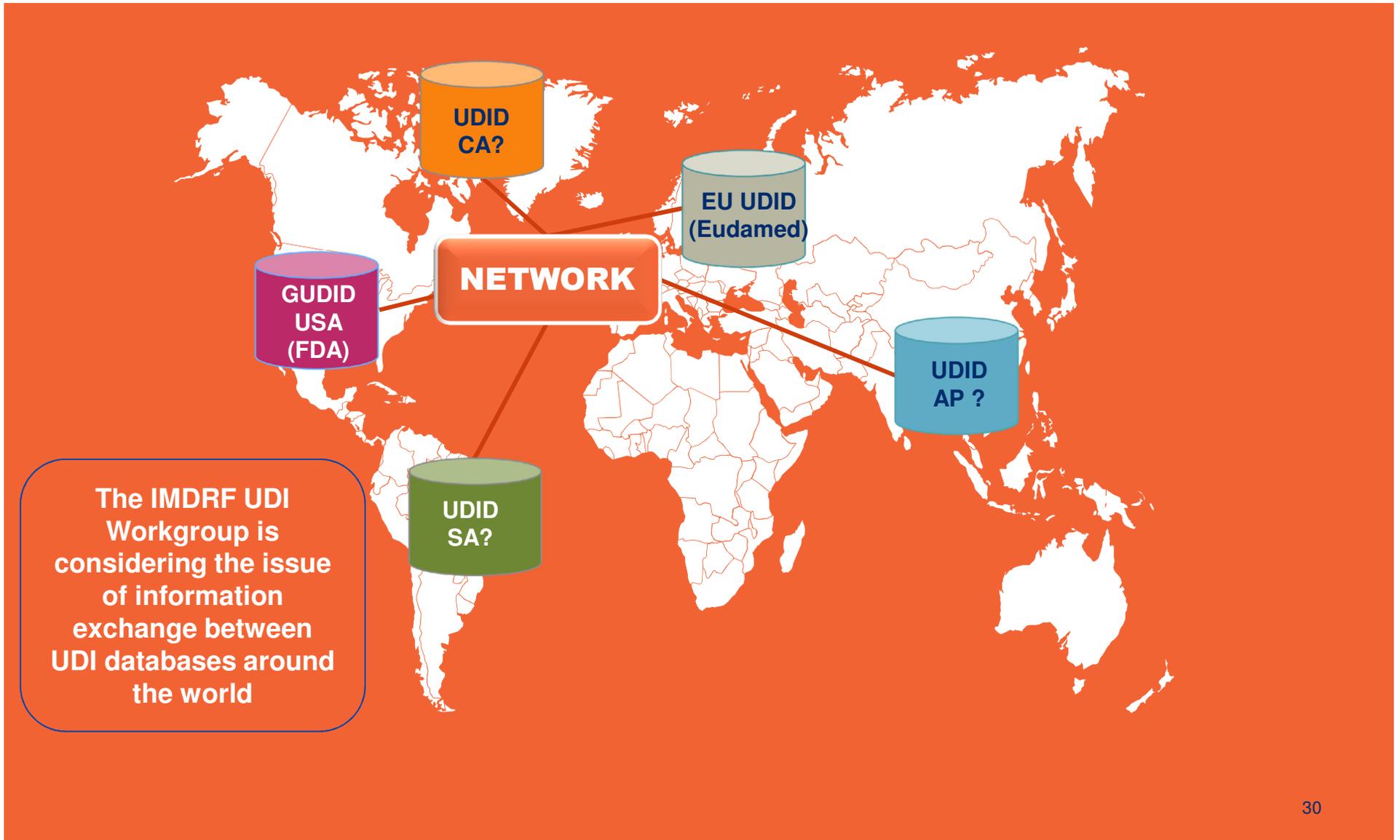
*Jay Crowley, Former Sr. Adviser for Patient Safety,
U.S FDA Center for Devices and Radiological Health*

FDA working on conforming amendments for:

- Premarket approvals
- Reports of Corrections and Removals
- Medical Device Recall Authority
- Quality System Regulation
- Medical Device Tracking Requirements
- Post Market Surveillance



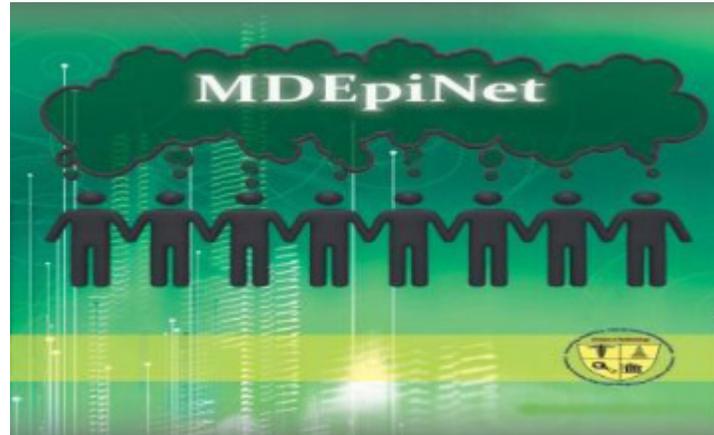
A Global UDI Database Network



The IMDRF UDI Workgroup is considering the issue of information exchange between UDI databases around the world



UDI for Post Market Research

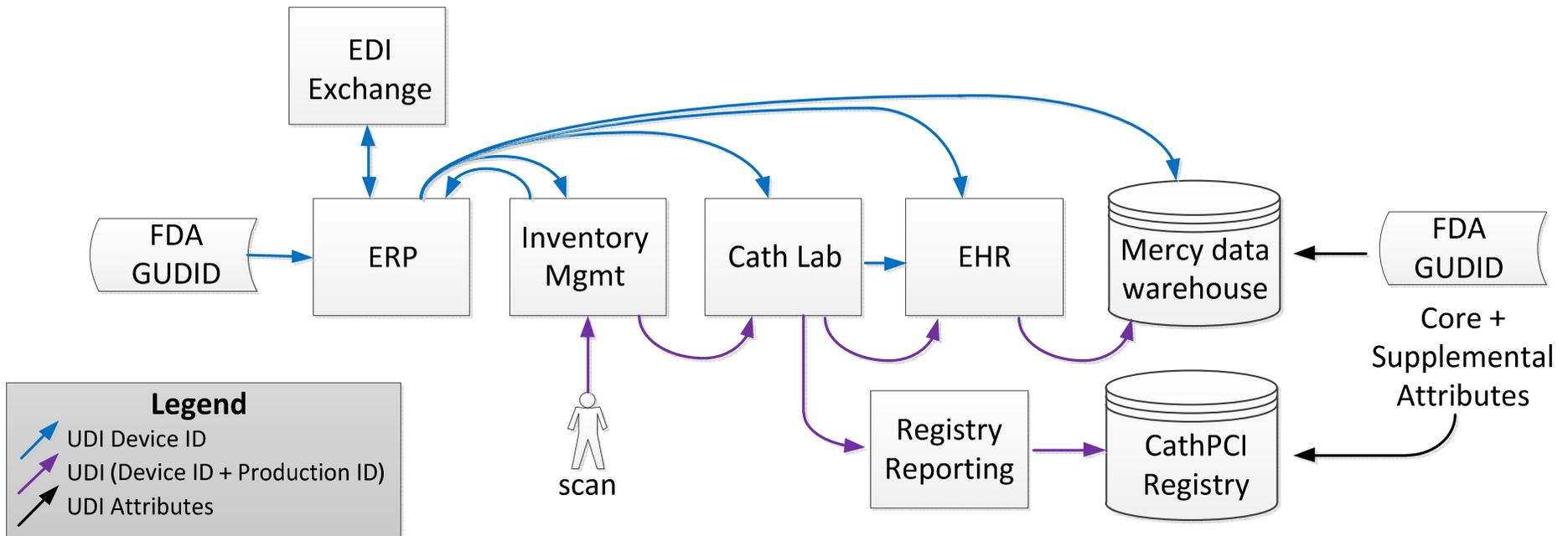


Unique Device Identifier Demonstration Project

- Utilize electronic health records and clinical registries to assess the safety and effectiveness of medical devices after they have reached the marketplace
- *Stents first, then ICDs*

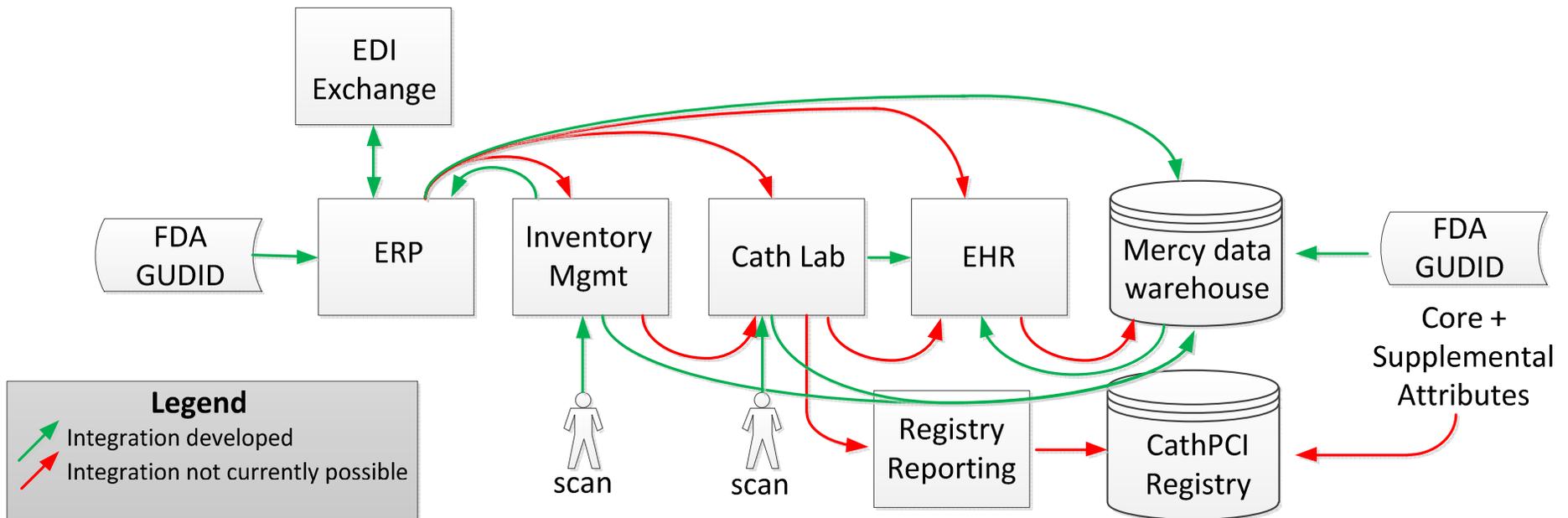
International Consortium of Orthopedic Registries

- Identify and capture clinical attributes that impact performance
- Address differences in orthopedic registries to better utilize available data
- *Demonstration projects: bearing surface, femoral head size, fixed vs. mobile knees, pediatric joints*



- Retrieve UDI (Device Identifier) from GUDID for ERP
- Utilize ERP as master source of UDI (Device Identifier) + attributes for EHR

UDI Implementation Project



- ERP/Supply Chain systems implementing UDI but working through bugs
- Clinical systems in planning phase for UDI



Healthcare System Value

- Electronic Health Records
- Point of Use/Care Capture
- Charge Capture and Reimbursement
- Purchasing
- Contracting
- Payment
- Inventory Management
- Adverse Event Reporting
- Recall Management
- Comparative Effectiveness





Leverage UDI Throughout the Supply Chain

Pursue a Global UDI Submission Strategy

- Connections to multiple UDI Databases
- Develop a Global Data Governance approach

UDI

Gain Incremental Business Value from UDI Investment

- Build systems do more than check the FDA Regulatory box
- Leverage the UDI throughout the Supply Chain/Patient Care Chain
- Create a win/win relationship with your customers on UDI data



Global Medical Device Nomenclature (GMDN), GTIN and UDI

Mark Wasmuth, GMDN



What is the GMDN?

Global Medical Device Nomenclature (GMDN)

- The international standard (ISO 15225) for naming Medical Devices
- Used by 70 national Medical Device Regulators - Backed by IMDRF
- Over 4000 Manufacturers worldwide
- Translated into 25 languages
- 22,000 Preferred Terms (product groups)
- Controlled distribution and updating
- International acceptance

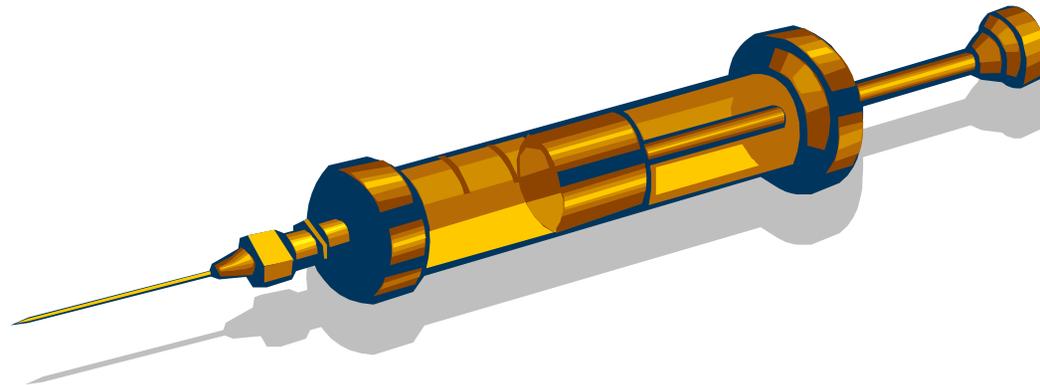
Global acceptance?

- ❑ **IMDRF** (previously GHTF) proposes GMDN
- ❑ EC proposes GMDN for the **EUDAMED** (market surveillance database)
- ❑ **EUCOMED / EDMA / ADVAMED** supports the use of GMDN in meeting the needs of manufacturers
- ❑ EC has translated the GMDN into **20 languages**
- ❑ **WHO & MSF** use GMDN in their guidance documents for developing countries
- ❑ Aligned with **Snomed CT** standard for patient records
- ❑ US **FDA** are using GMDN in the first national implementation of UDI

GMDN Term Structure

Each GMDN Term consists of 3 parts:

- **Term Name:** General-purpose syringe
- **Definition:** A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical
- **Code:** 47017



How can you find GMDN Codes?

www.gmdnagency.org

The screenshot shows the GMDN Agency website homepage. At the top, there is a navigation menu with links for "GMDN Home Page", "About GMDN", "Membership", "FAQ", "Contact Us", and "Login". A language dropdown menu is set to "English" with a "Select Language" button. The GMDN Agency logo is prominently displayed on the left. The main content area is divided into four sections: "News (click on a link below)" with four news items, "I am a GMDN member" with a login form, "GMDN Agency Service" with a list of services, and "Actions" with six options, each with a "Continue" link.

GMDN Home Page About GMDN Membership FAQ Contact Us Login English Select Language

G·M·D·N AGENCY

News (click on a link below)

- [GHTF endorses GMDN for global use](#)
- [US FDA outlines recommendations for UDI](#)
- [New GMDN Terms for Complementary Therapy](#)
- [European Regulators are using GMDN](#)

I am a GMDN member

Login

Password

[Forgotten your password?](#)

GMDN Agency Service

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
- A link from the GMDN database to the user's in-house data system through a licence agreement and a specialized software link.
- Application form for new terms or modification of existing terms/definitions for the identification of the user's product.
- Access to GMDN terminology and information.
- Guidance on how to use the GMDN.
- Access to Collective Terms and codes.
- GMDN translation software tool.

Actions

- [I would like to become a member of GMDN Continue](#)
- [I would like to submit a proposal for a GMDN term Continue](#)
- [I would like to learn about the GMDN Continue](#)
- [I would like to contact the GMDN Agency Continue](#)
- [I would like a free copy of the GMDN User Guidance Continue](#)
- [I would like to bookmark this page. Continue](#)

Reveal the GMDN Code

Show results with one or more options

Search text :

For :

All the words GMDN Code(s)

Any of the words Original Source Code(s)

The exact phrase Translation Code(s)

None of these words

In :

Search Terms

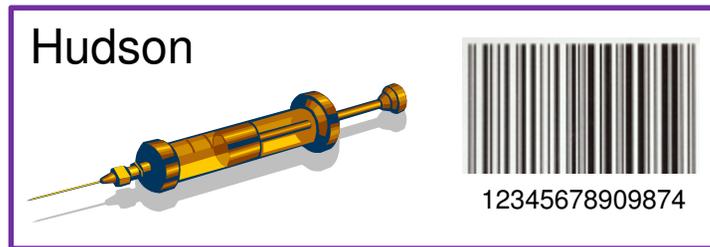
Records 1-1 from 1

Term	Type	GMDN Code	Definition
1. <u>General-purpose syringe</u> Categories: 10 Single-use devices			
<u>General-purpose syringe</u>	P	47017	A sterile device that consists of a calibrated hollow barrel (cylinder) into, and/or withdraw fluids/gas from, the barrel. One end of the barrel is a male connector (typically a Luer-lock type) and the other end is a female connector (typically a Luer-lock type) or a needle or an administration set. It is typically made of plastic (internally precoated with compatible substances) allowing syringe to be used as a single-use device.

GMDN and UDI Relationship

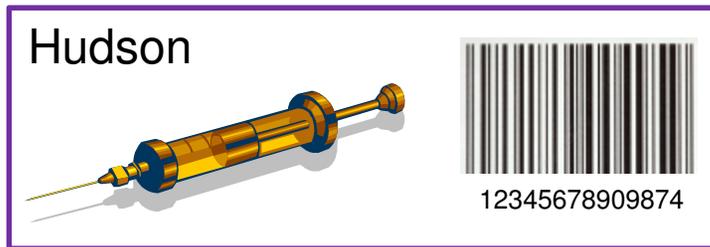
Pack / Device – Unique Device Identifier

(e.g. 12345678909874)

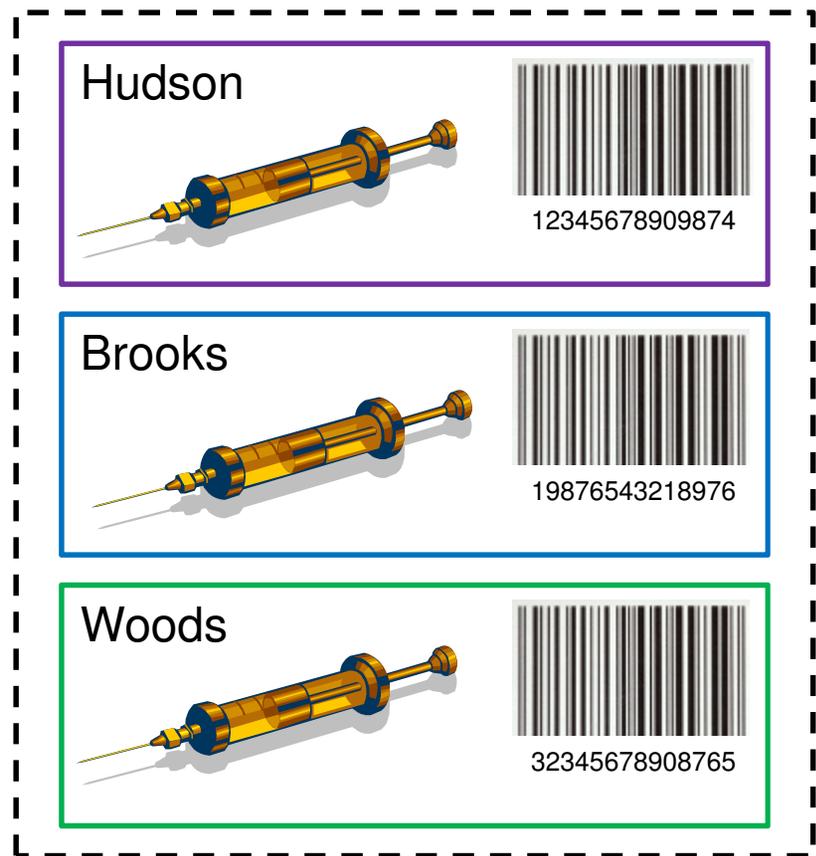


GMDN and GTIN Relationship

Pack / Device – Unique Device Identifier
(e.g. GTIN 12345678909874)



Generic Device Group - GMDN Term
(e.g. GMDN Code 47071)



When you can't find a Term?

If you can't find a GMDN Term for your product:

1. Ask us for assistance
2. Apply for a new Term:
 - On-line Request Application
 - Attach your product datasheet / pictures
 - We discuss the draft Term with you
 - Two week public comment period
 - Database updated daily

Modifying or Obsoleting Terms?

- We modify existing Terms
 - To increase the scope
 - Improve the definitions
- Make Terms Obsolete
 - To remove inadequate Terms
 - Reducing over time
- Notifications by email to Members



GDSN Success Story

Rob Webb, Cook Medical





Who we are

USA headquartered medical device company specialising in the manufacture of minimally invasive medical devices

Founded by Bill Cook, who made his first catheter in his second bedroom in Bloomington, IN, USA, in 1963

World's largest family owned medical device company, employing over 10,000 people with annual sales of > \$2 billion

Manufacturing base in Brisbane, over 500 staff, exports to over 70 countries (global manufacturing in USA, Denmark, Ireland, Australia)

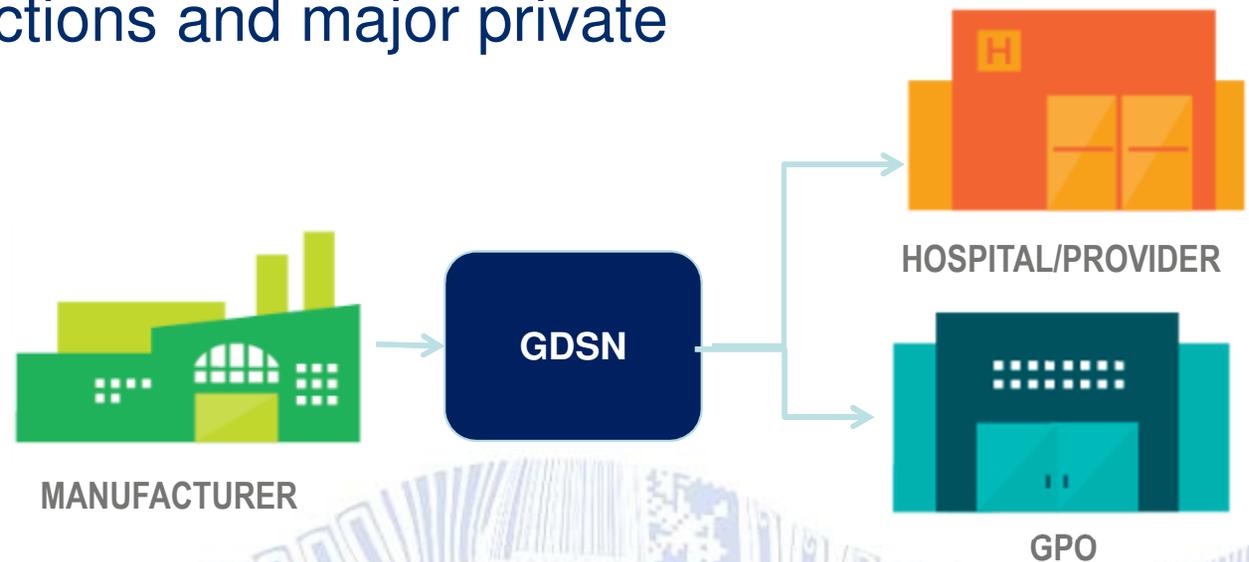


APAC Regional Offices in
Brisbane, Singapore and Hong
Kong



GDSN in Australia

- National Product Catalogue (NPC)
- National E-Health Transition Authority
- Hosted on GS1net
- GDSN compliant data pool
- All health jurisdictions and major private sector hospitals





Cook Medical – NPC challenges



Attended GS1 / NEHTA training and seminars to understand what was needed to upload 5800 products (6300 GTINs). Internal ERP systems had to be cleansed and made ready for the NPC which allowed us to improve our own internal processes.

GS1 NPC catalogue required more information than Cook carried in its ERP systems, hence we partnered with an external contractor for the final point of translating Cook's data to NPC standards.



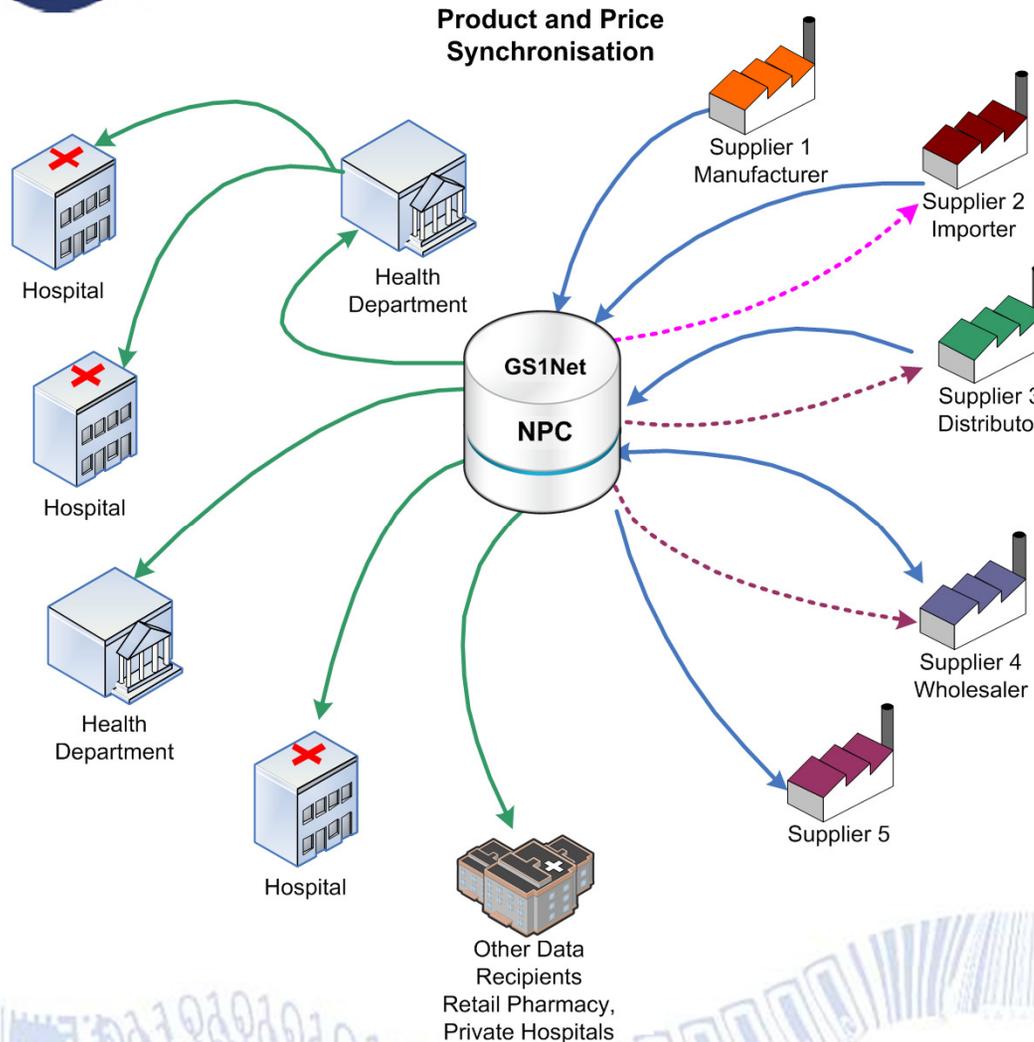
COOK[®]
MEDICAL

- **4 months to NPC compliance**
- **6 months to first EDI customer**



Data Sync enables EDI

nehta



EDI how it works



1. Hospital updates internal catalogue with Cook's catalogue from the NPC on to their ERP system;
2. Cook receives purchase order from hospitals;
3. Order is processed to DC;
4. POR's including dispatch notice, invoices

Product data is common to all - Price data is customer specific



Return on EDI Investment (ROI)

ROI (example of 1 order with 10 line items)	Manual	EDI
Faxed / email order comes in	2 mins	EDI auto
Customer service picks up and passes to right staff	2 mins	no pickup required
Purchase Order (PO) is checked and entered in internal ordering system for correctness - product / price	5 mins	PO processed with only the line item with errors rejected or substituted & processed
if Error in PO, call up hospital and fix error	30 to 45 mins	auto
NEW approved PO is re-faxed, CS picks up and processes PO	6 mins	auto
Total time	Up to 1 hour / order of 10 line items	3 minutes
Cost approximately	\$5.50 per order of 10 line items	.50c
@ 1000 orders per day savings add up	\$5,500	\$500
@ 25,000 order per month savings really add up	\$137,500	\$12,500



Advantages of NPC/EDI efforts



Cook Medical Shanghai warehouse



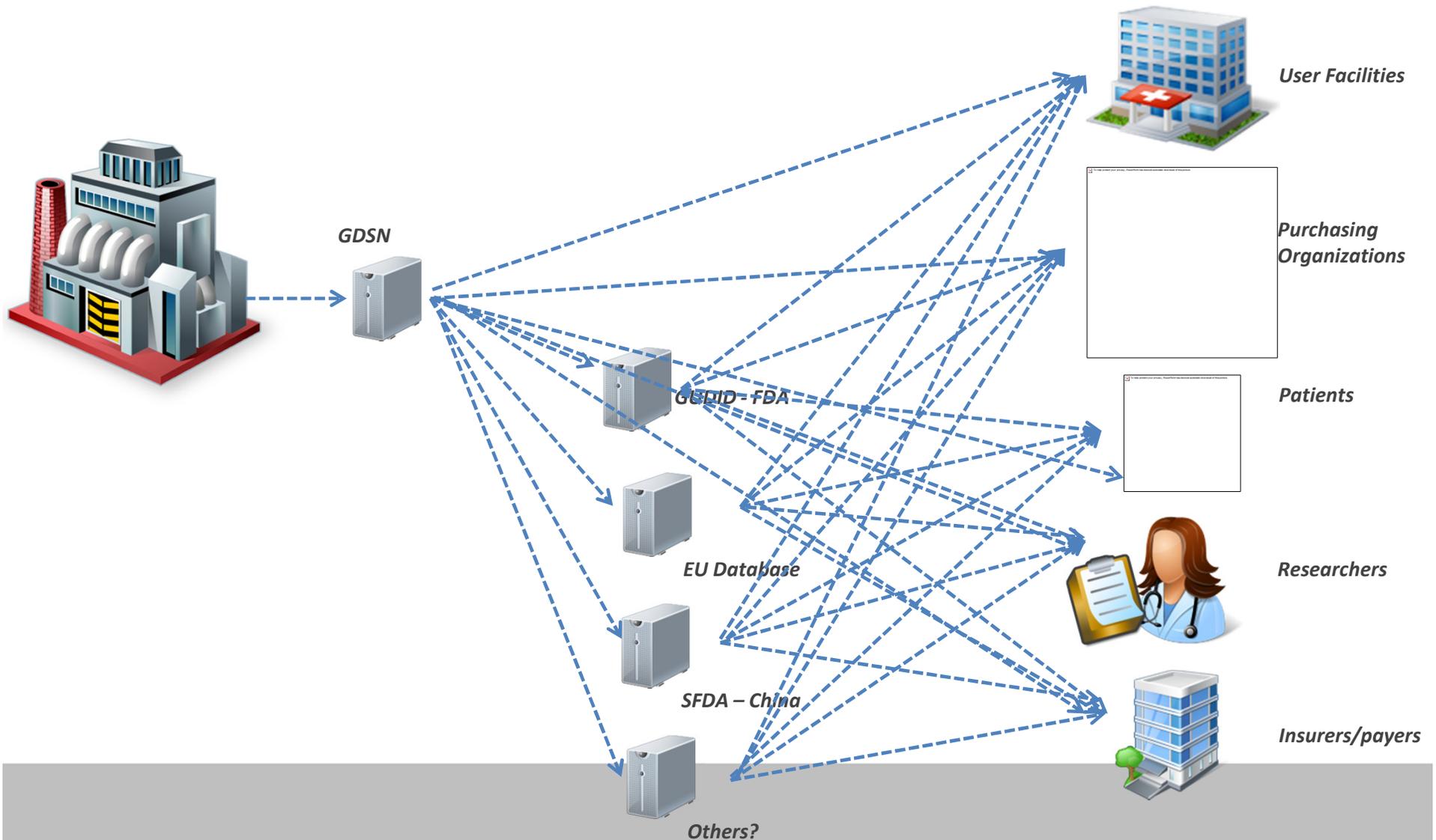
- ✓ Helps maintain Cook's position as an innovative market leader.
- ✓ Real-time access of Cook's product catalogue for its customers via NPC.
- ✓ Customer service team on both sides work with lower error rates, thereby providing efficiency and savings in supply-chain.
- ✓ Customers can choose to receive electronic dispatch notices, Invoices, Credit notes etc.
- ✓ 2 FTEs saved in principle – no actual job loss as staff redeployed to other tasks
- ✓ System caters for sale or return, consignment product, and procedure based ordering

950 active customers

>250 full EDI – app. 34% of orders and growing



The Next Step - Global Data Systems





Questions?





For more information
regarding this presentation,
GDSN in healthcare and
UDI Databases, contact:

Peter Alvarez
GS1 Global Office

peter.alvarez@gs1.org

Office: +1 609 557 4547

