Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli (1523)

USDM Simplify, Unify, Optimize
Life Science Compliance for Regulated Systems

Global GS1 Healthcare Conference

The US FDA UDI Final Rule

1 April 2014

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USDM Life Sciences

Class III and PHS Act Devices
Implementation by:
September 24, 2014

which is
5 months and 23 days from today

or
25 weeks
176 days
4224 hours

USDM Life Sciences

CORPORATE PROFILE

FOUNDED IN 1999

HEADQUARTERED IN SANTA BARBARA, CA

- Focused exclusively Life Sciences Industry Professional Services Firm
- Privately Held
- Over 150 team members
- Over 25% growth for 10 consecutive years
- Industry leading UDI Practice
- Compliance partner for many Life Sciences Companies, Industry Organizations and best of breed solution Vendors
- Solve Compliance Issues & assist clients under regulatory distress
- Services and solutions for the emerging, mid-tier, and large multi-national Life Science companies
- Strategic and tactical delivery models
- Focused Practice Groups spanning the entire Drug Development Lifecycle from R&D through to Distribution
- Over 1000 projects in over 200 life sciences organizations

UDI Timeline

- 1999 December – US IOM Report – To Err is Human
- 2004 February – FDA Pharmaceutical Barcode Rule
- 2007 September – FDA Amendments Act of 2007
- 2008 October – GHTF forms UDI ad-hoc Working Group
- 2011 September – GHTF UDI Guidance published
- 2012 February – IMDRF continues UDI WG
- 2012 July 10th – FDA publishes UDI Proposed Regulation
- 2012 July – FDASIA provisions added
- 2013 April – EU publishes UDI recommendations
- 2013 September 24 – US publishes UDI Final Rule and *draft* GUDID Guidance
- 2013 December – IMDRF publishes UDI guidance 2.0

US Legislation (FDAAA 07; FDASIA 12)

Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. *The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.*

Public Health Benefits

The UDI system provides global visibility and supports:

- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

US FDA UDI Rule Intent/Objective

- Provide standardized granular identification of medical devices and associated meta-data to support various public-health initiatives
- Most notably FDA's postmarket surveillance activities – including:
  - adverse event reporting/aggregation
  - recalls
  - device and disease specific registries
  - EHRs
  - large population-based data sets, e.g., claims data
- Understand stakeholders/users needs anduse

Global Harmonization

A globally harmonized approach to UDI can:

- Allow device manufacturers to apply and use a single UDI across a wide array of regulators
- Provide a foundation for a global, secure supply chain
- Facilitate global visibility/track and trace
- Allow for automated import review
- Facilitate global efforts to address counterfeiting and diversion
- Support DoD, WHO and other efforts requiring global device identification

GHTF/IMDRF UDI AHWG

- Formed October 2008
- Members US, Europe, Japan, Canada – and AHWP
- GHTF Guidance published September 2011 - framework for regulator developing a UDI System
- Morphed into IMDRF
- Update to Guidance published December 2013
- Available at: www.imdrf.org/consultations
- It is critical that these systems are implemented without regional or national differences.
- Intended to provide a single, globally harmonized system for positive identification of medical devices.

US FDA UDI Overview

1. Standardized Date Format
2. Establishing a UDI System
3. What Device Manufactures/Labelers Need To Do

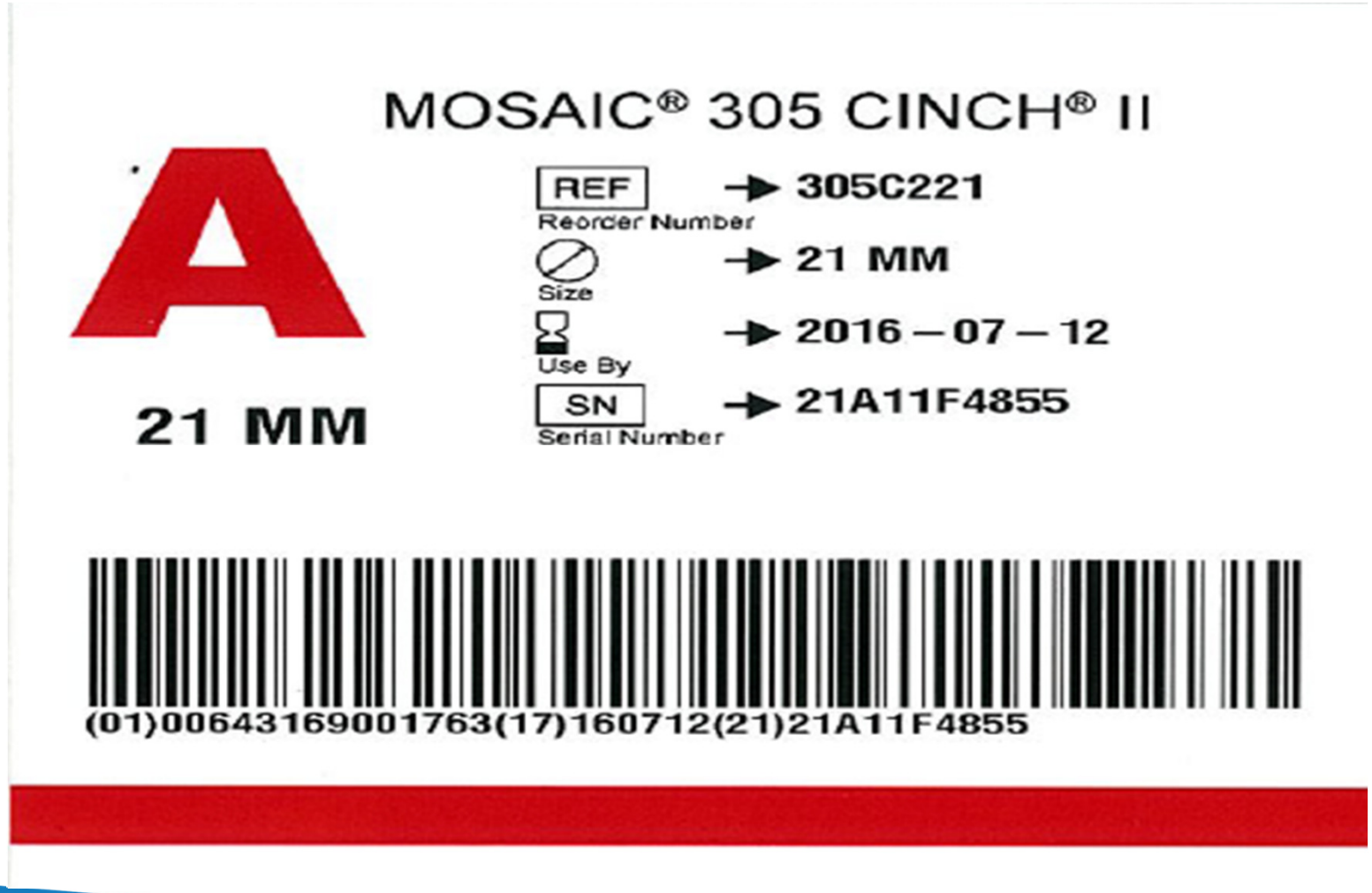
Standardized Date Format

If label includes a date to be read by user (e.g., expiration, manufacturing):

- All numeric: YYYY-MM-DD (2013-06-19)
- **Day must always be included**
- Same Compliance Date as other UDI requirements
- Applies to all labels (even if exempt from UDI)
- If not subject to UDI – applies at year 5
- A combination product with NDC number is exempt.

- **Does NOT apply to date format in UDI.**

UDI Application Example



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Establishing a US UDI System

Combination of 3 distinct steps:

1. Develop Unique Device Identifiers (UDIs) for all devices
2. Place UDI on the label in both plain text (HRI) and AIDC
3. Submit data to US FDA's Global UDI Database (GUDID)

What is a UDI?

Identifier/code on device label and packaging (and, in some cases, on the device itself)

Two parts : UDI = DI+PI

- Device Identifier (DI) (static) – specific to a device version or model
- Production Identifier(s) (PI) (dynamic) – one or more currently used control/production identifiers that is lot/batch number, serial number, manufacturing date, expiration date
  - If on the label – then needs to be part of the PIs
  - Not requiring any changes to currently used PIs

UDI General Rule

- The label* of EVERY medical device (including all IVDs) must have a UDI.
- EVERY device package (contains a fixed quantity of a version or model) must have a UDI.

Any other approach is an exception to or alternative from these requirements.

* Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...

Who is the “Labeler”…?

ENDOPATH®
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REF	FMF02	LOT	1Q34
	080100	QTY	4

(01) 2 081019001 002 4

(17)080100(10)1Q34

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CE 0344

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Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22

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a Johnson & Johnson company

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Ethicon Endo-Surgery Inc
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Do not use if package is open or damaged

Single patient use only

Does not contain latex or PVC

STERILE R

℞ Only

0-45

D150PPLB02 Rev.D

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dextrus™
Finger-Mounted
Locking Forceps

REF FMF02

Create and assign DIs

- Work with one (or more) FDA accredited issuing agencies – GS1, HIBCC, and ICCBBA/ISBT-128
- Assign Device Identifiers to all devices – including:
  - Kits
  - Complex systems
  - Combination products
  - Configurable devices

Assign a New DI

A new DI is required whenever:

- A change to a device results in a new version or model
- Create a new device package (including changes to #)
- No relationship to premarket requirements

Place UDI (DI+PI) on Device Label

- Different DI applied to the label (default location) AND (higher levels) device packages
- In plain text (HRI) AND encoded in AIDC technology
- No specific technology (technology neutral)
- If AIDC technology is not evident – requires that the label "disclose" the presence of AIDC technology.

Direct Marking

- In addition to label requirements – Direct Marking (DM) – not necessarily Direct Part Marking (DPM) for:
  - device intended to be used more than once, and
  - ***reprocessed*** (clean, clean + disinfected, or clean + sterilized) before use

- Direct Part Marking (DPM) – for certain devices where necessary

UDI applied to trays, sets, etc…

- Many different types of “kits”
- “Kit” exception is only about ***not*** marking the individual devices within the kit.
- Still need to be able to provide visibility/traceability
- May need to change business processes and/or way kits are created and distributed.

UDI for Stand-Alone Software

Need to determine if SaS is regulated as device.

Means of displaying its UDI:

- through, for example, help, about, start-up screen
- If also packaged, needs labeled UDI too
- Version = lot
- Major vs minor revision (see IMDRF guidance)
- Major (new DI) – includes complex or significant changes affecting safety, intended use, performance or effectiveness.
- Minor (new PI) – generally bug fixes, usability enhancements (not safety), or security patches.

UDI applied to a “1-in-1”

- Multiple packages at the unit of use (a 1-in-a-1) – not a higher level of packaging issue.
- UDI needs to be on the “label” to facilitate the identification of the device through “distribution and use.”
- Typically – outer pack is sufficient (assuming device is stored and “used” that way).
- But – need to look/document specific use cases.

General Exceptions

- Class I Devices do NOT need to include PIs
- GMP-exempt Class I devices
- If UDI on kit/CP, components or CP constituent parts

and others…

SUD *Packaging* Exception

UDI can go on SUD next higher level of packaging when:

The individual single-use devices (SUDs) are:

- distributed together in a single device package,
- intended to be stored in that package until used, and
- which are not intended for individual distribution.
  - Can *not* be used for implants (do you know if your device is an implant?)

-- And Unit of Use (UofU/"virtual") DI required in GUDID

“Shipping Container” Exception

- Exception – UDI does not need to be on shipping container.
- Shipping container – means “a container used during shipment or transportation… and ***whose contents may vary*** from one shipment to another.”
- Shipping container ≠ “shipper”
- Higher levels of packaging requirement intended to end when no longer homogenous (e.g., pallet, tote).

Direct Marking Exceptions

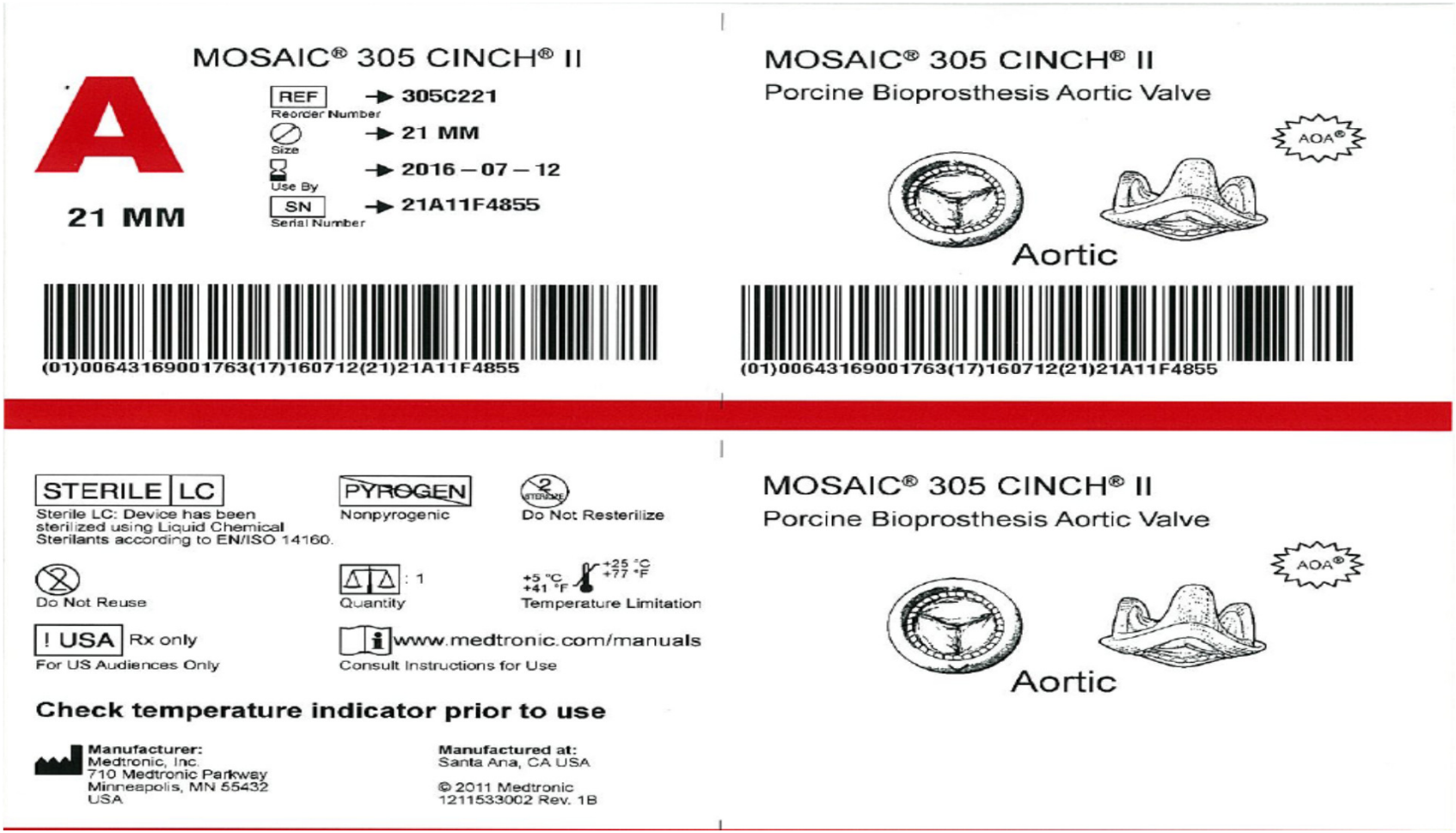
1. Direct marking would interfere with the safety or effectiveness of the device;
2. Direct marking is not technologically feasible;
3. The device is a reprocessed single-use device
4. The device has been previously marked

Exception to be noted in design history file – do not need to submit exception request.

Exception/Alternative Process

1. Identify the device(s) subject to exception/alternative
2. Identify the provisions subject to the request
3. If exception – explain why the requirements are ***not technologically feasible***.
4. If an alternative, describe the alternative and
   a. why it would ***provide for more accurate, precise, or rapid device identification*** – or
   b. how it ***would better ensure the safety or effectiveness of the device***
5. Estimate the number of affected labelers and devices

UDI Application Example



UDI Application Example

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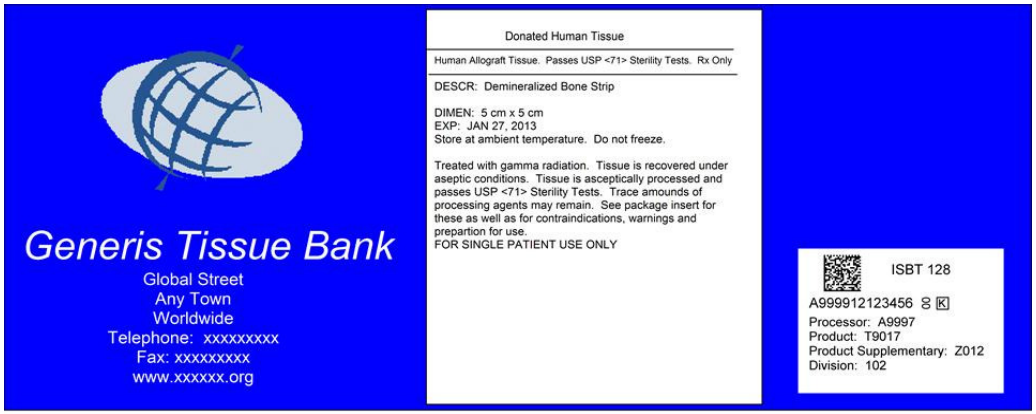
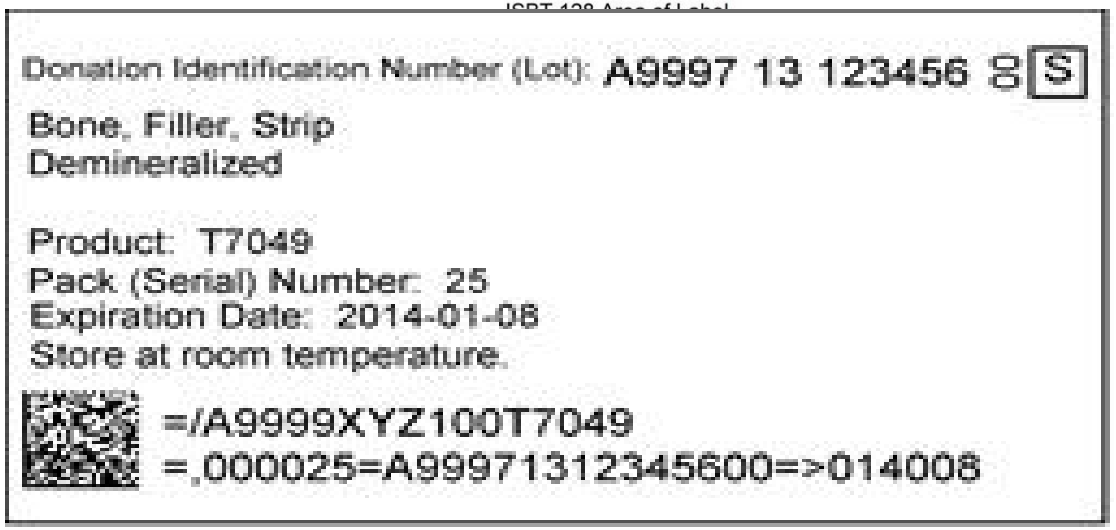




ISBT128

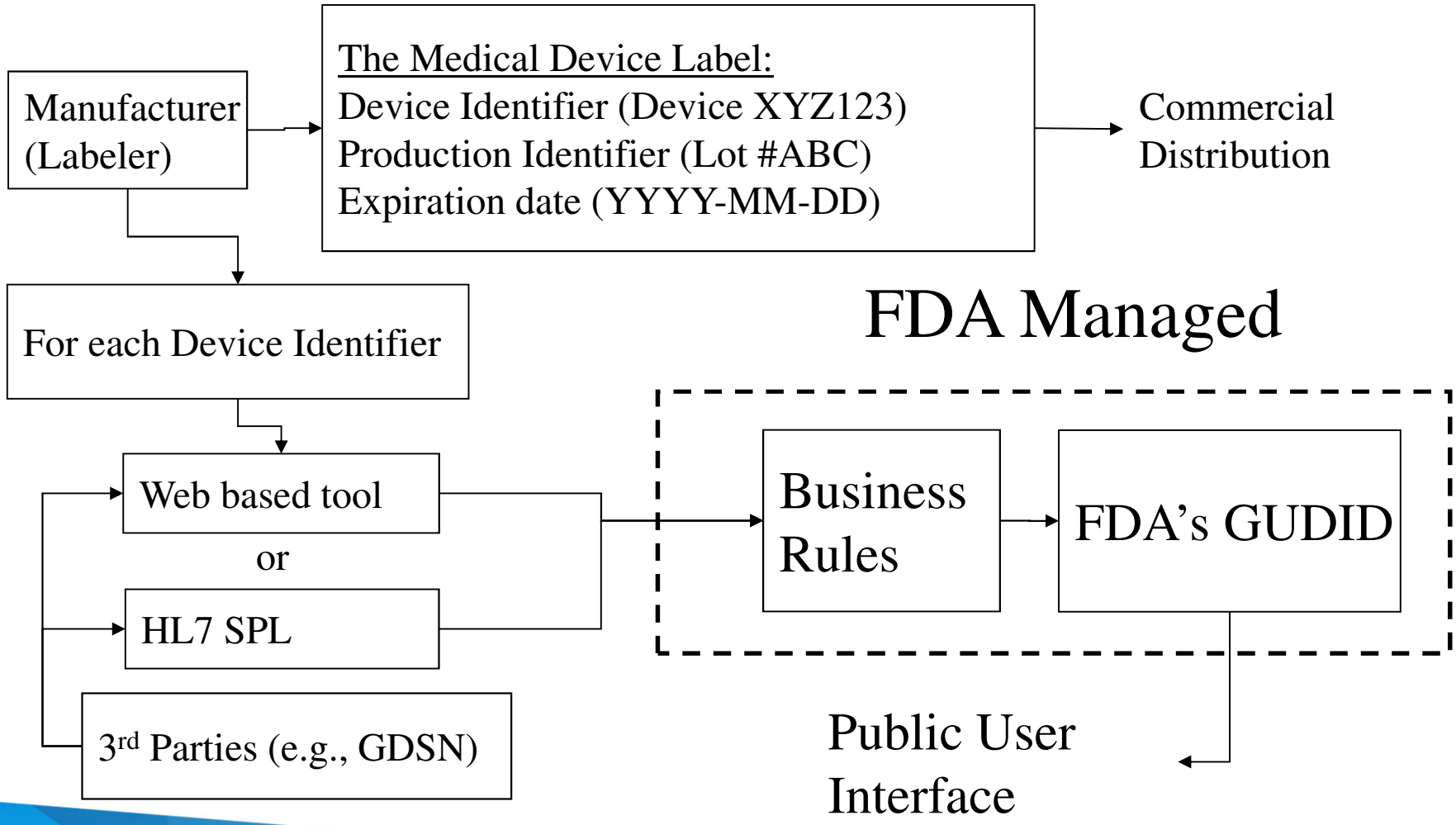
Device Identifier (Product Processor Identifier Code): A9997T9017Z012

- A9997 is the processor identifier assigned by ICCBBA ≡ manufacturer identifier
- T9017Z012 is the product identifier ≡ catalogue number

Production Identifier: A999912123456102

- A999912123456 is the donation identification number ≡ Lot no.
- 102 is the division number ≡ serial number

3rd – Submit data to FDA's GUDID



3rd – Global UDI Database (1/2)

For each and every Device Identifier (DI) (*no PIs*):

- The labeled proprietary/trade/brand name
- The labeled version or model number
- Previous DI if a new version or model
- If direct marked, DI if different than label
- The size of the version or model
- The type of production identifiers on the label
- FDA premarket submission and listing number(s)
- Global Medical Device Nomenclature (GMDN) term
- FDA product code (procode)
- The number of individual devices in each package.

3rd – Global UDI Database (2/2)

- Commercial distribution status
- Higher levels of packaging (not separate record)
- Whether it is a kit; combination product; HCT/P

Whether the device is labeled:

- As sterile or sterilize before use (and how)
- As containing natural rubber latex,
- With MRI compatibility (safe, conditional, unsafe)
- As Rx and/or OTC

- Base package is the lowest level of packaging required to have a (full, required) UDI

GUDID Data Elements

IDENTIFICATION

- Pri DI Issuing Agency
- Primary DI #
- Brand Name
- Version / Model #
- Catalog #
- Device Description
- Sec DI Issuing Agency
- Secondary DI #
- DM Exempt (Y/N)
- DM DI Different (Y/N)
- DM DI #

LABELER

- Labeler DUNS #
- Labeler Name*
- Labeler Address*
- Contact Phone
- Contact E-mail

REGULATORY

- Publish Date
- Distribution End Date
- Distribution Status*
- Premrkt Exempt (Y/N)
- Premrkt Submission #
- Supplement #
- FDA Listing #
- Product Code
- Product Code Name*
- GMDN Code
- GMDN Name*
- GMDN Definition*
- Rx (Y/N)
- OTC (Y/N)

PACKAGING

- Device Count
- Unit of Use DI #
- Kit (Y/N)
- Pkg DI #
- Pkg Quantity
- Pkg Contains DI #
- Pkg Type
- Pkg Discontinue Date
- Pkg Status*

PRODUCTION

- Lot / Batch Control (Y/N)
- Serial # Control (Y/N)
- Mfg Date Control (Y/N)
- Expiration Control Date (Y/N)

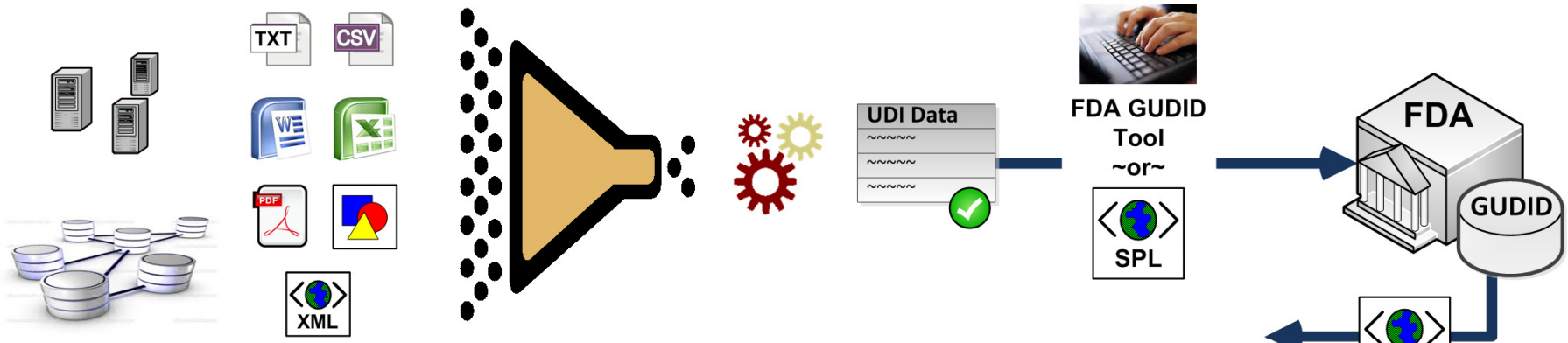
CHARACTERISTICS

- Single Use (Y/N)
- Combo Product (Y/N)
- HTC/P (Y/N)
- Contains Rubber (Y/N)
- Made with Rubber (Y/N)
- MRI Safety (Y/N)
- MRI Safety Status
- Size Type
- Size Value
- Size Unit
- Size Text
- Storage & Handling Type
- S&H Low Value
- S&H High Value
- S&H Unit
- Storage Conditions
- Sterile Pkg (Y/N)
- Sterile Req'd
- Sterile Method

55	Submitted by Labeler (some can have multiple values)
7	Populated by FDA GUDID System

* = Populated by FDA GUDID System

GUDID Data Collection and Submission Steps



Multiple Storage Locations & Formats

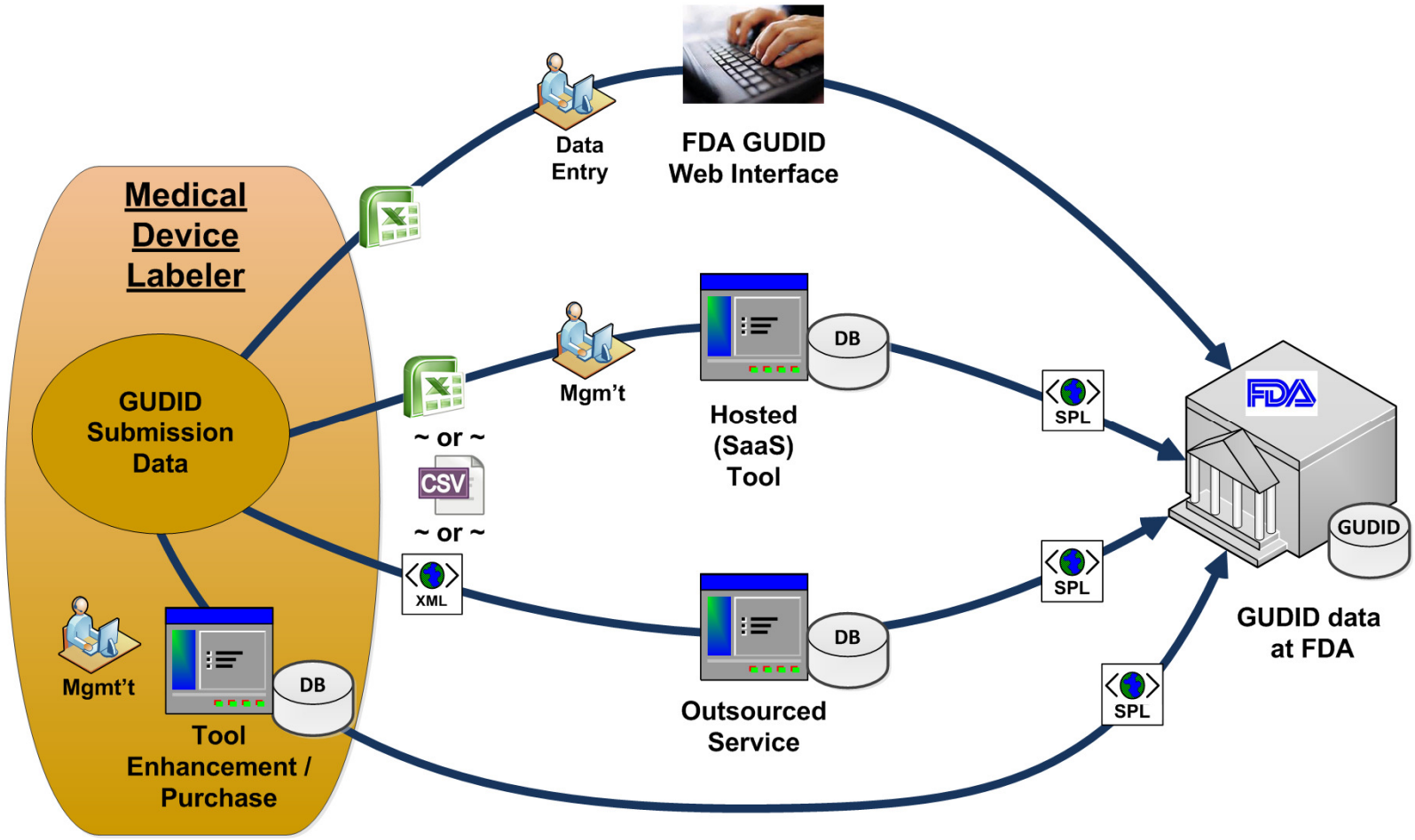
Data Collection

Data Normalization & Validation

FDA Tool Entry *or* SPL-UDI Build

Data Submission to FDA & ACK Response

GUDID Data Submission Models



* SaaS – Software as a Service

Initial GUDID Implementation

- Database access initially limited to Class III and PHS Act Device Labelers
- Encourage Class III to submit as early as possible
- Online Helpdesk and Data Stewards available to receive feedback
- Input by initial submitters will be invaluable for future enhancements

- www.fda.gov/udi will serve as the main portal for all GUDID information. Visit the website for GUDID information, checklists, and other helpful resources.

GUDID Data Submission Plans

1. Evaluate your "data situation" (location, gaps, owners, formats, etc.)
2. Determine your best GUDID data submission method/tool
3. Collect, Normalize, and Validate source GUDID data
   - If necessary, capture data from Label (e.g., single use icon)
   - If desired, collect additional data fields for future UDI submissions to international Regulatory Authorities and/or your internal purposes
   - Merge partial records from multiple "data sources"
   - "Normalize" data to FDA GUDID specs (e.g., Business Rules, Controlled Vocabularies)
4. For Manual Entry: enter data via FDA GUDID Tool
5. For Automated Entry:
   - Create fully-valid SPL UDI submissions per FDA business rules
   - Submit SPL UDIs to FDA via ESG (WebTrader, AS2)
6. Submit changes/revisions and new device records

GUDID Implementation Issues

- Data is most likely in disparate systems
- Some data NOT in electronic format
- Need to create, approve, and manage the changes
- Conduct data normalization and validation
- Develop business rules
- Understand the controlled vocabularies
- Identify restricted vs controlled data
- Address Part 11 compliance issues

Search and Retrieval

GUDID Search and Retrieval is temporarily disabled and will be enabled at a future date when the database is populated.

Compliance Dates

Implementation (compliance) timeframes – September 24:

- 2014: class III and devices licensed under PHS Act
- 2015: class II/I implants and life-supporting/sustaining
- 2016: rest of class II
- 2018: class I

For Direct Marking:

- Compliance dates are extended by 2 years
- except for FDASIA (year 2) devices – still at year 2.

Exception to Compliance Dates

- FDA may grant a **1-year extension** of the compliance date for class III devices or a device licensed under the PHS Act – when it is in the best interest of the public health.

- Provides an exception for a **finished device** that is manufactured ***and labeled*** **prior to the compliance** date – exception expires 3 years after the compliance date [existing inventory].

Conforming Amendments

Adds to each the requirement to use UDI:

- Part 803 – Medical Device Reporting
- Part 806 – Reports of Corrections And Removals
- Part 810 – Medical Device Recall Authority
- Part 814 – Premarket Approvals
- Part 820 – Quality System Regulation
- Part 821 – Medical Device Tracking Requirements
- Part 822 – Postmarket Surveillance

How to Contact FDA

- UDI Website is key resource – www.fda.gov/UDI
- Contact us: click on UDI Help Desk link for Regulatory and GUDID Questions
- Receive Notifications from us: click on Unique Device Identification: Get e-mail updates 
- Look for Schedule of planned and Notification of unplanned downtimes
- FDA ESG questions (HL7 SPL submission)
  - Policy questions – esgprep@fda.hhs.gov
  - Technical questions – esgreg@gnsi.com

Other Issues to Consider

- Global landscape
- Private label – both for you and for others
- DUNS numbers (same product – multiple facilities)
- Packaging hierarchy
- MDM: locate, control, cleanse, transform, validate, load
- Accessories vs spare/service parts
- Classification vs premarket path
- Class II OTC
- Production controls
- Gain efficiency and reduce risks
- Postmarket surveillance

What do device manufacturers (labelers) need to do to prepare for UDI…

Device Manufactures Need To…
Develop UDI Corporate Policy and Strategy

1. Understand the UDI final rule and GUDID guidance
2. Develop corporate UDI policy and strategy
3. Establish enterprise-wide UDI program/plan
4. Apply to device portfolio and compliance timeline
5. Develop master data management plan
6. Establish/develop GUDID interface plan

Device Manufacturers Need To…
Build and Execute UDI Programs and Systems

1. Update/redesign labels and packaging (UDI and date)
2. Purchase/enhance/validate labeling & packaging equipment
3. Design, develop, implement and validate IT systems
4. Load GUDID and confirm capability of equipment, systems, and processes
5. Develop production SOPs and execute process validation
6. Incorporate UDI requirements into new devices and new versions of existing devices

Ask where you are relative to…

A. Analysis, Strategy and Planning

1. Determine FDA UDI requirements impact by device and organize products by:
   Class, Market, Production Location, CPO, Label and Packaging Components
2. Analyze gaps between FDA requirements and current labeling/packaging for each product.
3. Determine your FDA-accredited organization for assignment of UDIs and auto ID barcode
4. Analyze gaps between current PLM, connectivity to GUDID, labeling/packaging/inspection and supply chain systems and requirements for UDI.
5. Establish the Strategy and Plan (Activities, Schedule, Budgets, Responsibilities, Partners) to:
   a) Remediate gaps in Labels and Packaging
   b) Develop the interface to GUDID
   c) Remediate PLM and Supply Chain Systems, labeling/packaging equipment and Processes
   d) Establish validation and compliance strategy and plan

B. Build and Execute

6. Update Product Label/Packaging design and materials – sequence by compliance date
7. Design, Develop, Implement and Validate IT system changes and interfaces
8. Purchase or enhance printing, labeling, packaging equipment and validate
9. Execute dry runs to update GUDID and confirm capability of equipment, systems, and processes
10. Develop production SOPs and execute process validation

C. Commercialization

11. Manage the cutover to production for the first run of each product
12. Incorporate UDI requirements into new products and new versions of existing products
13. Registration of new products and new versions of existing products with the GUDID

USDM Simplify, Unify, Optimize
Life Science Compliance for Regulated Systems

Thank you!

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