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

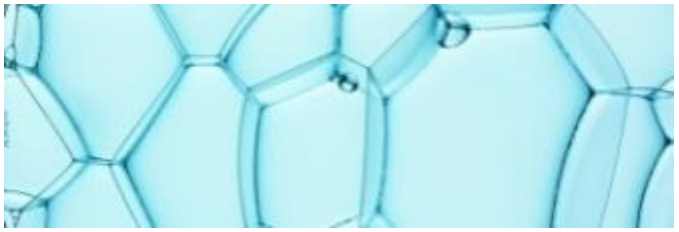
Preparing to meet the U.S. FDA Unique Device Identification (UDI) Regulation

Mike Wallace, Abbott

Our Work

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

Abbott
A Promise for Life



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

Abbott
A Promise for Life

US FDA UDI
Major Component Summary

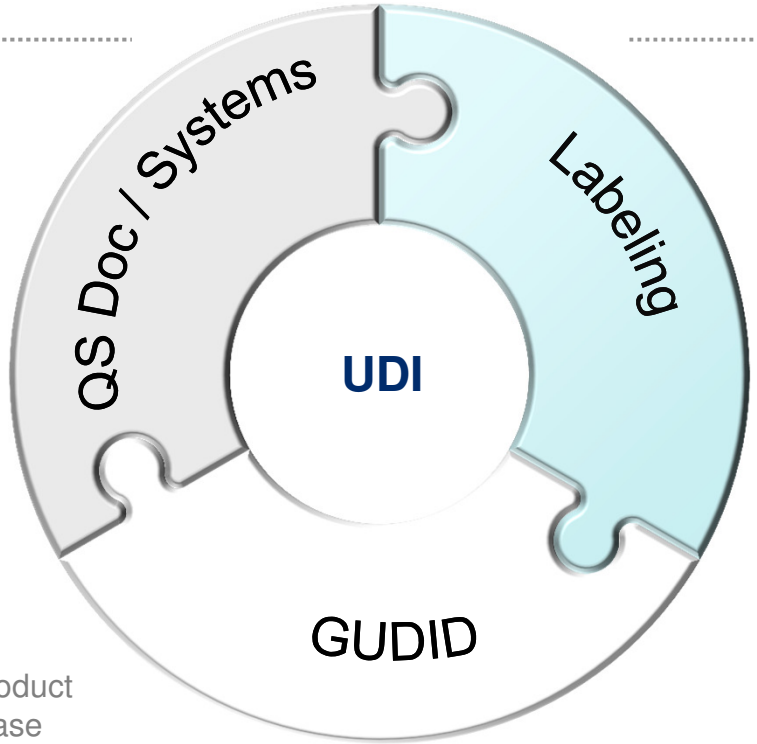
QS Doc / Systems

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

IT Systems:
- GDSN
- LANSA
- IQ
- Various Divisions Systems

GUDID

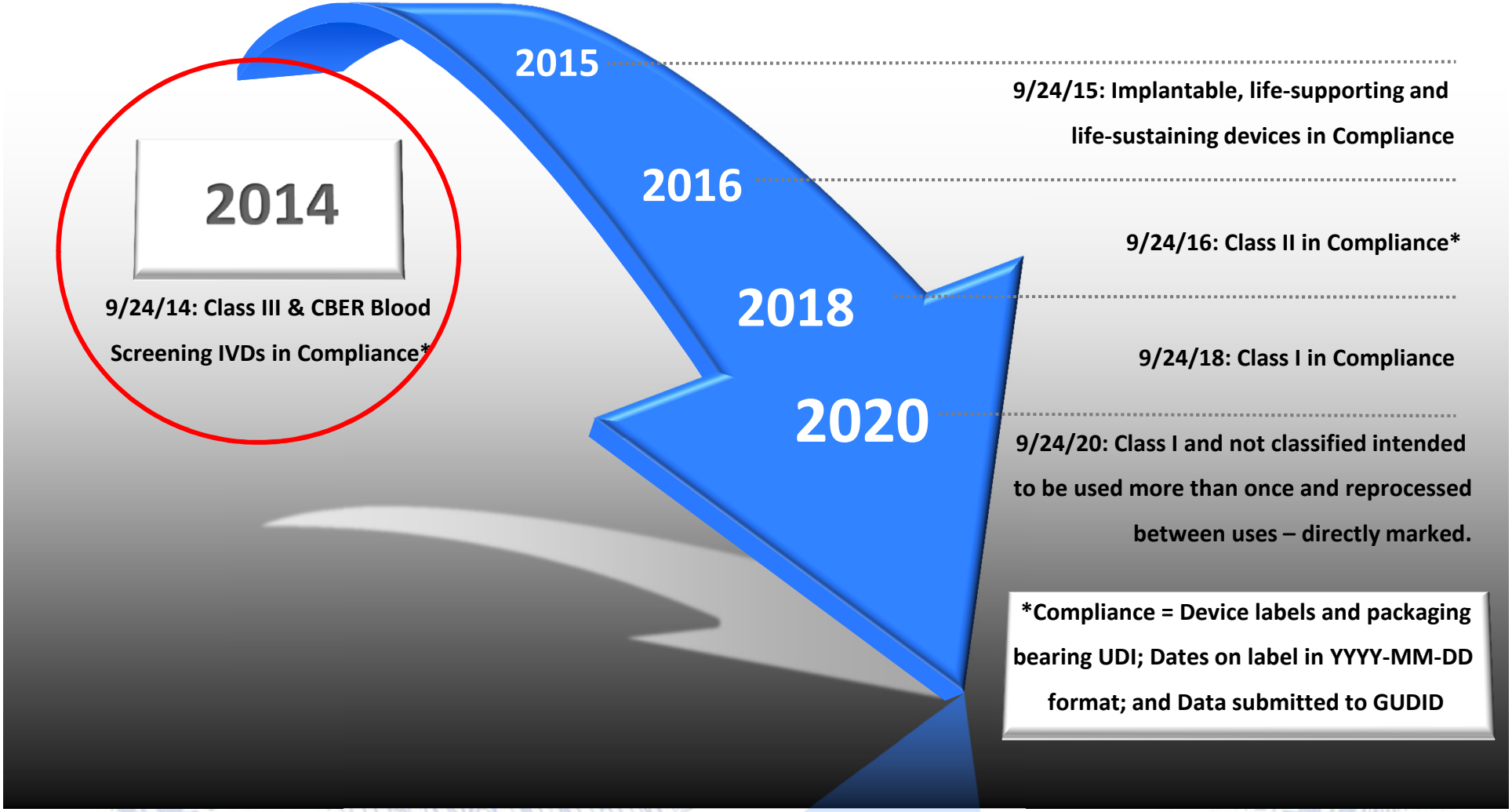
- 60+ Data attributes per unique product
- Publication to FDA GUDID database



Labeling - Barcodes

LNs 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

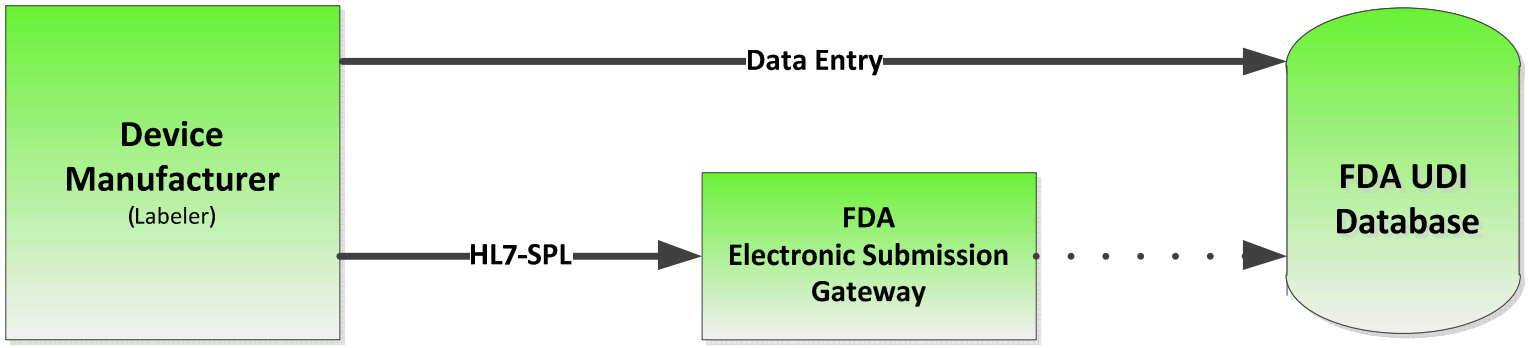
- Obtain sponsor, funding, prioritization
- Understand the requirements, education
- Assemble the multi-functional team, leader(s)

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



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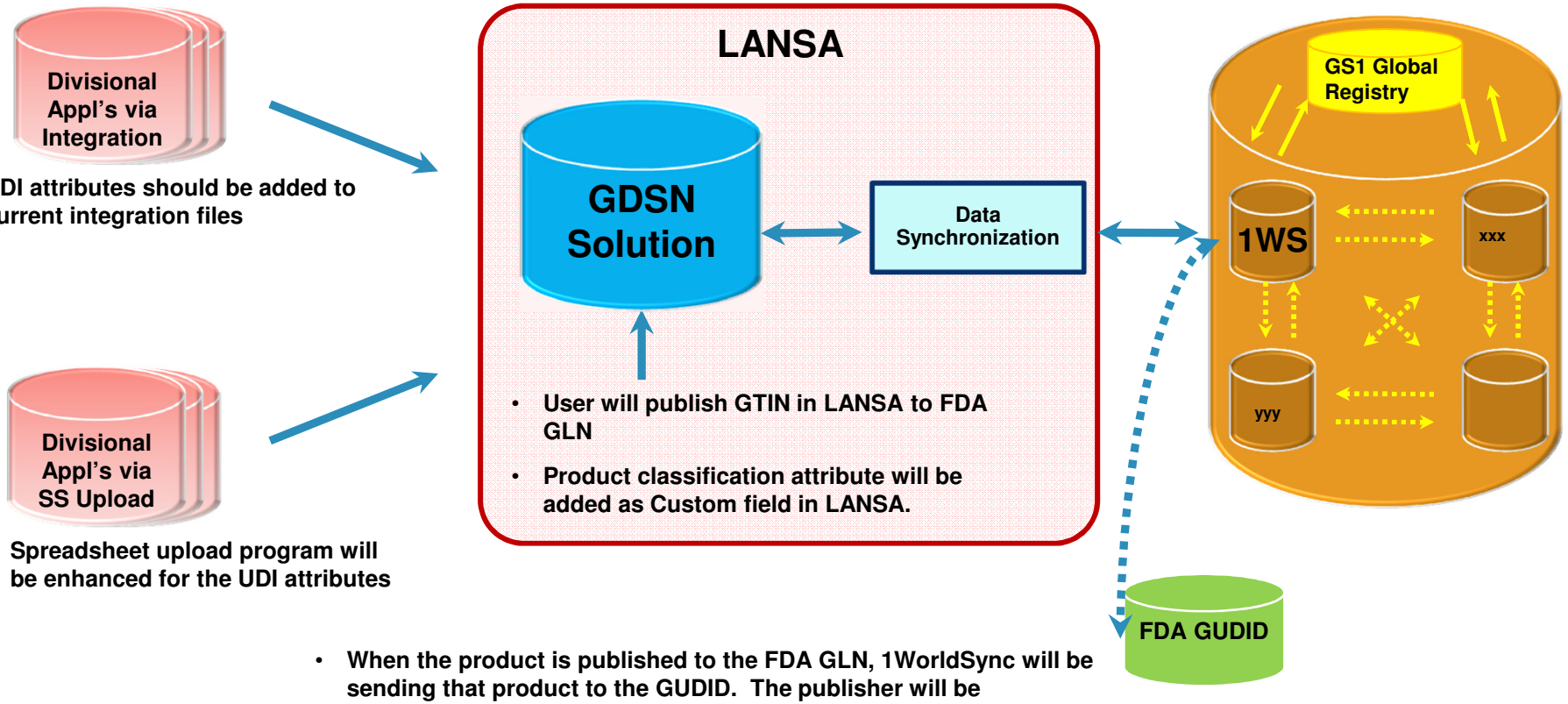
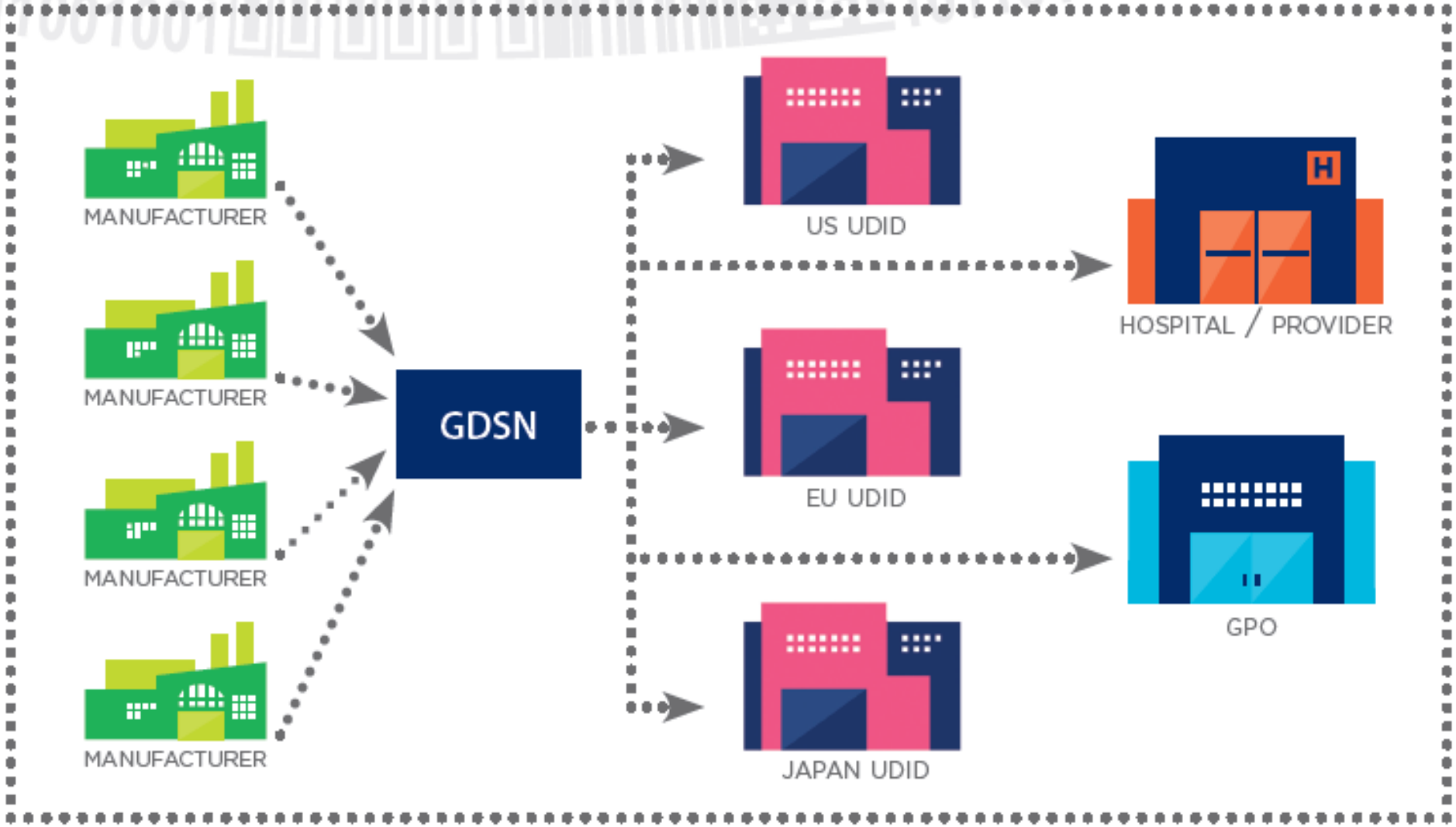
Using a GDSN Solution to Populate the GUDID



- UDI attributes should be added to current integration files
- Spreadsheet upload program will be enhanced for the UDI attributes

- When the product is published to the FDA GLN, 1WorldSync will be sending that product to the GUDID. The publisher will be responsible for sending that transaction from LANSA to 1WorldSync
- Some data elements such as product code and 510K listing number will only be sent to the GUDID.
- All other data attributes tied to that GTIN record will be sent to all published trading partners. (e.g. GPO, Healthcare Providers, etc.)

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***

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Manufacturer Lessons Learned

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

You are here

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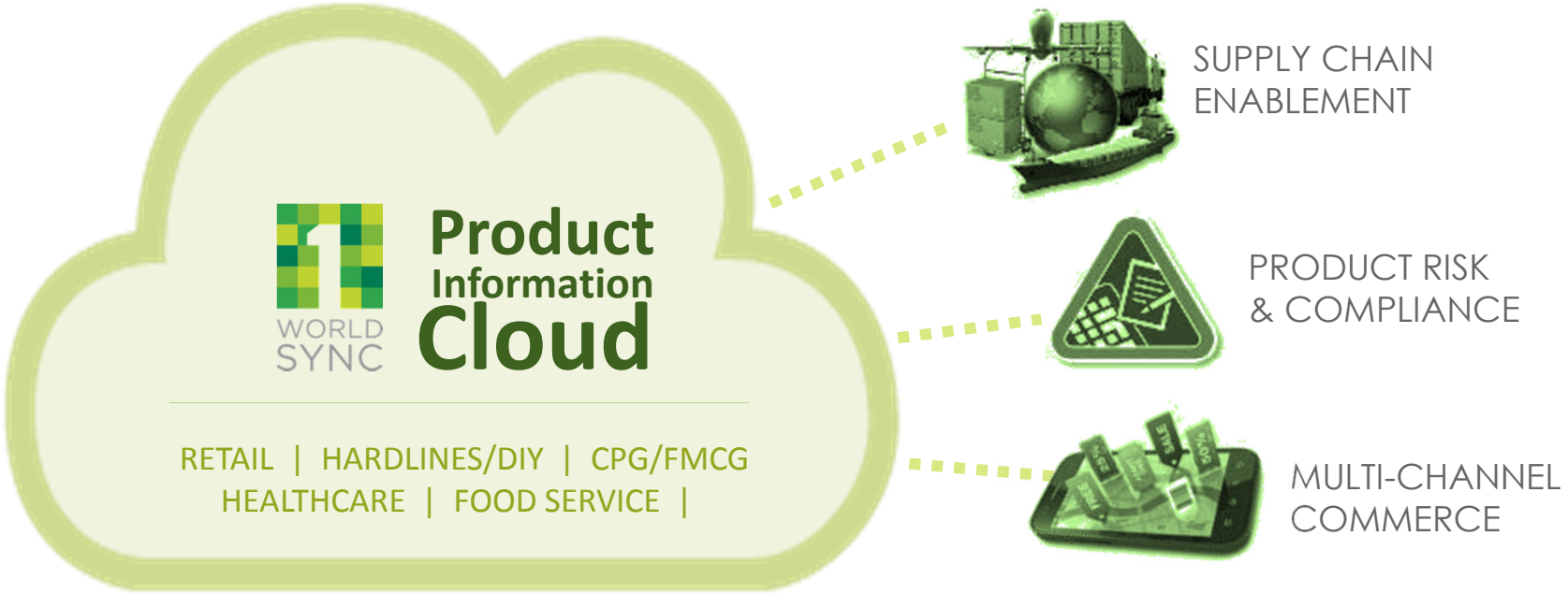
GDSN & UDI Readiness

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.

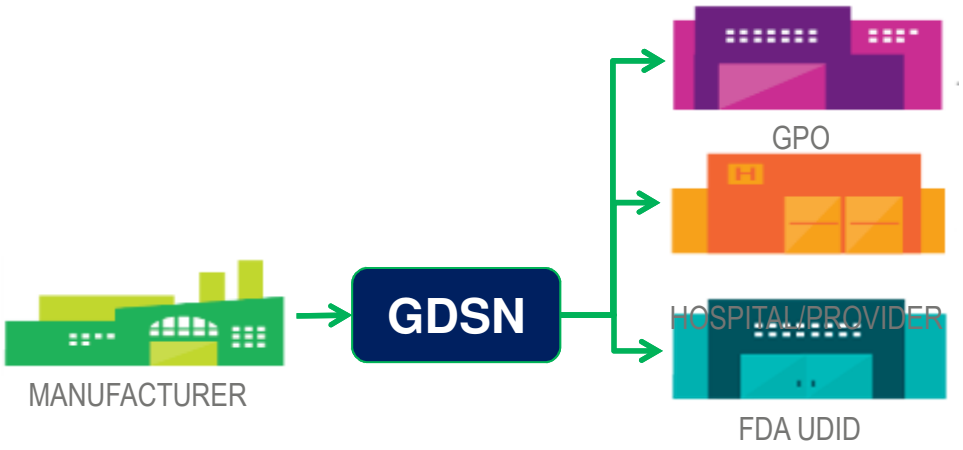
Product Information For

Marketing & Multi-channel Commerce

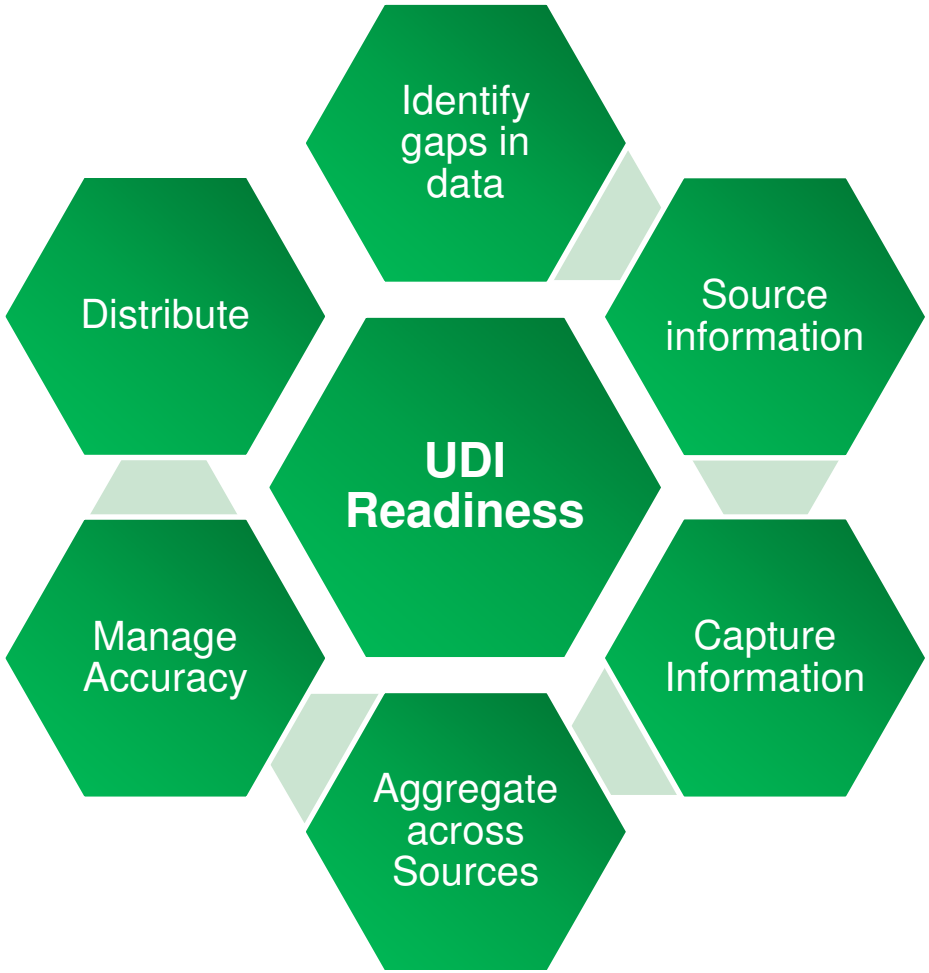
Enabling marketing , eCommerce & Application Developers to acquire trusted product images, assets, information and more – sourced directly from and approved by its original owner.

Benefits of Using GDSN for the GUDID

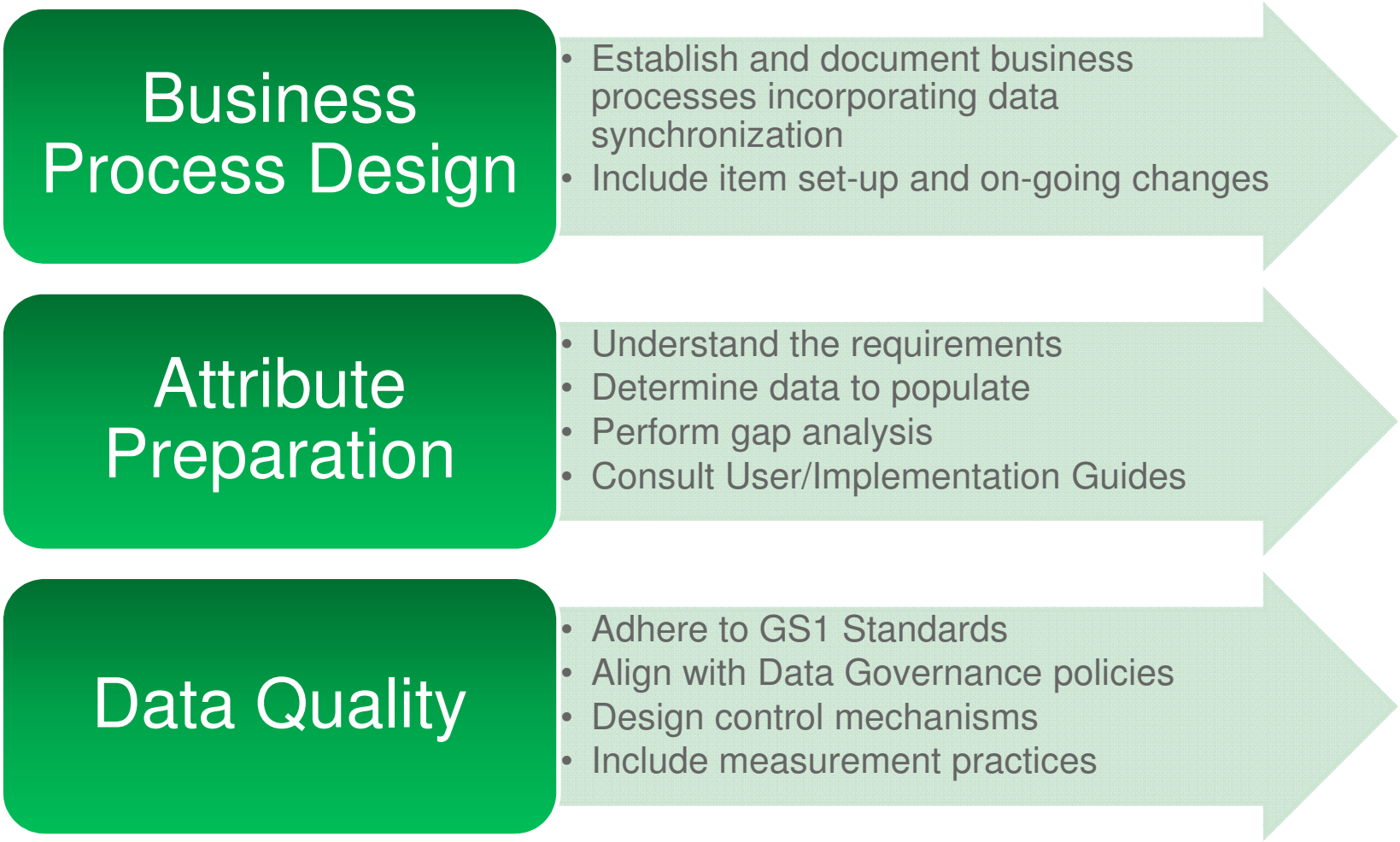
- GPOs and Providers receive public UDID data elements
- UDID data to the FDA and other similar UDI databases globally
- The electronic transfer of standardized product and location information
- Continuous synchronization of that data over time between two or more parties as part of an ongoing standards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



Preparing your Data for Compliance



Preparing your Organization for Compliance



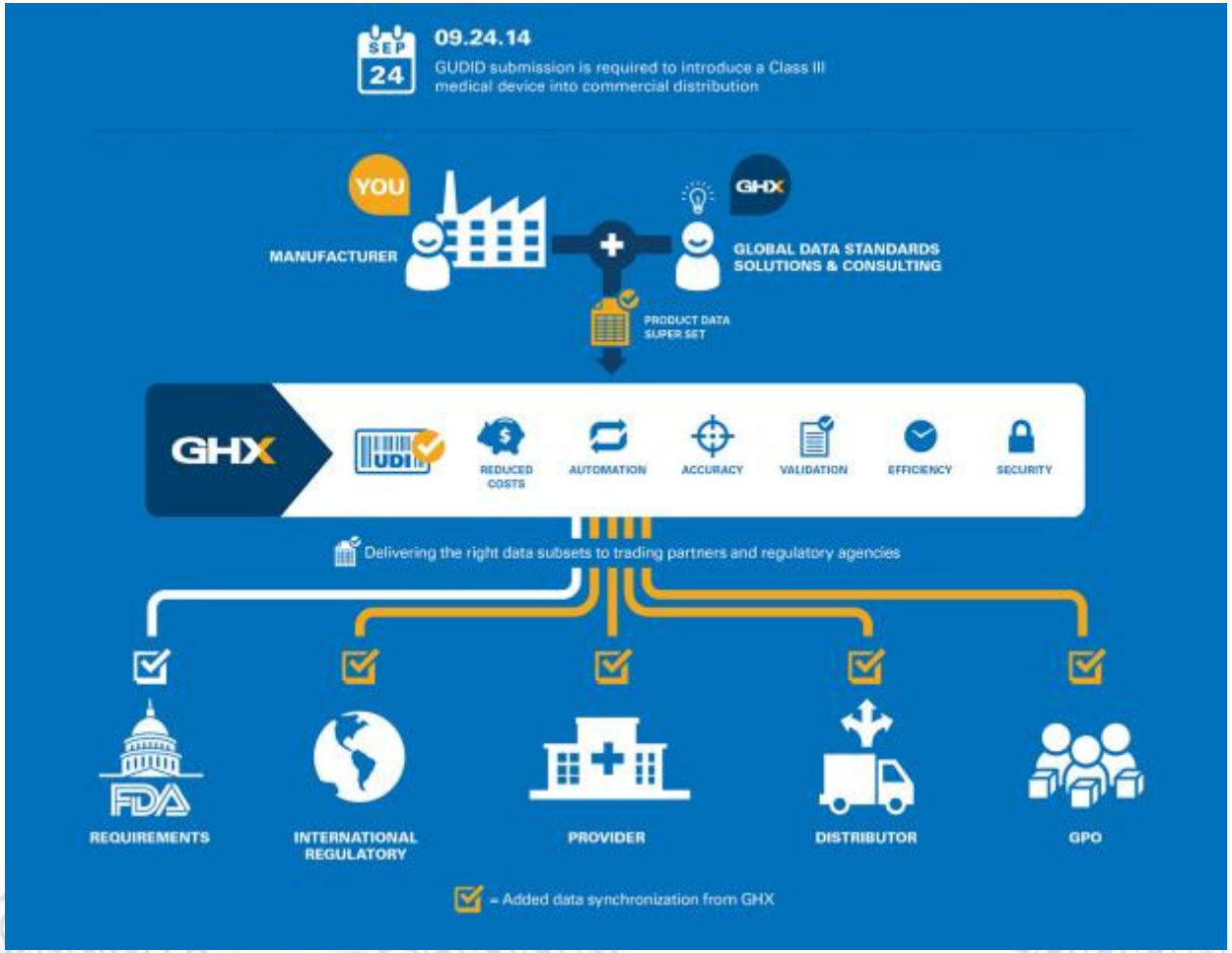
What to do next…

- 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

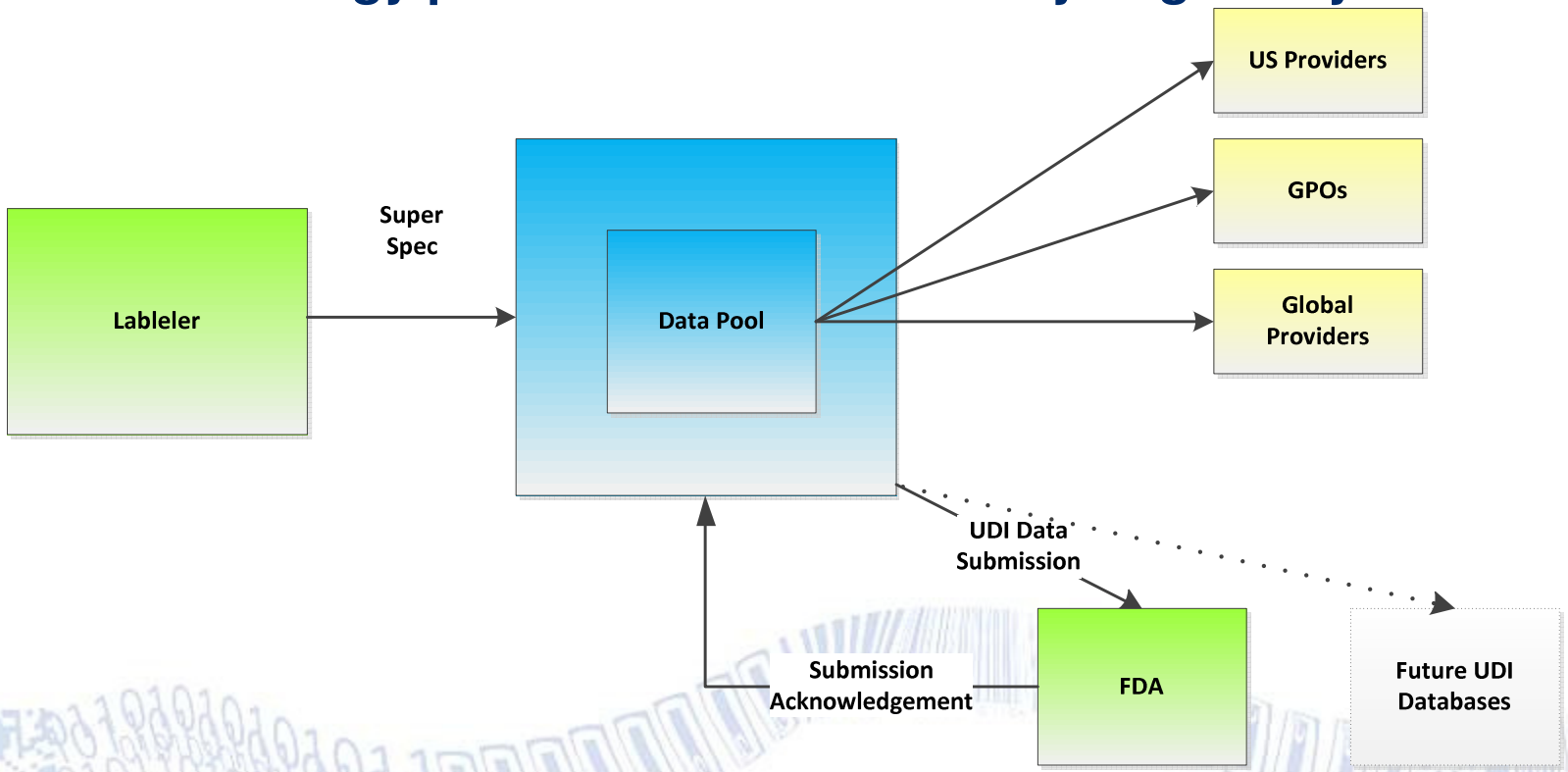
Margot Drees, GHX

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

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

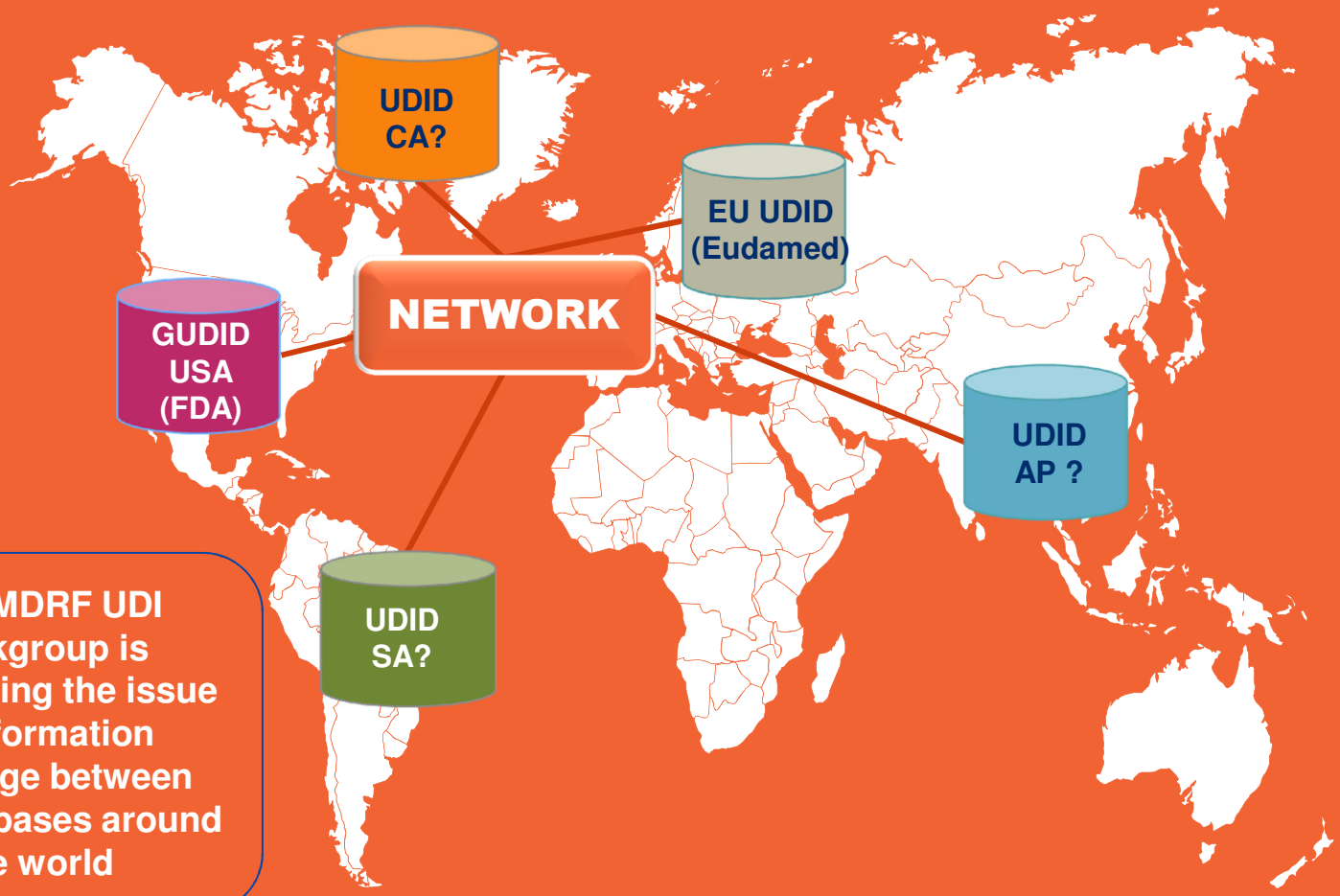
"This is not about just being able to identify devices. We (FDA) are talking about a holistic approach to integrating medical device identification throughout the entire healthcare system. UDI will be a fundamental piece of everything we do going forward."

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

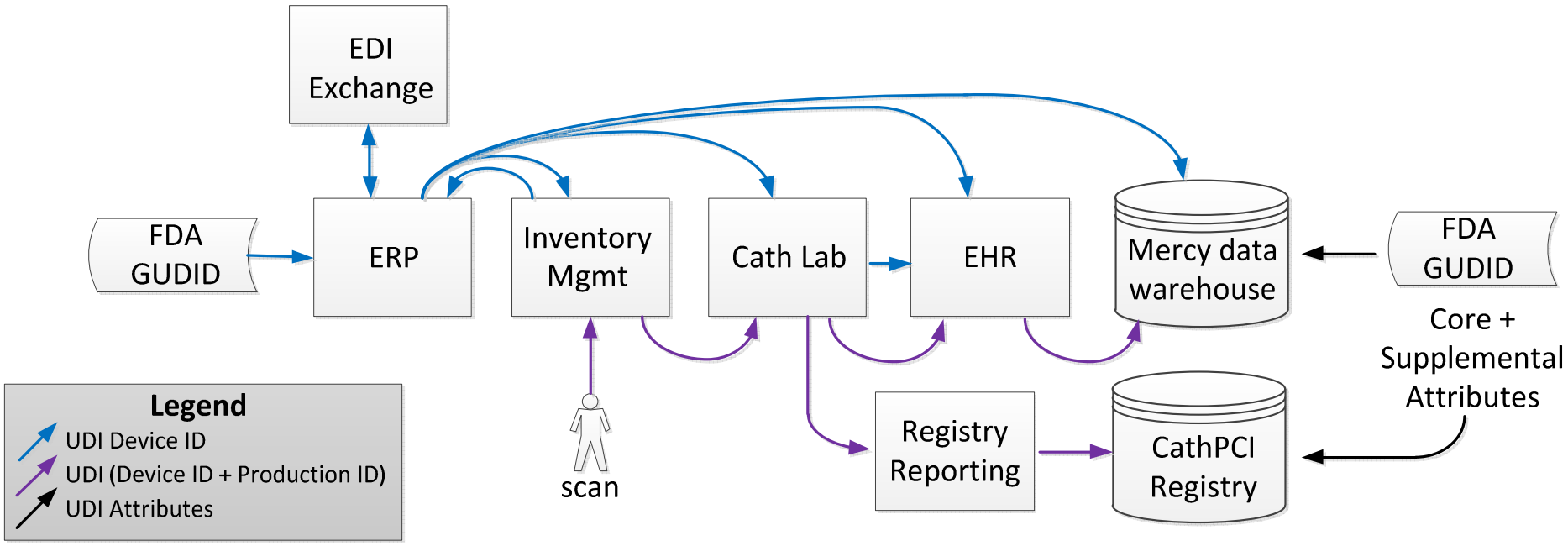
Unique Device Identifier Demonstration Project

- 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

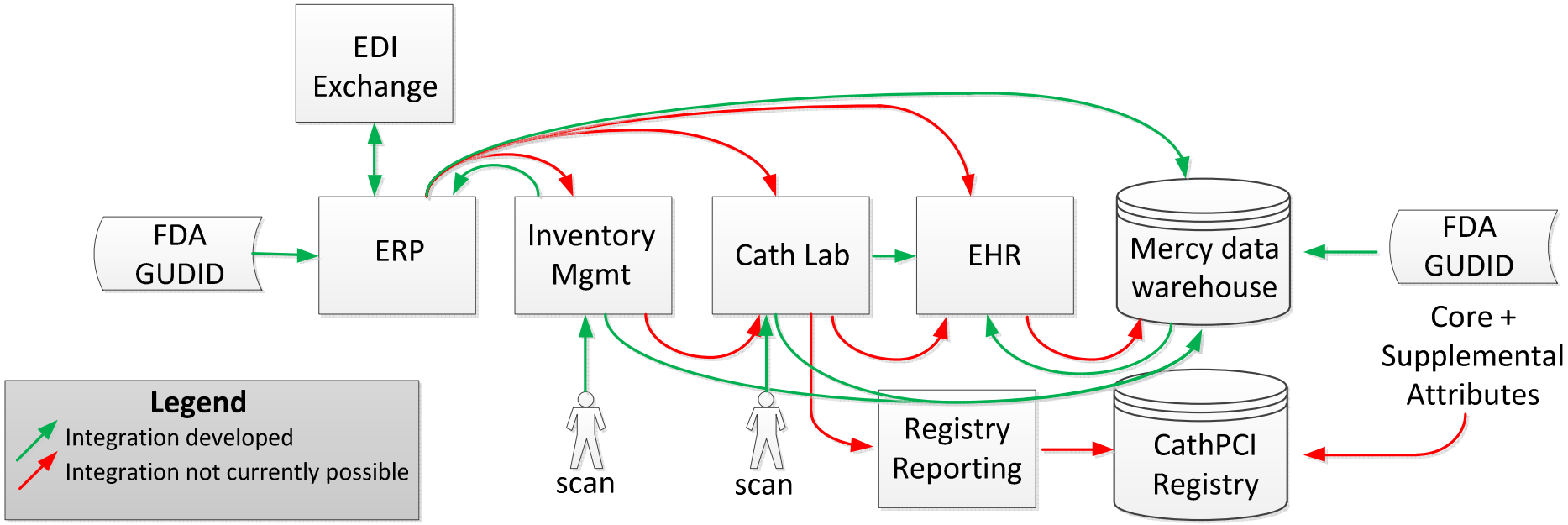
- Identify and capture clinical attributes that impact performance
- Address differences in orthopedic registries to better utilize available data
- *Demonstration projects: bearing surface, femoral head size, fixed vs. mobile knees, pediatric joints*

UDI Implementation Project



- 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

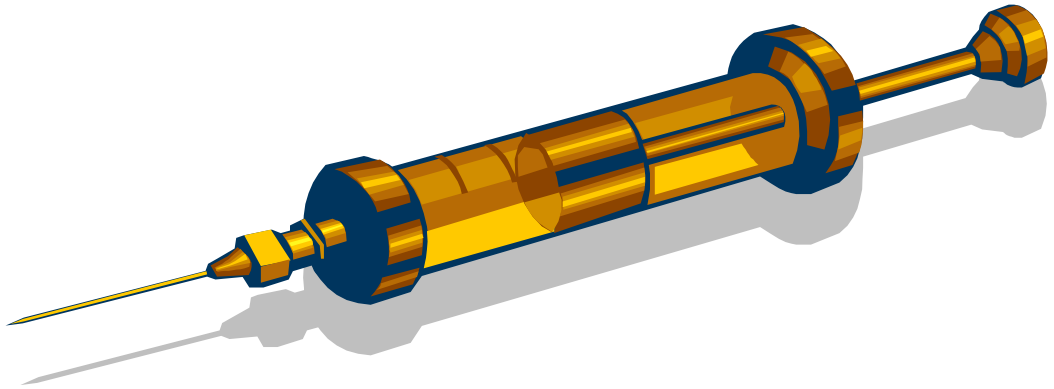
Global acceptance?

- **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:

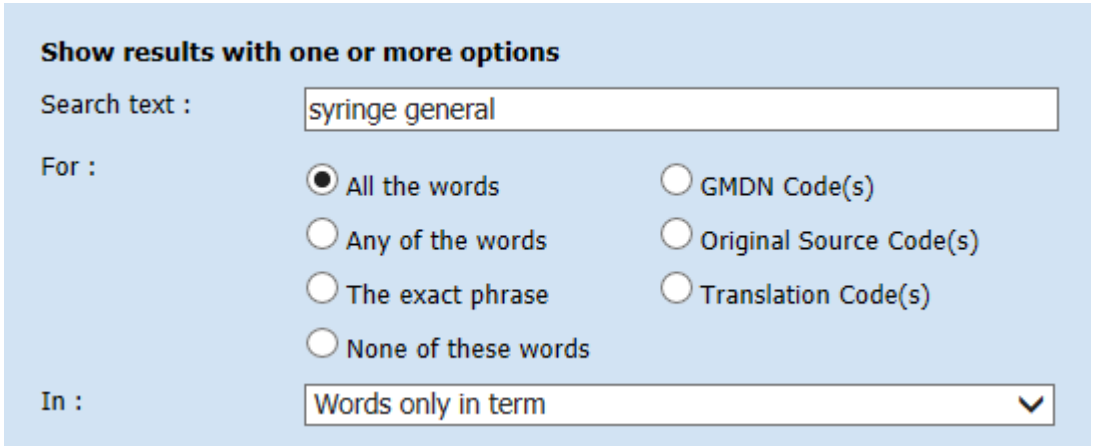
- **Term Name:** General-purpose syringe
- **Definition:** A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical
- **Code:**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

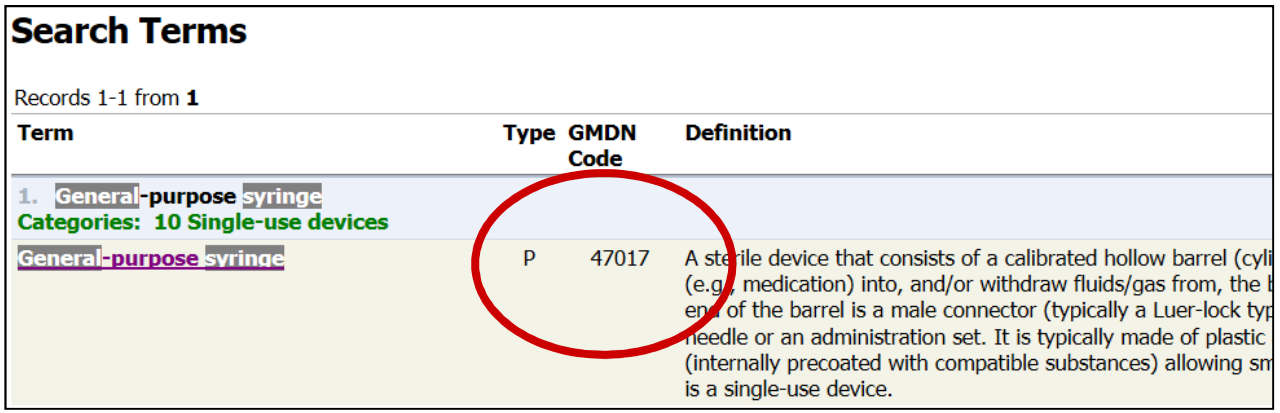


How can you find GMDN Codes?

www.gmdnagency.org

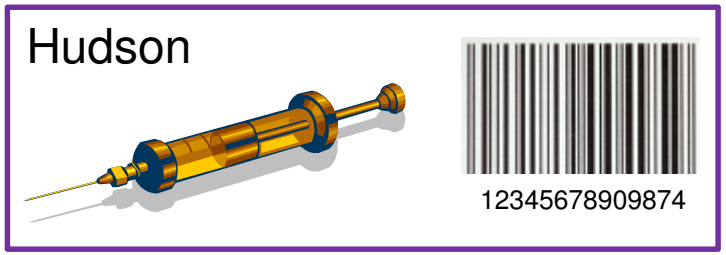
Reveal the GMDN Code





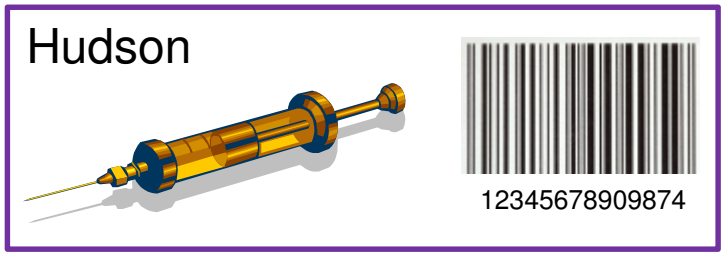
GMDN and UDI Relationship

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

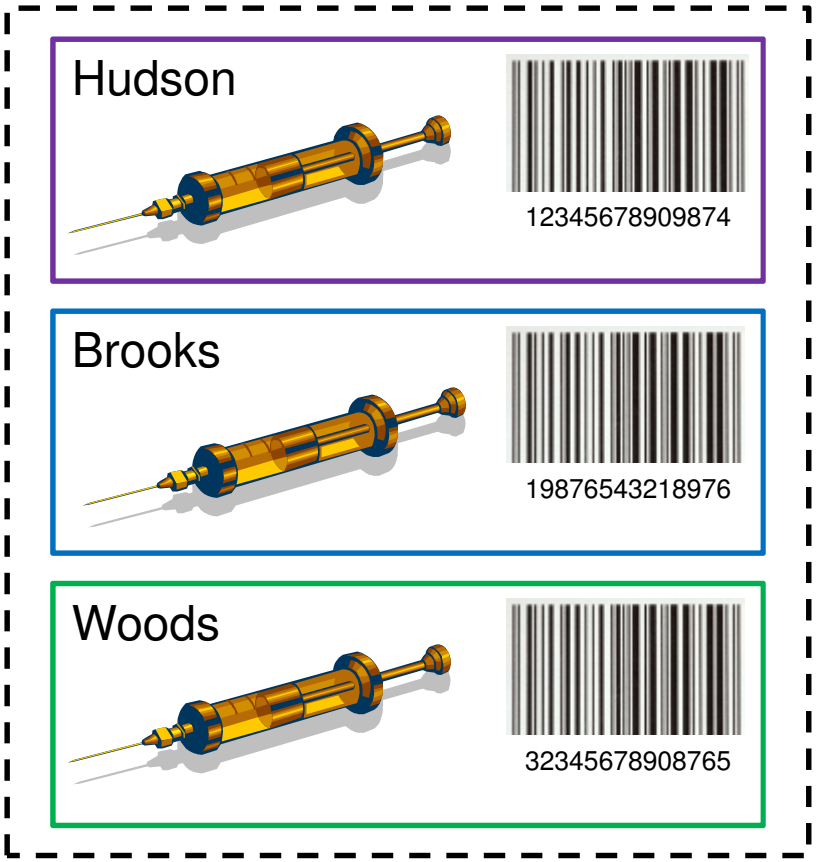


GMDN and GTIN Relationship

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

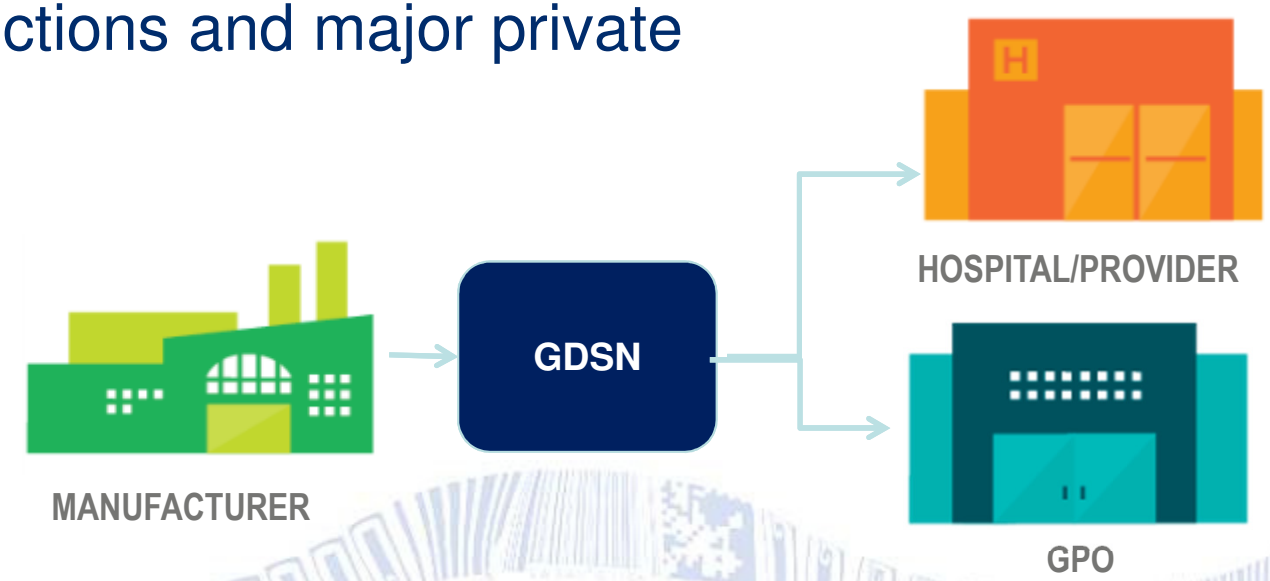
Manufacturing base in Brisbane, over 500 staff, exports to over 70 countries

(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



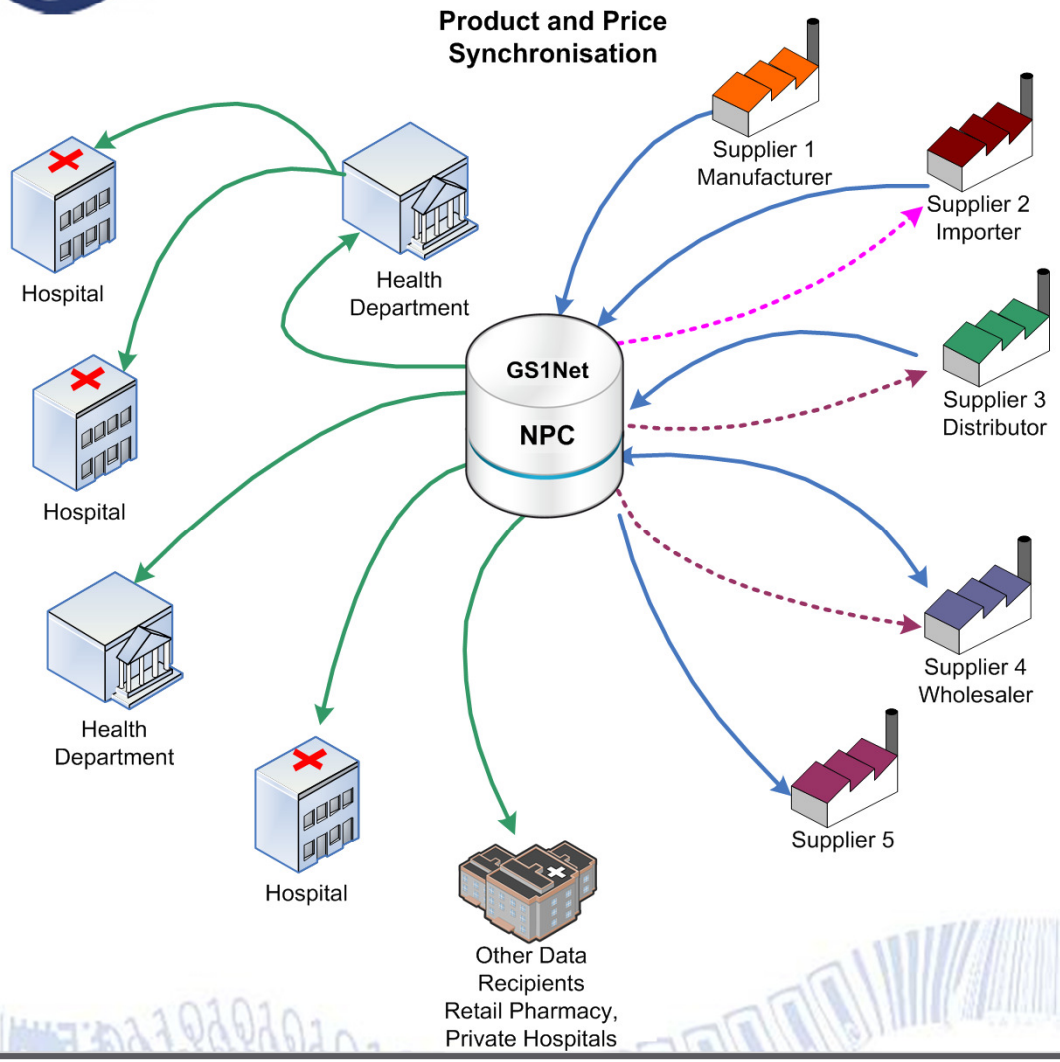
Cook Medical – NPC challenges

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.

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

Data Sync enables EDI



EDI how it works

COOK MEDICAL → Hospital

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**

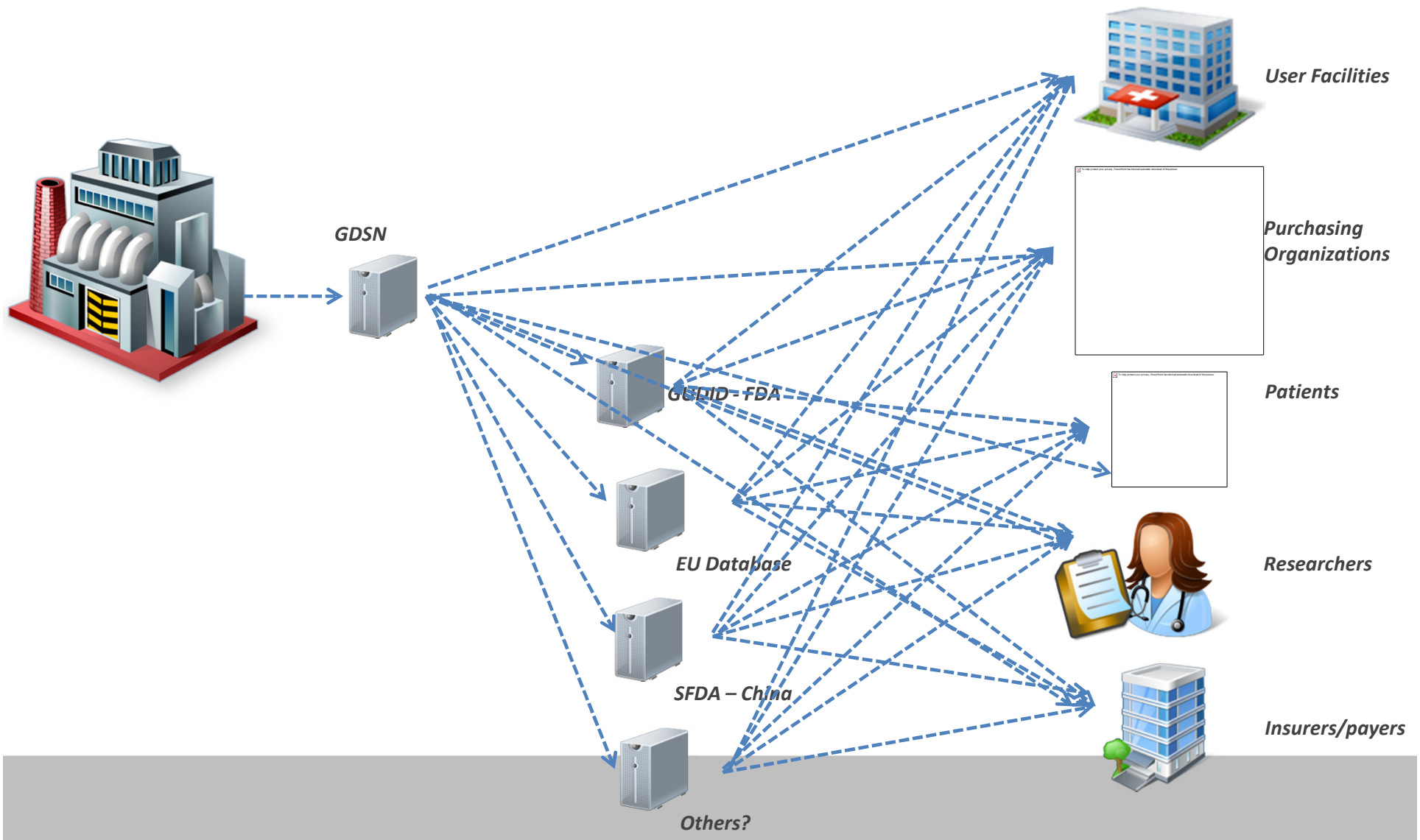
Advantages of NPC/EDI efforts


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:

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