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UDI – The Next Step in Device & Healthcare Management

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UDI – What Is It?

Both a process & a tool for clearly, distinctly and unambiguously identifying medical devices, components, sets, kits and systems within the healthcare supply & use chains

Unique Device Identification – the Process

- general term for creating a series of numeric or alphanumeric characters through a globally accepted device identification and coding standard
  - i.e. GS1, HIBCC, ICCBBA
- allows the unambiguous identification of a specific device on the market
- “unique" does not imply serialization of individual production units

Unique Device Identifier – the Tool

- unique numeric or alpha-numeric code that includes:

Device Identifier (UDI-DI)

\+ **Production Identifier** (UDI-PI)

Unique Device Identifier (UDI)

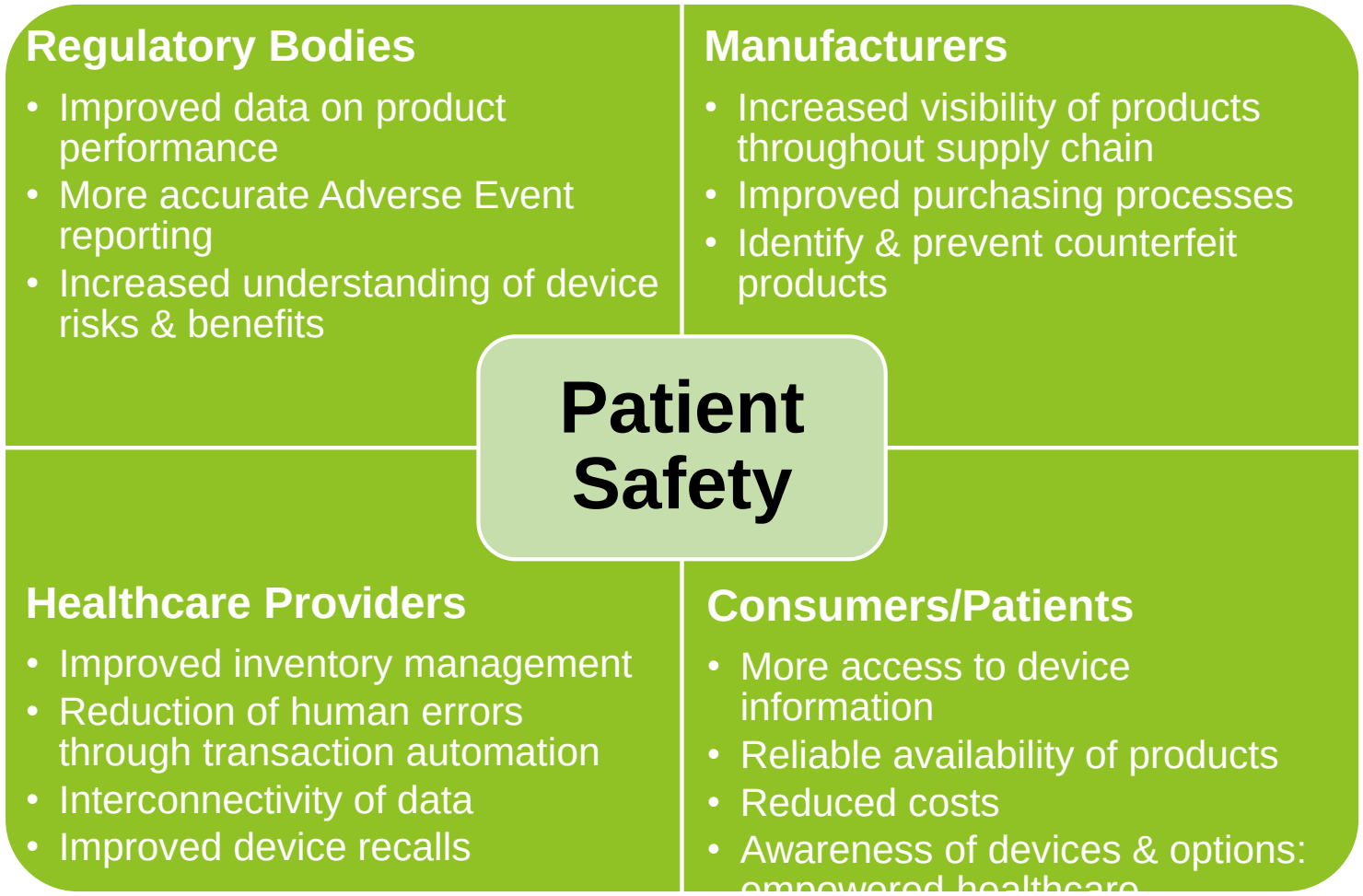
Static Information:
Identifies Company & Product

Variable Information:
Contains production & control information

UDI – Why Do We Need It?

- Provide more efficiency, accuracy and automation for capturing device information through automation
  - Supply chain
  - Electronic health records
  - Global device registries
- Better visibility of device supply & movement through the supply & distribution chain all the way to the patient
- Improved visibility & management of adverse events, recalls and post-market surveillance

UDI – Who Owns It?



UDI – Where Is It?

Country	Timeline	Coding Standard / Issuing Agency	Label Requirements
US	In process until 2018	GS1, HIBCC, ICCBBA	DI, PI, YYYY-MM-DD date format
EU	2017/2018	GS1, HIBCC, ICCBBA	DI, PI to Unit of Use
Australia	TBD	GS1, HIBCC, ICCBBA	Follow IMDRF
Brazil	TBD	GS1, HIBCC, ICCBBA	Follow IMDRF
Canada	TBD	GS1, HIBCC, ICCBBA	Follow IMDRF
China	TBD	International (GS1) &/or National	DI, PI to Unit of Use
Japan	TBD	GS1	DI, PI
Saudi Arabia	2018	GS1, HIBCC, ICCBBA	DI, PI to Unit of Use
Taiwan	TBD	GS1, HIBCC, ICCBBA	DI, PI to Unit of Use
Turkey	2017	GS1, HIBCC	DI, PI to Unit of Use
Oman	2017	GS1	DI, PI

US FDA UDI Compliance Date: Sept 24, 20xx

Compliance Year	Labels/Packages Must Have a UDI	Date Formatting (YYYY-MM-DD)	Data Submitted to the GUDID	Direct Marking (DM)
2014 ✓	Class III	Class III	Class III	
2015 ✓	Implantable, life-supporting & life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Implantable, life-supporting, life-sustaining devices	Life-supporting, life-sustaining devices
2016 ✓	Class II	Class II	Class II	Class III
2018	**Class I & Non-Classified**	**Class I & Non-Classified**	**Class I & Non-Classified**	**Class II**
2020				**Class I**

Examples:
Class III: pacemakers, heart valves, cerebral stimulators
Class II: Infusion pumps, needles, surgical drapes, powered wheelchairs
Class I: general instruments, examination gloves, bandages

EU MDR UDI Compliance Timeline (anticipated)

Regulation shall enter into force 20 days after publication in the Official Journal of EU

- Expected December 2016/January 2017

Followed by a 3-year transition

UDI Requirement in MDR	Application of Regulation	Direct Marking Compliance
Class III & Implantable	1 year	+2 years
Class IIa & Class IIb	3 years	+2 years
Class I	5 years	+2 years

UDI – How Do We Do It?

62 FDA GUDID Data Elements

Vs

33 European Commission Data Elements

vs

44 IMDRF Data Elements

3 Buckets of Data

- Device Information – 28 possible
- Device Status – 12 possible
- Device Characteristics – 30 possible

Core Elements = the minimum requirements

Device Information

DATA ELEMENT	FDA	EC	IMDRF
Primary DI Issuing Agency	FDA		
Primary DI Number	FDA		
Device Count	FDA	EC	IMDRF
Unit of Use DI Number	FDA		IMDRF
Labeler DUNS number	FDA		
Company Name	FDA	EC	IMDRF
Company Physical Address	FDA	EC	IMDRF
Brand Name	FDA	EC	IMDRF
Version or Model	FDA	EC	IMDRF
Catalog Number	FDA	EC	IMDRF
Device Description	FDA	EC	IMDRF
DI Record Publish Date	FDA		
Commercial Distribution End Date	FDA		IMDRF
Commercial Distribution Status	FDA		
Device Subject to DM, but Exempt?	FDA		
DM DI Different from Primary DI	FDA		
DM DI Number	FDA		
Secondary DI Issuing Agency	FDA		
Secondary DI Number	FDA	EC	IMDRF
Package DI Number	FDA		IMDRF
Quantity per Package	FDA	EC	IMDRF
Contains DI Package	FDA		IMDRF
Package Type	FDA		
Package Discontinue Date	FDA		
Package Status	FDA		
Customer Contact Phone	FDA		IMDRF
Customer Contact Email	FDA		IMDRF
Additional Trade Names		EC	

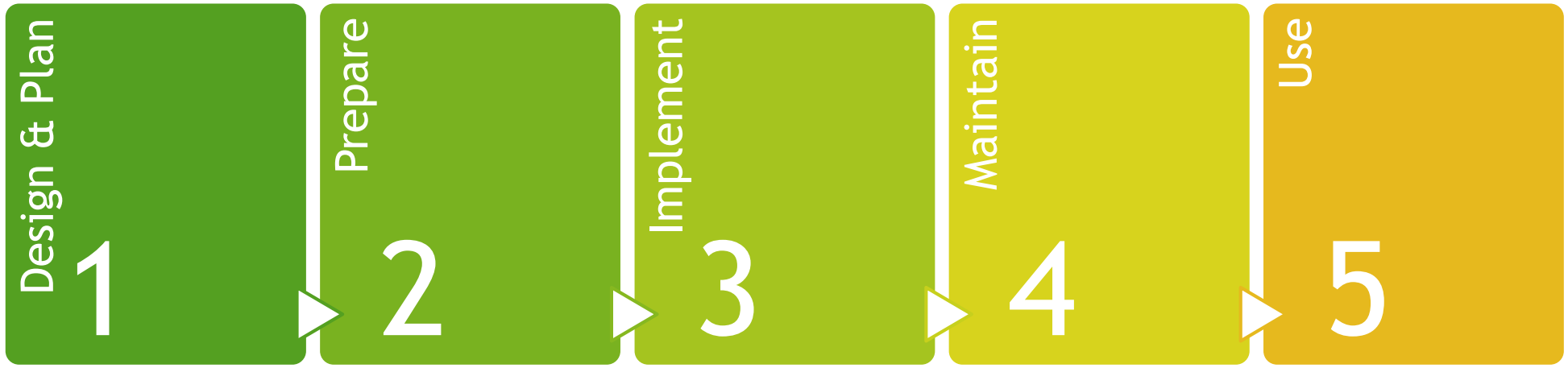
Device Status

DATA ELEMENT	FDA	EC	IMDRF
HCT/P?	FDA		
Kit?	**FDA**		
Combination Product?	FDA		
Device Exempt from Premarket Submission	FDA		
FDA Premarket Submission Number	FDA		
FDA Supplement Number	FDA		
FDA Product Code	FDA		
FDA Product Code Name	FDA		
FDA Listing Number	FDA		IMDRF
GMDN Code	**FDA**	EC	IMDRF
GMDN Name	FDA		
GMDN Definition	FDA		

Device Characteristics

DATA ELEMENT	FDA	EC	IMDRF
For Single Use?	FDA	EC	IMDRF
Lot or Batch Number Control?	FDA	EC	IMDRF
Manufacturing Date Control?	FDA	EC	IMDRF
Serial Number Control?	FDA	EC	IMDRF
Expiration Date Control?	FDA	EC	IMDRF
Donation ID Number Control?	FDA		
Labeled as Containing Natural Rubber?	FDA	EC	IMDRF
Labeled as Not Made with Natural Rubber?	FDA		
Prescription Use (Rx)?	FDA		
Over the Counter (OTC)?	FDA		
What MRI safety information does the labeling contain?	FDA		IMDRF
Size Type	FDA	EC	IMDRF
Size Value	FDA	EC	IMDRF
Size Unit of Measure	FDA	EC	IMDRF
Size Type Text	FDA		IMDRF
Storage & Handling Type	FDA	EC	IMDRF
S & H Low Value	FDA	EC	IMDRF
S & H High Value	FDA	EC	IMDRF
S & H Unit of Measure	FDA	EC	IMDRF
Special Storage Conditions	FDA		IMDRF
Device Packaged as Sterile?	FDA	EC	IMDRF
Requires Sterilization Prior to Use?	FDA	EC	IMDRF
Sterilization Method	FDA		IMDRF
Authorized Representative's Name		EC	IMDRF
Authorized Rep. Contact Information		EC	IMDRF
SaMD Version			IMDRF
Restricted Number of Reuses		EC	IMDRF
URL for Additional Information		EC	IMDRF
Labeled as Containing DEHP?		EC	IMDRF
Critical Warnings or Contraindications		EC	IMDRF

Five Stages for a Sustainable UDI Program



1. Design & Plan – ALL STAKEHOLDERS

Design & Plan

Top Level

- Regulators / Manufacturers / Users

Flexible

- Allow for growth, change & sustainability

Time Consuming

- Avoid excessive & lengthy delays

Buy-In = Support

- Won’t make everyone happy
- Listen to all voices

Lessons Learned

- 2005 – 2013 (Concept to Realization)
- Prolonged process led to doubts and skepticism by manufacturers (“the boy who cried wolf”)
- How to reach out & involve as many manufacturers & users as possible
- Communicate consistent information
- General enough to apply to all products but still provide clear requirements
  - Not a consensus program like standards organizations

2. Prepare – Government Agencies, Regulators

Prepare

Communication to industry

- Don’t assume everyone was listening

Enforcement plans

- Accountability
- Consequences of noncompliance
- Auditing
- Customs / Border Control

Highlight benefits

- Include users

Lessons Learned

- Final Rule – 24 Sept 2013
- Class III – 1 year to implement!
- Phased in approach
  - GOOD – prevented overloading FDA system
  - BAD – confusing
- Many smaller companies still not aware of UDI requirements
- Communication of enforcement plans was/is lacking

3. Implement – Manufacturers, Distributors

Implement

Process versus Project

- Look beyond the requirements

Allow as much time as possible

- Encourage early adoption

Data gathering & cleansing

- Single Source of Truth

Lessons Learned

- Don’t underestimate the time & expense required
- Data – major challenge
  - Make requirements very clear
  - You don’t know your data until you start pulling it together
- Load testing of system
  - Can it support massive volumes of data?
- Prevent bottlenecks
  - Delays in creating accounts
  - Slow response time from Help Desk

4. Maintain – Government Agencies, Regulators, Manufacturers & Distributors

Maintain

Routine review of data

- Coordination between departments

Changes to requirements

- Communication – internal & external

Dedicated resource

- Controls the data
- Restricts the change

Lessons Learned

- Still learning!
- Don’t underestimate the impact of UDI – every department is involved
- Communication is key
- UDI is not implemented and then done

5. Use – ALL STAKEHOLDERS

Use

Unlimited possibilities

- Internal & external uses

Incentives / Benefits for use

- Compliance – legal
- Financial – reimbursement, discounts, cost savings
- Streamline processes

Requires change

- Workflows, systems, other processes
- Technology

Lessons Learned

- Still learning!
- UDI is not just about patient safety
  - Supply chain efficiencies & security
  - Customs
- Technology is prohibitive and/or not available
  - EHR vendors expect to offer software with UDI capture capabilities by 2018
- Centers for Medicare and Medicaid Services (CMS)
  - Wants UDI on universal health insurance claims forms
  - Provide for better value-based reimbursement based on device performance
- Improve device evaluation and post-market surveillance

Have Questions? Need Help?

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