



GS1 Healthcare Global Conference GUDID Implementation Reality

San Francisco, CA, U.S.A.
1 October 2013





“How to get ready to provide data to the FDA’s Global Unique Device Identification Database (GUDID)”

Panelists:

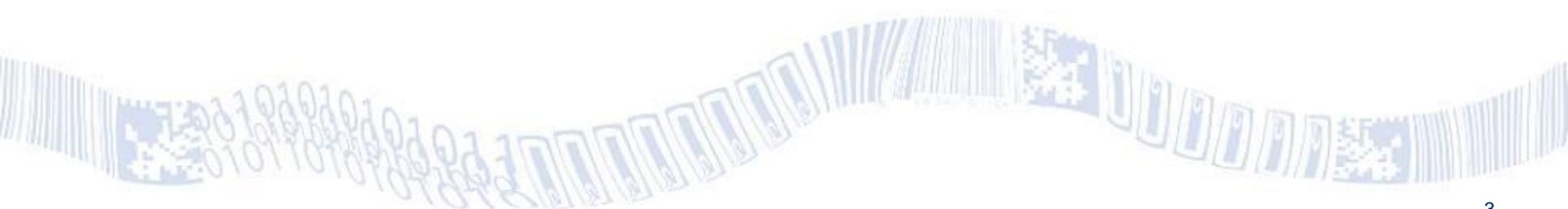
- **Brad Depke, Director GS1 Program, Abbott Laboratories**
- **Craig Karagitz, Manager, PMO, Terumo Cardiovascular Group**
- **Andy Martin, Product Manager, GHX Health ConneXion**
- **Todd Silberlust, Key Account Manager, 1WorldSync**



Agenda

How to get ready to provide data to the FDA GUDID

- About the presenters
- Manufacturer perspectives
 - High-level overview
 - Key steps to load data, Key Choices, Key questions
 - Lessons learned, Challenges ahead
- Data Pool perspectives
 - Overview
 - Benefits of the GDSN for the FDA GUDID
- Q & A throughout





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Terumo Overview

Terumo Corporation, Tokyo, Japan

Terumo Americas Holding (TAH), New Jersey

- Terumo Interventional Systems, New Jersey
- **Terumo Cardiovascular Group, Michigan**
- MicroVention, California
- Terumo Medical Products, New Jersey
- Harvest Technologies, Massachusetts
- Terumo Heart, Michigan
- Terumo BCT, Colorado
- Onset Medical, California



Terumo CV Group Overview

Terumo Cardiovascular Group

- Headquartered in Ann Arbor, Michigan
- Two distinct businesses: Cardiovascular Surgery and Perfusion Products
- Manufacturing centers in Michigan, Maryland and Massachusetts
- 1,300 U.S. based associates

Multiple Points of Cardiac and Vascular Market Leadership





TERUMO CARDIOVASCULAR GROUP

Our Mission and Vision

We will work as a team
to help save one more life,
today and every day.

We will do this by providing and advancing
life saving technology with
cardiac surgery teams around the world

**Every day my actions and decisions
help save one thousand lives**



Terumo CV Group and GS1 Compliance



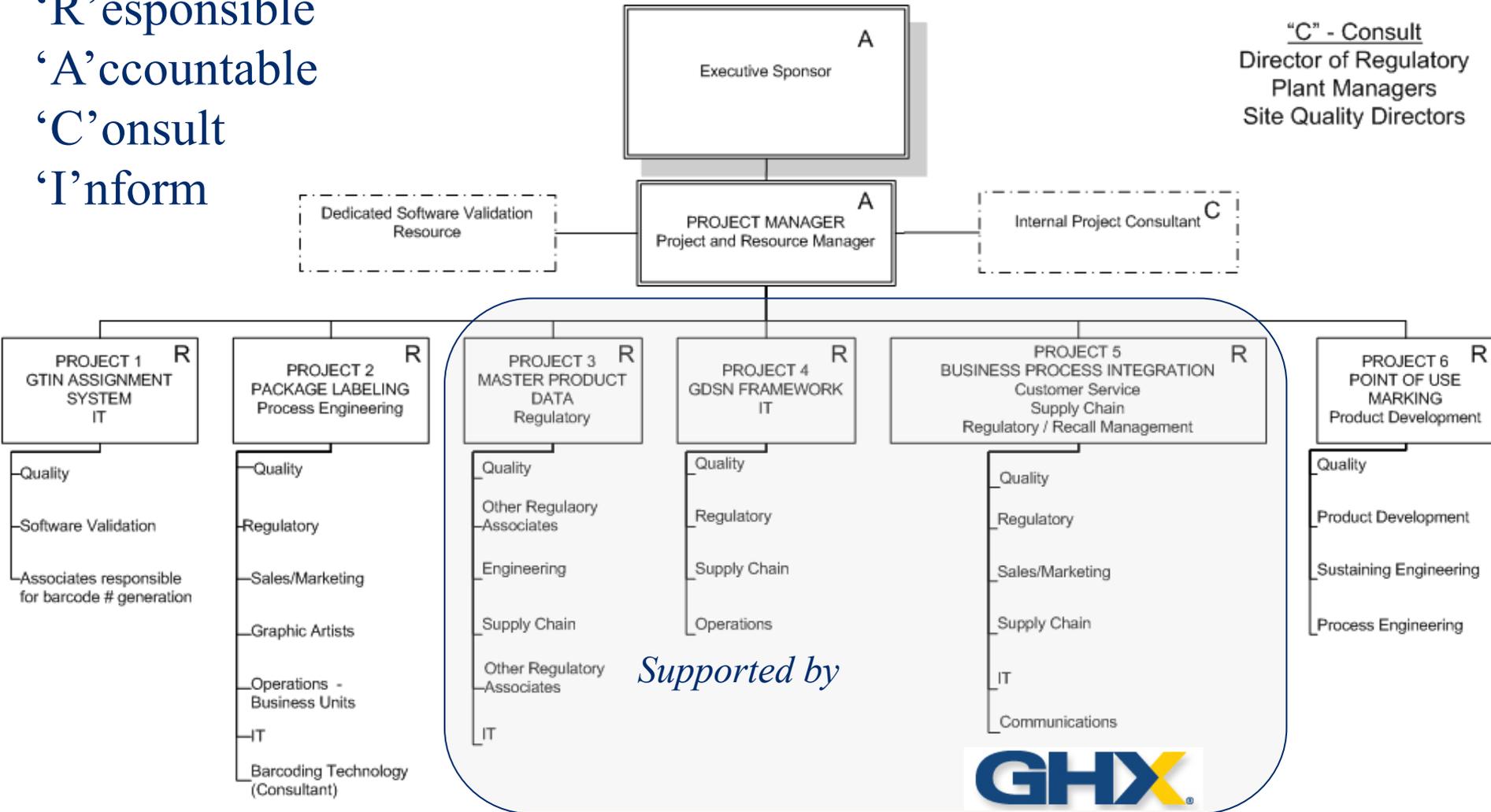
- Get a GLN
- Put GTIN's/barcodes on labels



Project Organization Chart

'R'esponsible
'A'ccountable
'C'onsult
'I'nform

"C" - Consult
Director of Regulatory
Plant Managers
Site Quality Directors



Supported by





Data Drives the Solution

- How big is your GTIN project? (Data Driven)
 - Terumo CV Group Example
 - Only FDA regulated devices (500)
 - Only marketed products
 - ✓ (stocked, advertised, cataloged) (1,400)
 - Anything that might be sold
 - ✓ (spare parts, repair parts, etc) (45,000)
 - EVERYTHING,
 - ✓ (parts, boxes, pre-printed labels, obsolete items, etc) (72,000)

No matter which size solution you choose...the same questions come back again and again...



Terumo CV Group GDSN Test Loads

- Load #1 – Sample data, GHX did all formatting
- Load #2 – More data, Less GHX involvement
- Load #3 – FDA Pilot submission, with GHX help
- Load #4 – GHX only Reviews, clean load, no KITs
- Load #4a – done by Terumo CV Group staff, included KITs
- Good Load – Success !



Terumo CV Group approach to Regulatory Affairs

- Most MRP, ERP systems Do Not have a Regulatory Affairs module
- Terumo CV Group is investing in a full featured RA System
 - Eliminates spreadsheets
 - True source of GTIN (UDI)
 - Control of label generation and contents
- Customer or FDA inquiries can be handled promptly
 - One source of all answers; old codes, GTIN code or product brand name code list cross-references

Our Work

Think Global, Act Local

- Corporate headquarters
 - North suburban Chicago, Illinois, U.S.A.
- Global reach
 - Serve people in more than 150 countries
- ~ 70,000 employees



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



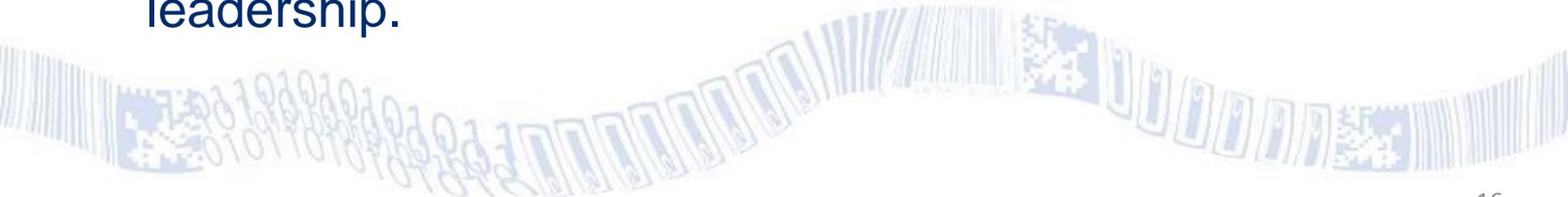
Global Standards & Serialization Office (GSSO)

VISION

Abbott will enhance its leadership position by leveraging GS1 standards implementation to drive business value.

MISSION

The GSSO collaborates with business units to implement GS1 standards to meet customer/regulatory requirements and capture business value by providing education and standards expertise, maintaining an implementation knowledge base and exercising external standards leadership.

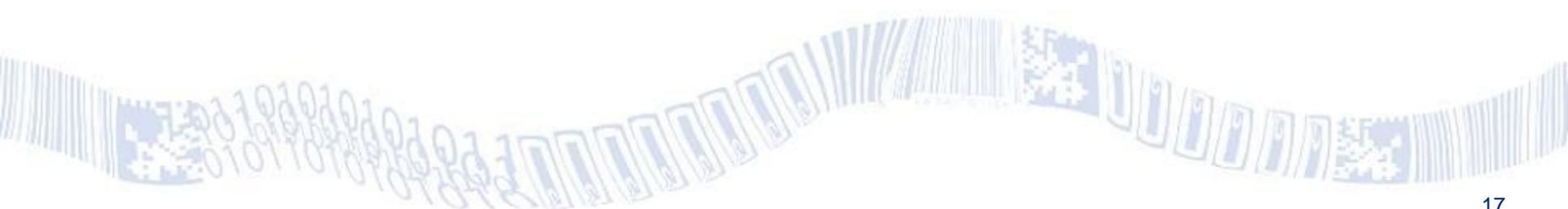




Impact to Abbott's GDSN Solution Application due to FDA UDI Rule

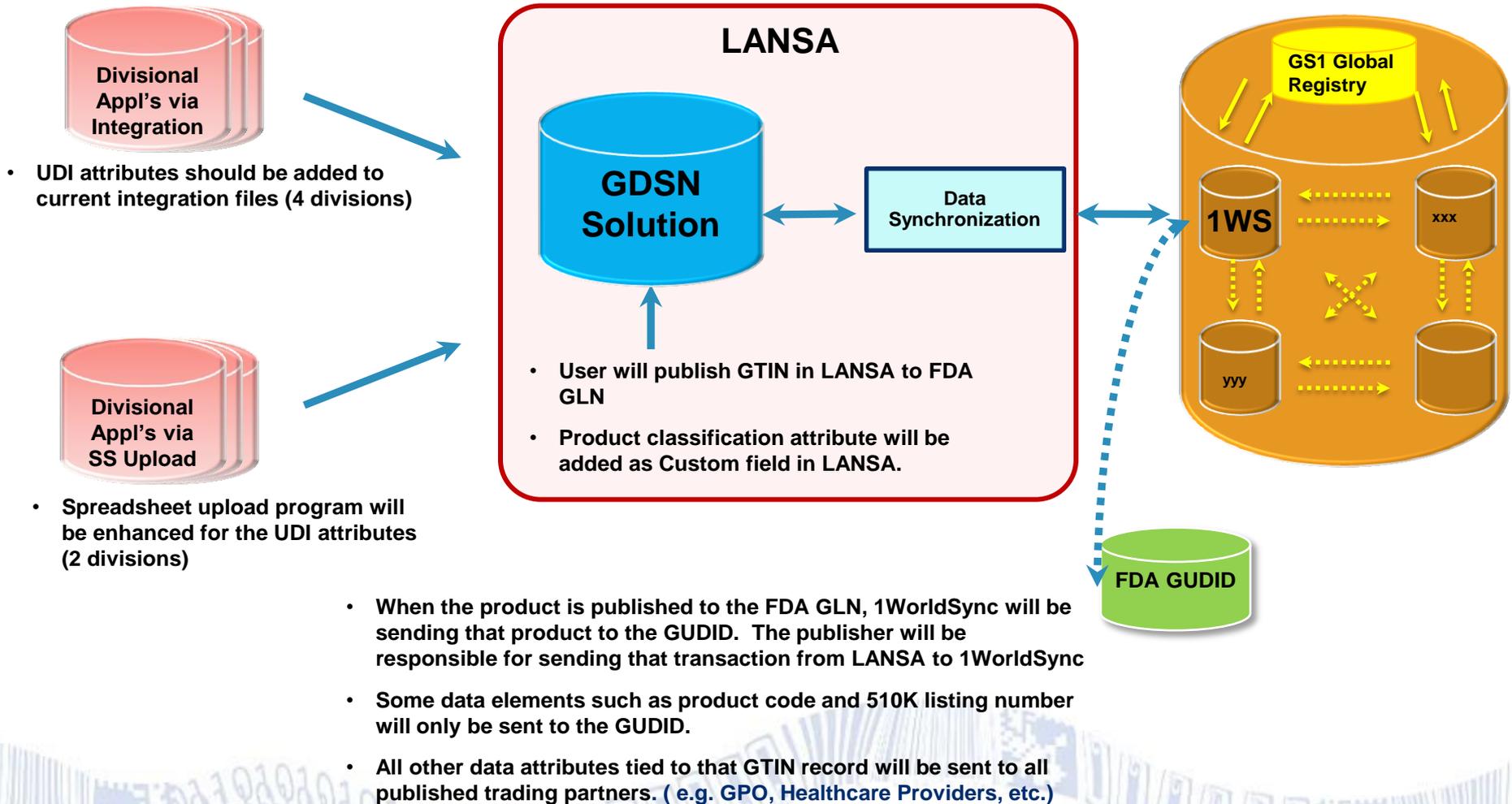
Within the UDI rule exists the requirement to submit product information for devices to the FDA's Global UDI Database (GUDID).

- The required UDI data will be collected from each divisional source system(s) and fed into LANSA Data Sync Direct either through system integrations or manual data loads.
- The data submitted for the GUDID will be loaded from LANSA Data Sync Direct to 1WorldSync.
- Via the established publication process in Abbott's GDSN solution, 1WorldSync will then send the required data. Abbott divisional publishing resources will manage where and when the data will be published.





Abbott's GDSN Solution: Process Flow for Population of GUDID





Tasks and Responsibilities

- Division Tasks (Div1, Div2, Div3, Div4, Div5, Div6)
 1. Add UDI attributes to divisional source systems
 2. Add UDI attributes to division's GDSN export file
 3. Validate source system and extract file according to division's policy and procedures
 4. Only four of six divisions have either Class III or BLA Devices
- LANSA Tasks
 1. Add UDI attributes to LANSA Data Sync Direct and spreadsheet upload program
- 1WorldSync Tasks
 1. Add UDI attributes to 1WorldSync Data pool
 2. Create mapping tool from 1WorldSync to GUDID for required attributes
 3. Create ability to capture messages generated by the GUDID and send to LANSA through existing messaging format
 4. Validate tool for capturing data from manufacturer and sending data to GUDID



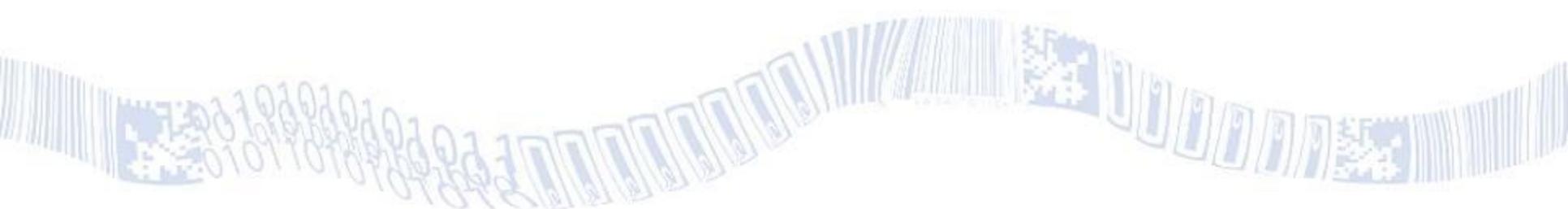
Tasks and Responsibilities

- IT Tasks

1. Install LANSA patch for UDI attributes and spreadsheet upload program
2. Add UDI attributes to four divisions TIBCO integrations
3. ***Validate GDSN Solution (end to end testing includes file from division to GUDID)***

- GSSO Tasks

1. Execute validation test protocols
2. Supply feedback and Business Owner approval for GIS Project Plan, Functional Requirements document, and Business Impact Assessment
3. Configure screens for UDI attributes
4. Add FDA as recipient GLN into LANSA
5. Authorize divisional publisher resource to access the FDA GLN.





Executive Scorecard for UDI Rule *

Divisional and Corporate Updates for Q3 2013

As of :
2013-MM-DD

EVP1			EVP2			EVP3
Div1	Div2	Div3	Div4	Div5	Div6	Div7

Data Management
(UDI Attributes, Systems Modifications, Systems Validation)

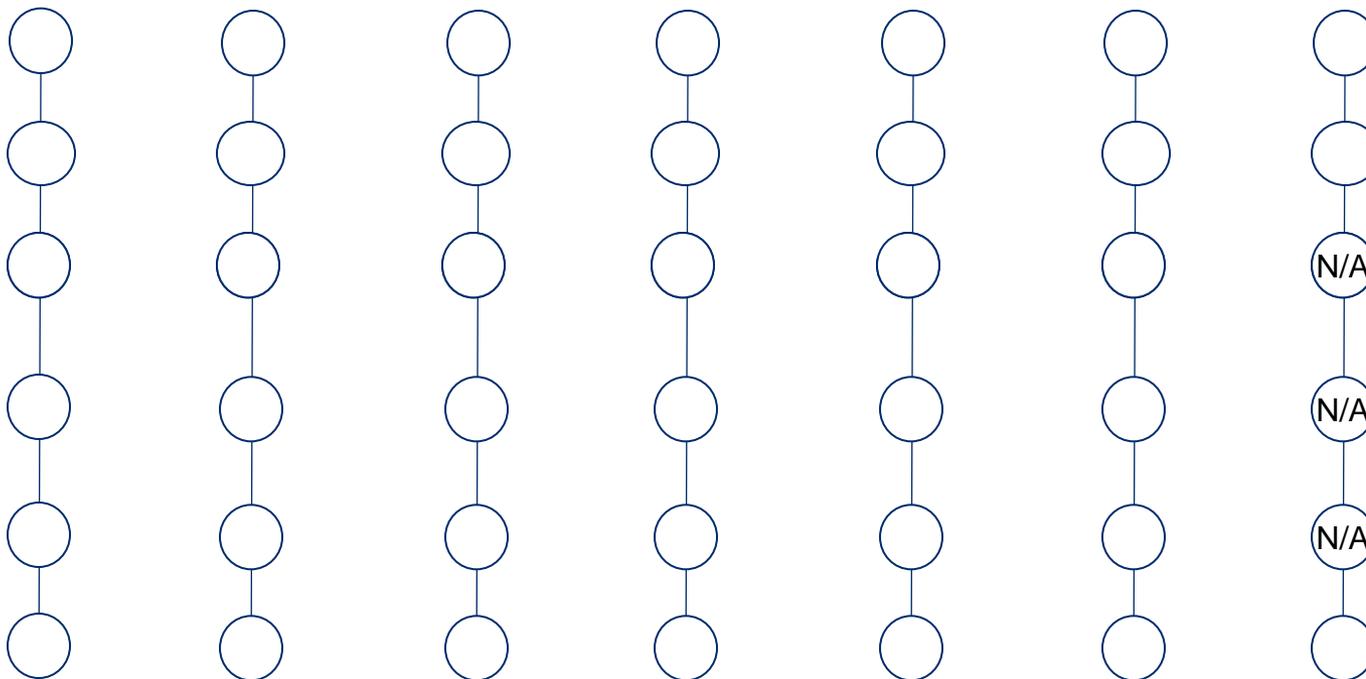
Procedures
(Quality Documents ID'd, UDI Req.mnts Applied, Documents in Production)

Direct Part Marking *
(Products Id'd, Marking Equipment Installed, Products Marked)

Labeling - Meet Bar Code Requirements *
(All Products Display Required Format, Device Identifier, Production Identifiers)

Labeling - Date Format
(All Products Display Required Format)

GUDID Implementation *
(All Products Loaded into FDA Database)



0%	1% - 25%	26% - 50%	51% - 99%	100%	Per Schedule (Timing)
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Definition of Complete

All FDA UDI regulations have been met per scope and timing.

*(e.g. Device Class III products first)



Key Steps to Load Data into GUDID

Standard Project Management

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

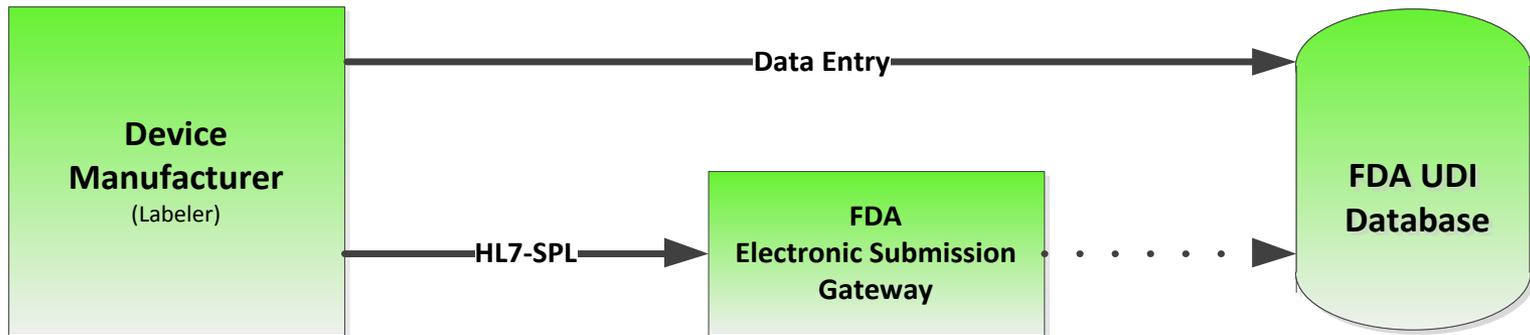
UDI Project Management

- 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 UDI Database

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





One connection to UDI databases



MANUFACTURER



MANUFACTURER



MANUFACTURER

GDSN



US UDID



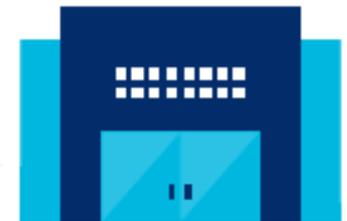
EU UDID



JAPAN UDID



HOSPITAL / PROVIDER



GPO



MANUFACTURER



Questions you need to ask...

PROJECT ORGANIZATION

- What is your mission?
- How big is your project - Who, What, When?
- Who will the FDA call at your company if the data is not in the GUDID on time?
- What is the real duration?
- How do we structure things?
- How do we control cost?
- What is your deadline and how do you hit it?
- How do *you* define success?
- What does being *finished* look like?

SOLUTION

- How many products does your company sell in the U.S.?
- Is your company already using a data pool to share product data commercially?
- Does your company already submit new product introductions to the FDA via internally supported processes?
- What is your company's IT expertise in the UDI requirements? GS1 Standards?
- How will your company respond to sharing data with third parties? (legal, purchasing, regulatory, quality, commercial, IT)

RESOURCES

- How do we identify the resources?
- How do we secure them?
- How do we educate them?

DATA

- What data do we need?
- How do we manage it?
- Who has it/owns it?
- What format is it in?
- How do we convert it?
- Can we trust it?
- How to digitize it?
(Manually, copying, scanning)



Manufacturer Lessons Learned

- **The requirement is real**
 - No longer question of “if or when”...it is “how”
 - Global changes may accelerate the urgency
- **UDI is not a “project”**
 - Creating a cross functional business process
 - Ongoing business requirements
- **A clear owner is not always evident**
 - Senior leadership must own the initiative
 - Sponsorship and management are required
- **Some GUDID attributes are more complex than others**
 - Latex
 - MRI Safety Status
 - Employ a data analyst



Manufacturer Lessons Learned

- **Takes longer than you expect**
 - Strategy and approach need to be defined up front!
 - All data attributes will not be in your ERP
 - Resource constraints / competing initiatives
 - Stay flexible – not everything is figured out yet
- **It's BIGGER than you think**
 - Segment the effort to smaller manageable chunks
 - Don't be surprised if you find yourself second guessing previous decisions
- **Not simply assigning a unique number**
 - Systems, customers, publishing considerations
 - Bar code / labeling requirements
 - Corporate or global SOP development



GUDID Challenges Ahead

- AIDC Challenges (attend other session)
- Quality System Document Updates
- Device Class Identification (III, II, I and Life Supporting/Sustaining)
- Date Format on Product Labels Identification
- Data Management (collection of data, 60+ attributes)
- DUNs #
- Manufacturing / Product Date
- GMDN Codes
- Validation of Application System(s)
- GS1 XML – HL7 SPL Protocol Conversion



Andy Martin

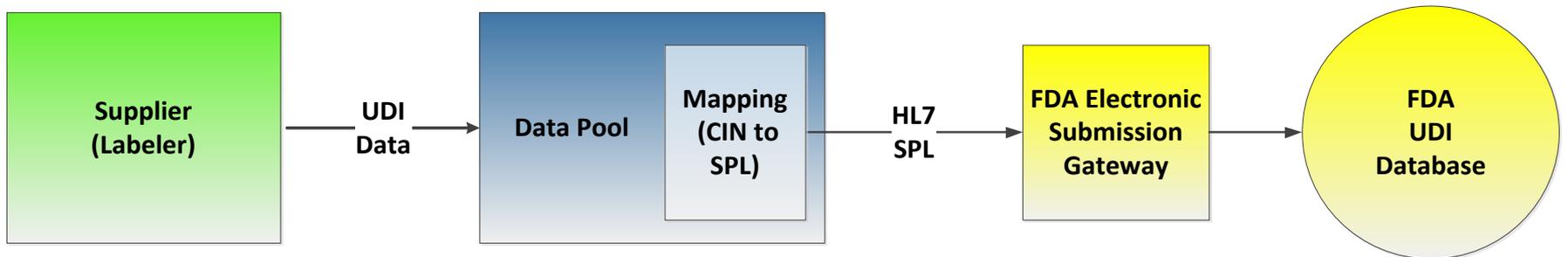
GHX Health ConneXion





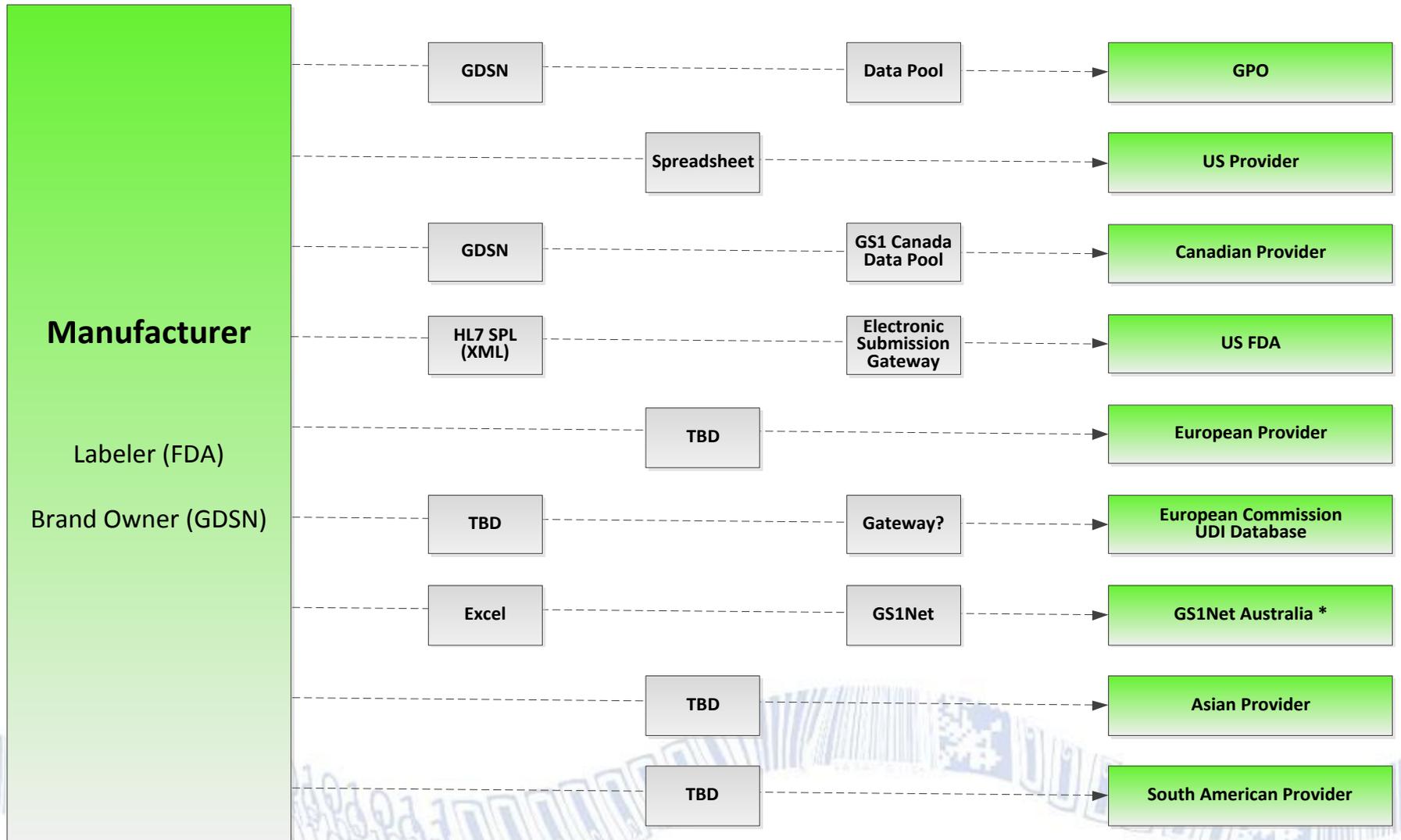
Proposed Solution

- Labeler sends data to Data Pool
- Data Pool Maps data from GDSN format to the FDA format
- Data Pool routes data via Electronic Submission Gateway





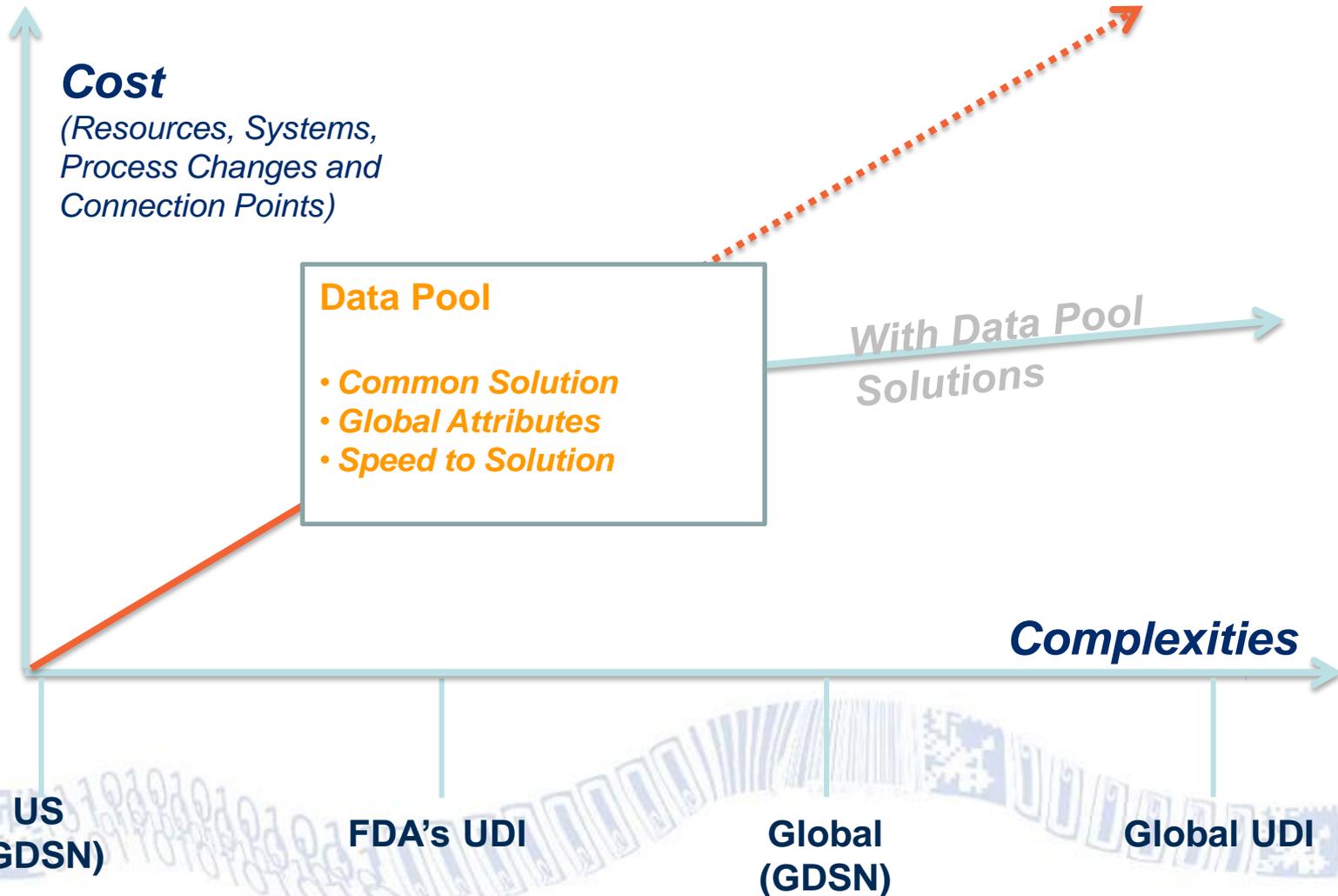
Data Synchronization without Data Pool





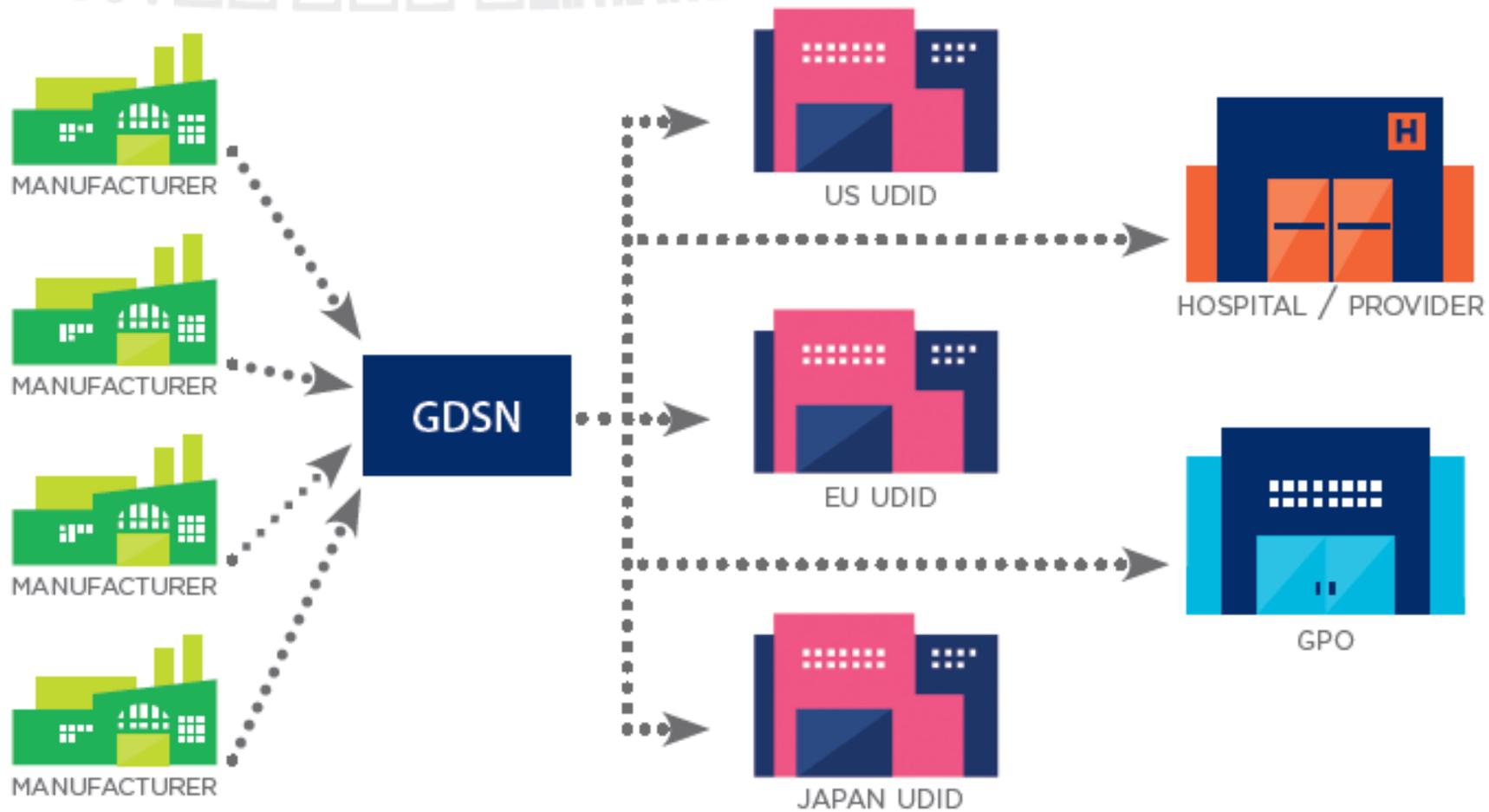
What is this going to cost?

Global suppliers bear the majority of the cost with data synchronization.





One connection to UDI databases





HL7 SPL Sample

```
<desc>Device 5 mm</desc>
  <generalizedMaterialKind>
    <code code="45613" codeSystem="2.16.840.1.113883.6.276" />
  <code code="C101717" codeSystem="2.16.840.1.113883.3.26.1.1" />
  <definingMaterialKind>
    <code code="67674521070400" codeSystem="1.3.160" />
    <representedOrganization>
      <assignedEntity1>
        <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1" />
        <representedOrganization>
          <id root="1.3.6.1.4.1.519.1" extension="805770828" />
        <!-- Premarket Authorization # -->
        <id root="2.16.840.1.113883.3.150" extension="K822572" />
        <code code="C80441" codeSystem="2.16.840.1.113883.3.26.1.1" />
      </marketingAct>
    <code code="C101667" codeSystem="2.16.840.1.113883.3.26.1.1" />
  <effectiveTime xsi:type="IVL_TS">
    <low value="20121003" />
    <high />
    <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="BL" value="false" />
  <characteristic>
    <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1" />
    <value xsi:type="BL" value="true" />
```

Mfr Part #

GTIN

DUNS #

PMA #

Publish Date

Controlled by Serial Number

Controlled by Lot Number



Mapping Samples

- The HL7 SPL data format is significantly different from the GDSN format. The following are some examples of the translation:
 - FDA identifies attributes with Concept Codes (C Codes)
 - Data remains as is, XML Tag is changed to support SPL
 - In some instances, the existence of data drives the true/false response
 - FDA considers the Base Unit as Primary

GDSN CIN Field	FDA Field	HL7 SPL Mapping Sample
GTIN	Primary DI #	<code code="123456789012" codeSystem="1.3.160"/>
additionalTradeItemIdentificatonType/Value	Model/Version #	<code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
TradeItemDescription	Device Description	<desc>add description here</desc>
effectiveDate	DI Record Publish Date	<code code="C101667" codeSystem="2.16.840.1.113883.3.26.1.1"/>
additionalClassificationAgencyName = 35	Code (GMDN)	<code code="11111" codeSystem="2.16.840.1.113883.6.276"/>
Additional Classification Category Description	Authorization #	<code code="C80441" codeSystem="2.16.840.1.113883.3.26.1.1"/>
doesTradeItemContainLatex	Contain Latex	<code code="C101673" codeSystem="2.16.840.1.113883.3.26.1.1"/> <value xsi:type="BL" value="true"/>
manufacturerDeclaredReusabilityType	For single-use	<code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/> <value xsi:type="BL" value="true"/>



Electronic Submissions Gateway (ESG)

FDA/CDRH UDID Organization Account Request

Organization Name _____

Organization DUNS Number*: _____

(*Parent DUNS number at the highest level in the organization)

Preferred Method of UDID Submission --

- Secure Online ONLY
- HL7 SPL files via FDA ESG ONLY
- Secure Online and HL7 SPL

Organization Point of Contact Information*:

(*Individual accountable for UDID submission requirements for the organization)

Name: _____

Physical Address: _____

Phone Number: _____

Email Address: _____

Each organization may have one or more Coordinators managing UDID submission for one or more Labeler DUNS numbers.

Coordinator Point of Contact Information*:

(*Individual accountable for management of UDID submission for the Labeler DUNS numbers listed below)

Name: _____

Physical Address: _____

Phone Number: _____

Email Address: _____

Labeler DUNS numbers² (managed by the Coordinator listed above)

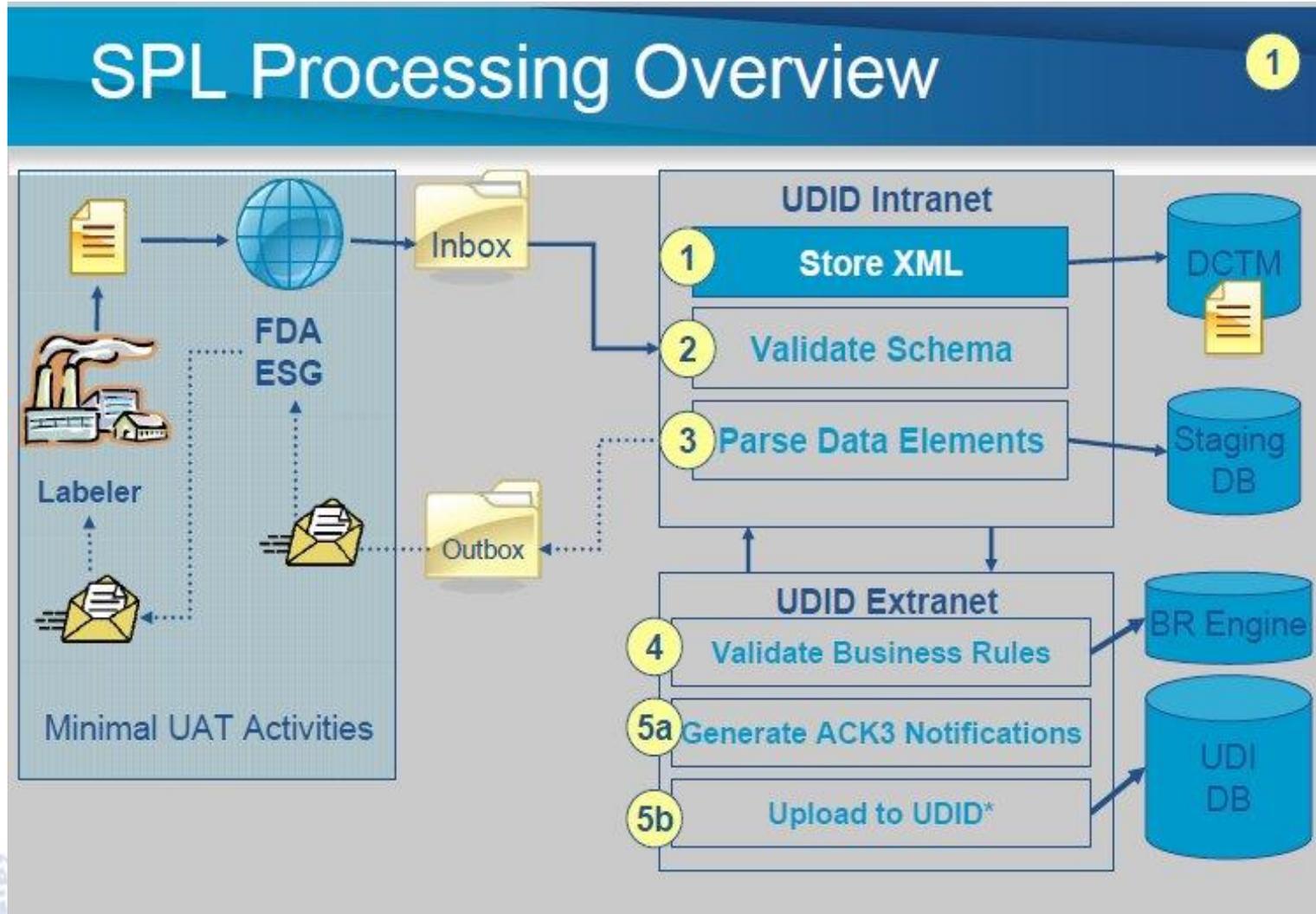
²Each organization must have at least one Labeler DUNS number, it may be the same as the Parent DUNS number provided above.)

Labeler DUNS Number _____

For Additional Coordinators and Labeler DUNS numbers, please provide the information above on another form



Electronic Submissions Gateway (ESG)





Todd Silberlust

1Worldsync





About 1WorldSync

- **Data Pool Services**

- Global - More than 15,000 subscribers across 54 different countries.
- Portfolio includes
 - New Product Introduction Portal
 - Data Loading
 - Data Accuracy Scorecard
- Joint Venture of GS1 US & GS1 Germany

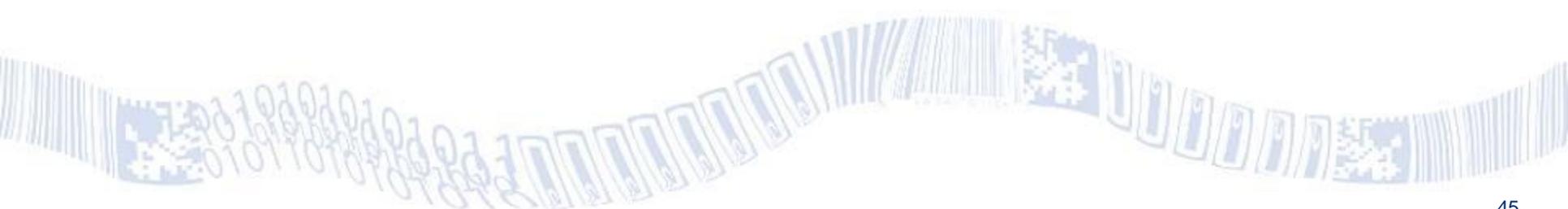
- **Product Data Management Professional Services**

- Readiness Assessments
- Attribute Mapping
- Education
- Data Governance



1World Healthcare Industry Vision

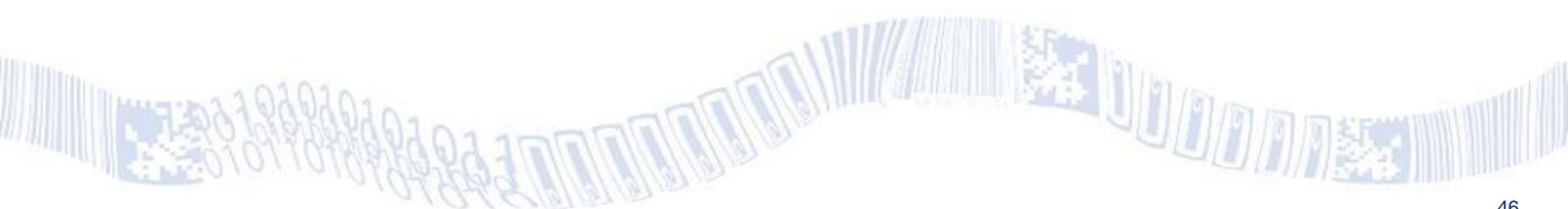
A provider of Product Data Management solutions that align to the healthcare industry's goals of regulatory compliance, improvements in patient safety, and increases in supply chain efficiencies.





Recommendations - Implementation

- Business Process
- Attributes/Requirements
- Data Quality
- Leveraging current information

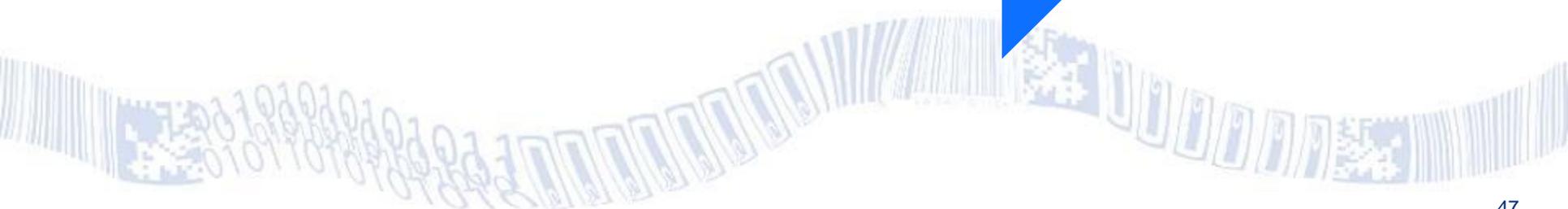




Preparation (Business Process)

Business Process Design

- Establish and document business processes incorporating data synchronization.
- What data will you be populating?
- What electronic and/or manual processes will you put in place for item lifecycle?
- How will you communicate these changes?





Preparation (Attributes)

Determine what attributes you will be populating

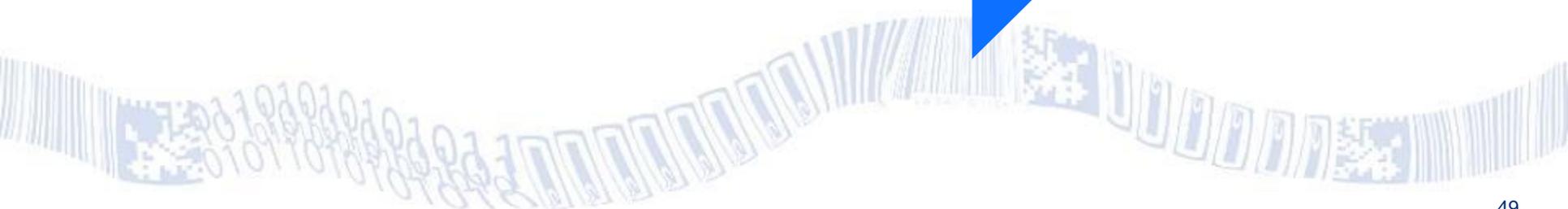
- Perform gap analysis
- Understand the requirements
- Consult User/Implementation Guides
 - Implementation Guides instruct you on steps to beginning the synchronization process with your recipient (i.e. setting up subscription)



Data Quality

Data Quality

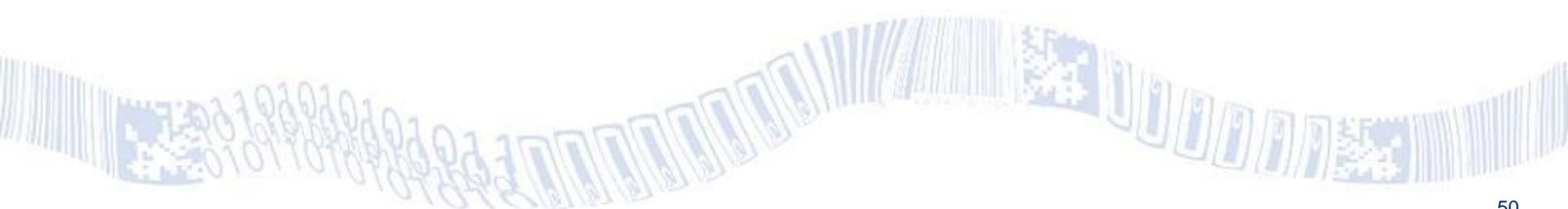
- Adhere to the attribute requirements (GS1 Standards)
- Alignment with Data Governance policies
 - Item set-up accountability
 - Control mechanisms
- Data Accuracy – Measurements





Leverage Resources

- Leverage the successful work done with other industry Best Practices
- Data Pool Provider Services
- Education – Local GS1 MO
- Data Quality Framework
- Get Started Right Away!

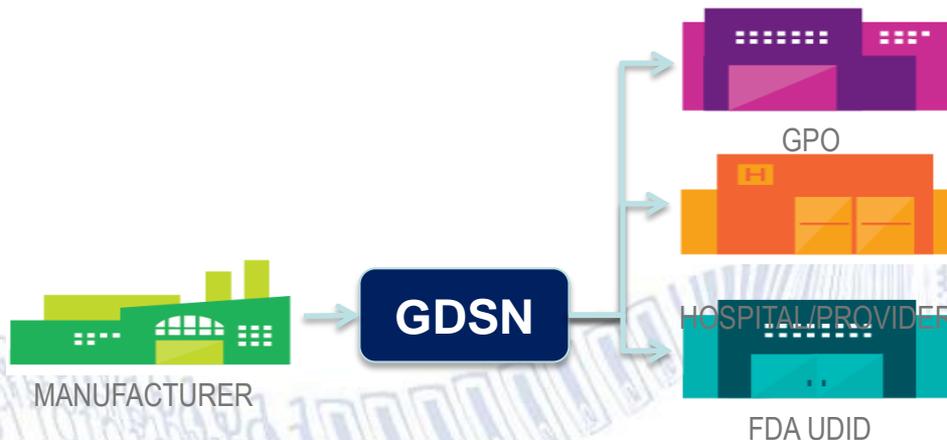




Using GDSN for the GUDID

- **Benefits to the approach**

- The GDSN as a single point of for publishing an item's master data
- Population of data one to many/Global Network
- Standards based
- GPOs and Providers receive public UDID data elements
- Supply Chain and Market data to GPOs and Providers
- UDID data to the FDA and other similar UDI databases globally





Contact Information

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