UDI Compliance Management

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Kodit UDI Ltd

Unique Device Identification (UDI)

Unique Device Identification Database (UDID)

FDA (GUDID)

Global Regulatory Change- UK, Europe

Recap on FDA UDI Compliance?

AN ADDITIONAL UNAVOIDABLE COST TO BUSINESS

Initial:

Labels: Produce compliant labels for all products and packaging levels.

Data: Produce a set of data and send to a database to be approved.

ONLY WHEN AN ORGANISATION HAS DONE THESE TWO THINGS HAVE THEY ACHIEVED INITIAL COMPLIANCE

Ongoing:

Keep data compliant as rules are updated or changes are made to existing data.

Keep labels compliant as rules are updated or changes are made to existing data.

Compliance for USA

- **Food and Drug Administration (FDA) rule**

- The FDA UDI ruling requires that all medical devices sold in the U.S.A. adhere to standards of labelling. The medical device manufacturer must also provide a set of device attributes for inclusion in a Global Unique Device Identification Database (GUDID).

- **USA Group Purchasing Organisations (GPO's)**

- Large USA buying groups, such as MedAssets and Kaiser Permanente, have published requirements that suppliers must deliver products with compliant labels, and also provide a set of data attributes delivered via a certified GS1 data pool provider.

Compliance by Classification

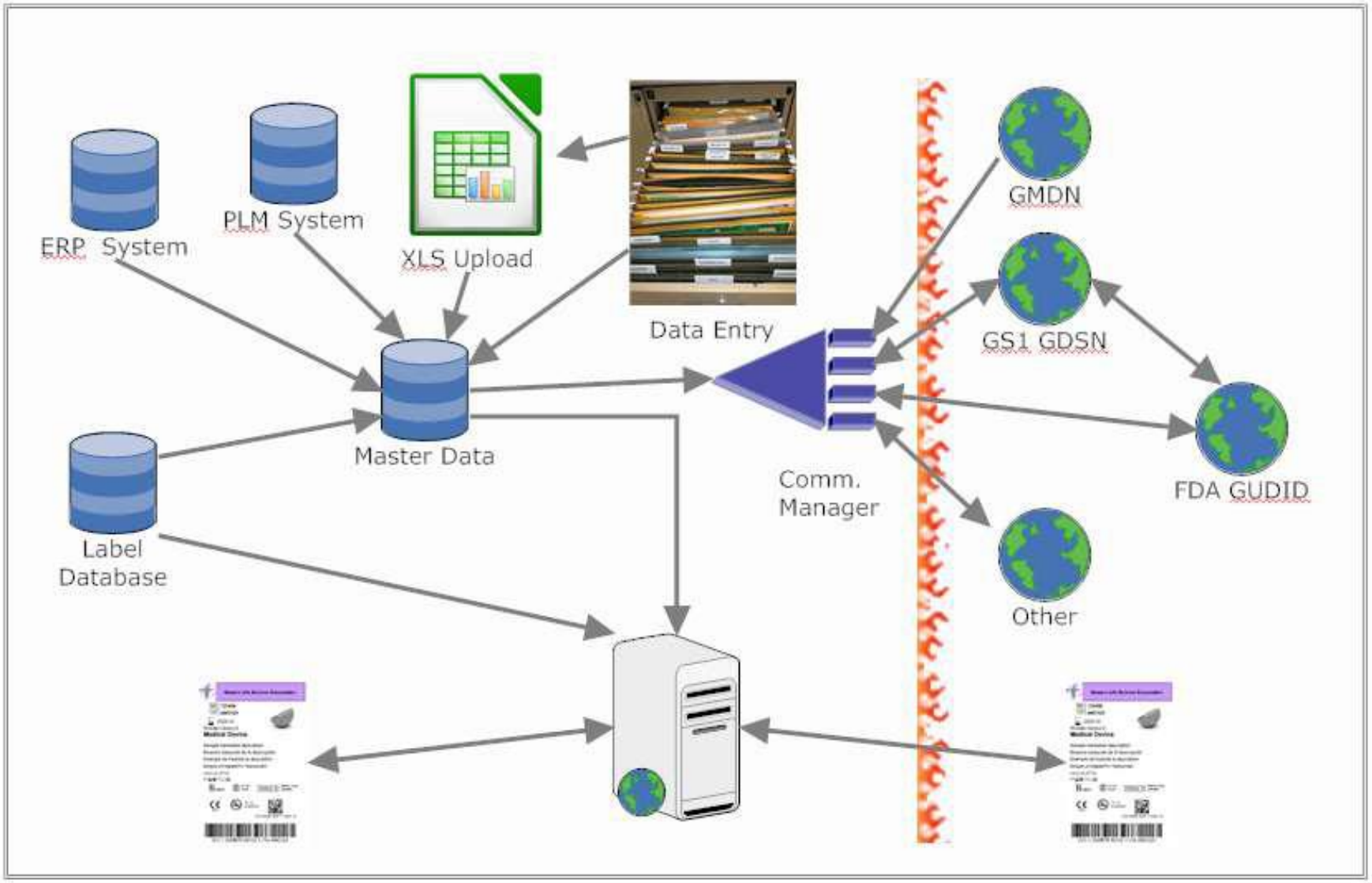
- FDA
  - September 25th 2015 Class I and II Lifesaving
  - September 25th 2016 Class II remainder
  - September 25th 2018 Class I remainder
- USA GPO's
  - Immediate All Classes*
- NHS
  - September 30th 2015 Medical Devices First**

  - * Each GPO has their own compliance dates
  - ** All suppliers phased in over period of 3-5 years**

Updating The FDA GUDID

- Manually via FDA Web Browser
    - Suitable for small number of packages
- Electronically (SPL/HL7 format)
    - Own Account
    - Third Party Provider

Getting Data to the FDA GUDID



What is a FDA Compliant Data Set?

FDA GUDID Data Elements v1.2.3 12th January 2015

Labeler Data		Device Information			Characteristics	
Labeler DUNS No		Primary DI Number			Single Use	Y / N
Labeler Name		Issuing Agency			Combination	Y / N
Labeler Address		Brand Name		Y / N	HTC/P	Y / N
Contact Telephone(s)		Device Description			Contains Rubber	Y / N
Contact E-mail(s)		Version / Model No			Made with Rubber	Y / N
		Catalog Number				
Production Identifier Data		Secondary DI Number			MRI Safety Status	Y / N
		Issuing Agency			Clinical Size Type (s)	
Lot / Batch Number	Y / N	Direct Marking Exempt	Y / N		Clinical Size Value (s)	
Serial Number	Y / N	Direct Marking DI Different	Y / N		Clinical Size Unit (s)	
Manufacturing Date	Y / N	Direct Marking DI No			Clinical Size Text	
Expiry Date	Y / N				Storage & Handling Type(s)	
Donation ID Number	Y / N				Low Value	
					High Value	
Product Classification		**Packaging Data**			Unit	
Publish Date		Device Count			Storage Conditions	
Distribution End Date		Unit of Use DI No			Sterile Packaging	Y / N
Distribution Status		Kit	Y / N		Sterile Required	Y / N
Premarket Exempt	Y / N	Packaging DI No			Sterile Method(s)	
Premarket Submission Number(s)		Packaging Quantity			Rx	Y / N
Supplement Number(s)		Package Contains DI No(s)			OTC	Y / N
FDA Listing Number(s)		Package Type				
FDA Product Code(s)		Package Discontinue Date			Auto Populated	
FDA Product Code Name		Package Status			Multiples	
GMDN Preferred Term Code(s)					Storage and Handling	
GMBN Name					New DI Record Required	
GMDN Definition					Data Must Match FDA	

What is a Compliant Data Set?

- Depends on which Rule…….
- There are some common data attributes …. But….. Each rule also has its own unique requirements and frequency of updates!!!
- FDA:- Upto 62 Data Attributes (Plus multiple fields)
- GPO:- Upto 90 Data Attributes (Plus multiple fields)
- NHS:- Upto 97 Data Attributes (Plus multiple fields) plus 27 price attributes
- Issue:- i) Keeping up to date on the changing requirements of the rules
  ii) Keeping IT systems up to date to accommodate changing data attributes.

Cost of Compliance- FDA

Cost Element	First Year Cost	Recurring
Administration and planning	$86,357,769	NA
Registration costs	$2,048,710	NA
Equipment and other investments	$47,527,879	$22,560,550
Incremental label cost	NA	$8,423,509
Label redesign cost	$47,724,259	NA
Software (with training)	$131,471,984	$14,660,866
Recordkeeping & Reporting (GUDID)	$26,540,230	$8,412,466
TOTAL	**$341,670,830**	**$54,057,391**

- Organizations @6000
- Source: **EASTERN RESEARCH GROUP, INC. Report to FDA July 11th 2013**

- **Note: Rest of the World** **$230,350,545** **$69,529,528**

- **Note:- All costs +/- 50%.....**

Cost of Compliance- FDA

- **Average Cost Y1 $56,945**
- **Cost over 3 years $2082**
- **Note:- All costs +/- 50%.....**

Keeping Compliance Costs Down

- **Key Questions:-**

- **Do you plan to do business outside the USA?**
- **How many BASE Packages do you have?**
- **What spare resource do you have?**
- **Internal IT Solution or Cloud Solution?**

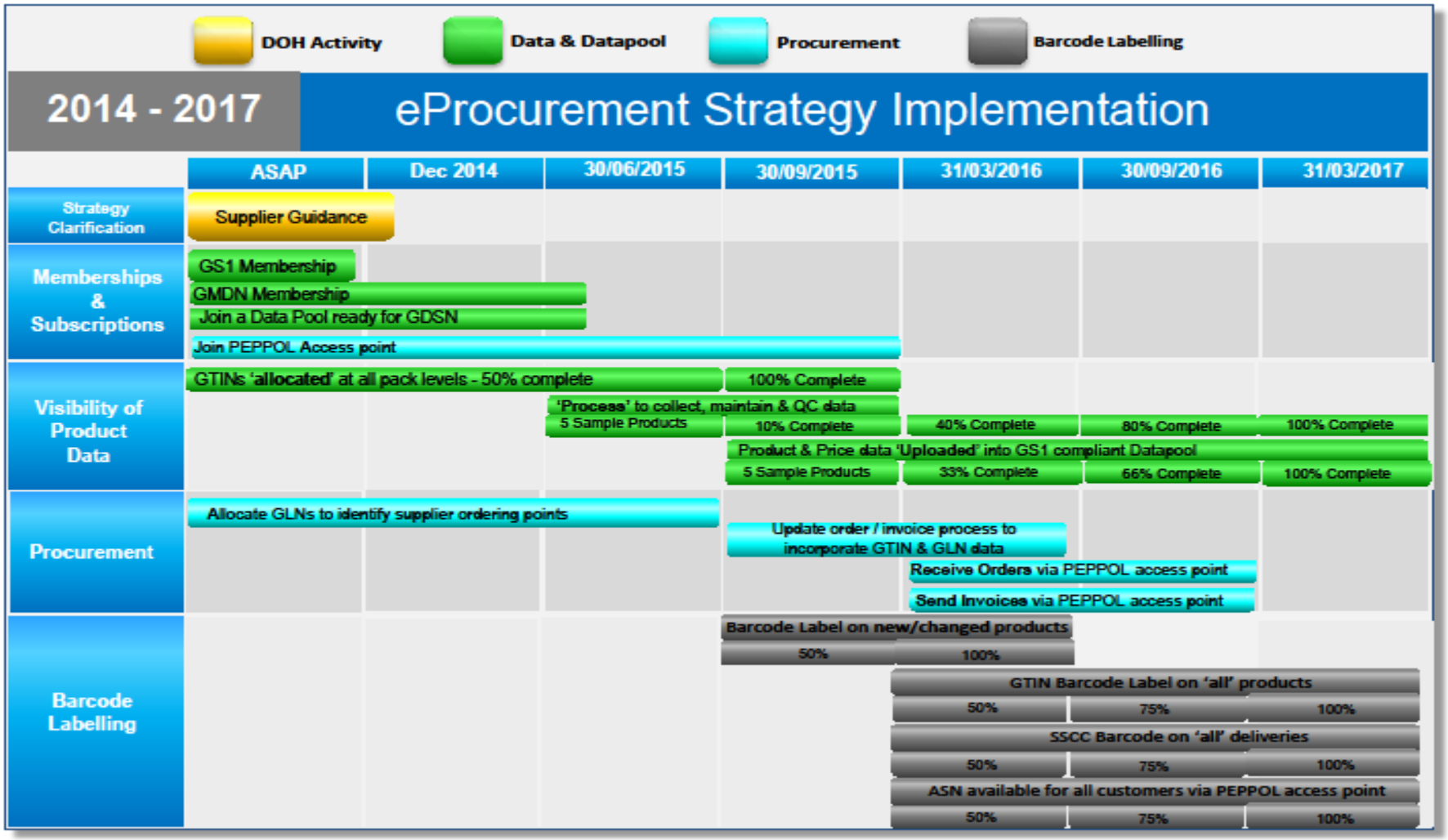
Compliance for NHS

- **National Health Service (NHS) eProcurement rule**

- The NHS eProcurement ruling requires that all medical devices sold to the NHS adhere to **GS1 standards** for labelling. The Medical Device Manufacturer must also provide a set of device attributes for inclusion in the NHS National Product Information Management (PIM) system. The device attributes **must** be sent to the NHS PIM via a certified **GS1 data pool** provider.

- In addition the NHS eProcurement ruling requires that all suppliers to the NHS will have to use the Pan European Public Online system (PEPPOL) to receive and send orders/invoices electronically.

NHS eProcurement Timeline



Compliance for NHS

- NHS Terms and Conditions of Contract altered August 2013
- ***"Suppliers MUST place product data in GS1 Datapool".***
- NHS Standard Contract altered 2014
- ***"Providers must comply with eProcurement Rule"***

Solution

- **Business Solution:**

- **Kodit, together with our global partners, have a detailed understanding of the steps required to both achieve, and maintain compliance, in the easiest and most cost effective method possible.**

Questions?

Upcoming UDI Webinars

UDI Labeling

Tue, May 19, 2015 2:00 PM - 3:00 PM Central Daylight Time

https://global.gotomeeting.com/join/995247997

Join the conference call.

(877) 416-0279, Code: 3826541998

UDI Verification

Tue, May 26, 2015 2:00 PM - 3:00 PM Central Daylight Time

https://global.gotomeeting.com/join/670061965

Join the conference call.

(877) 416-0279, Code: 3826541998

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