Unique Device Identification

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Outline

- Medical Device Regulation in the US
- UDI & GUDID
- Label Issues
- GUDID
- QMS Issues
- Summary and Conclusions
- Questions

Medical Device Regulation in the US

Medical Device Regulation

- In the US, the Food and Drug Administration (FDA) regulates Medical Devices
  - FDA regulates about 25% of the US commerce including food, drugs, biologics, lasers, microwave ovens, and tanning booths

- In other countries there is a different approach
  - Medical device manufacturers who market in different countries must follow the regulations of the country where the device is sold, not where it is manufactured.

Premarket Submission

- FDA classifies medical devices into 3 risk classes. For simplicity, call them:
  - Class I – Low Risk Devices
  - Class II – Medium Risk Devices
  - Class III – High Risk Devices

- To legally market a device, a company makes a submission to FDA. If the submission is successful, then FDA "grants permission" to market the device.
  - Class III devices generally require a Premarket Approval (PMA)
  - Class II devices generally require a Premarket Notification, called a 510(k)
  - Class I devices generally don't require "permission"

Register, List, and Inspections

- Medical device manufacturers must register the company to declare involvement with medical devices
  - The registration is annual
- Medical device manufacturers must list each of their medical devices
- Medical device manufacturers are subject to inspection by FDA Investigators
  - The law says that for most manufacturers there is a minimum of one inspection in every two-year period

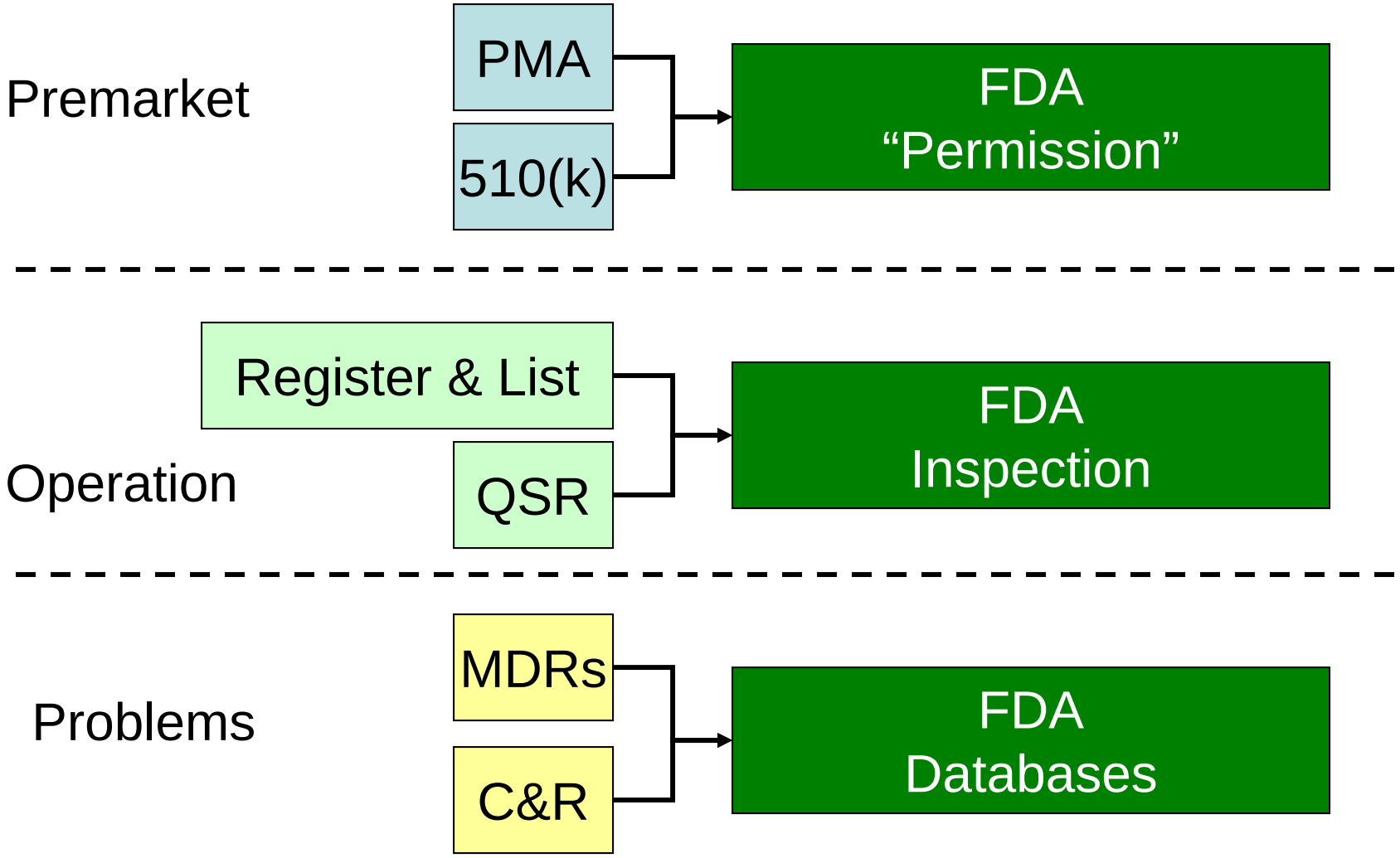
QMS and Reporting

- Medical device manufacturers must maintain a QMS, described in Part 820 of the regulations, called the Quality System Regulation (QSR).
  - QSR is based on ISO 9001:1994 and has not had any substantial changes

- When a person is injured and a medical device is involved, the manufacturer reports this to FDA.
  - It is called a Medical Device Report (MDR)

- When a manufacturer modifies a medical device that has been shipped, the manufacturer reports this to FDA.
  - It is called a Correction or Removal (C&R)
  - FDA will classify them as recalls

Overview


Premarket
PMA
510(k)
FDA
"Permission"
Operation
Register & List
QSR
FDA
Inspection
Problems
MDRs
C&R
FDA
Databases

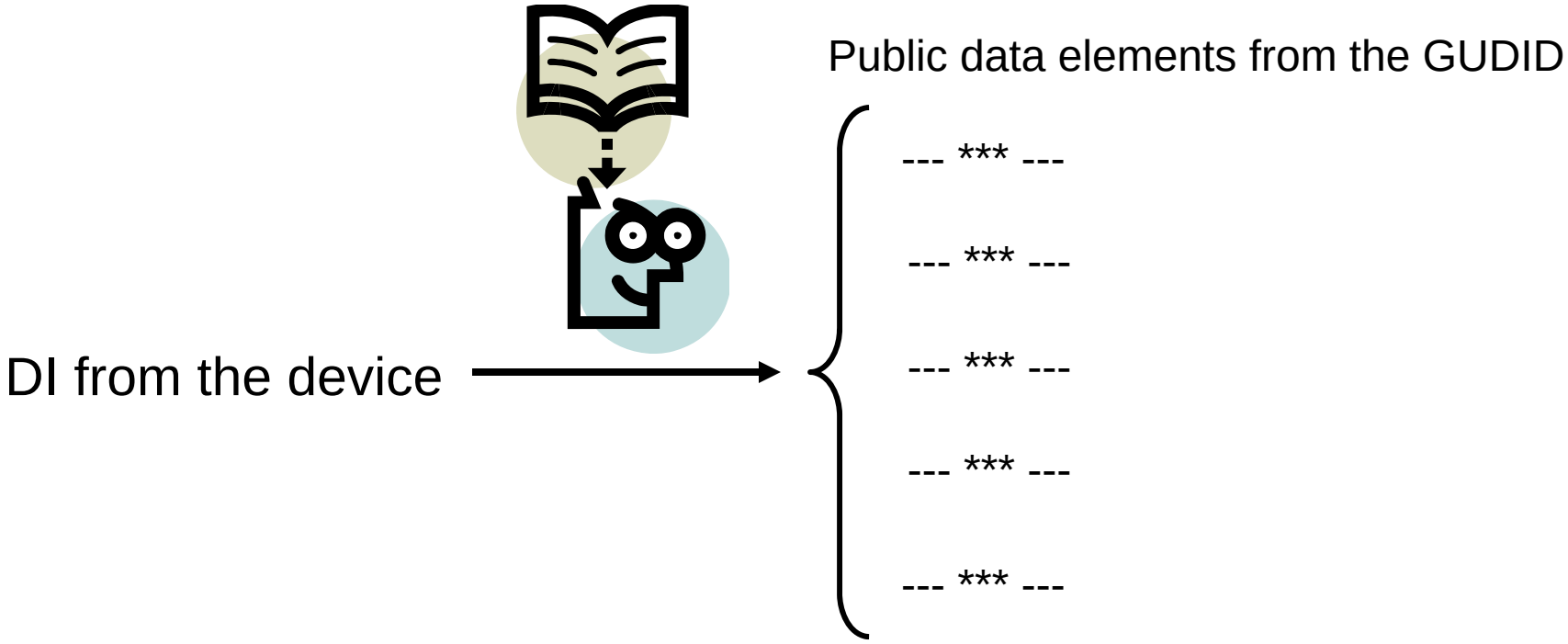
UDI & GUDID

The Basic Concept

- The label of a medical device uniquely identifies the version or model of a device using a Device Identifier (DI).
- The DI allows user access to a database (GUDID) that contains specific information and attributes about the device.
- The manufacturer (labeler) populates the information in the GUDID.

Identification

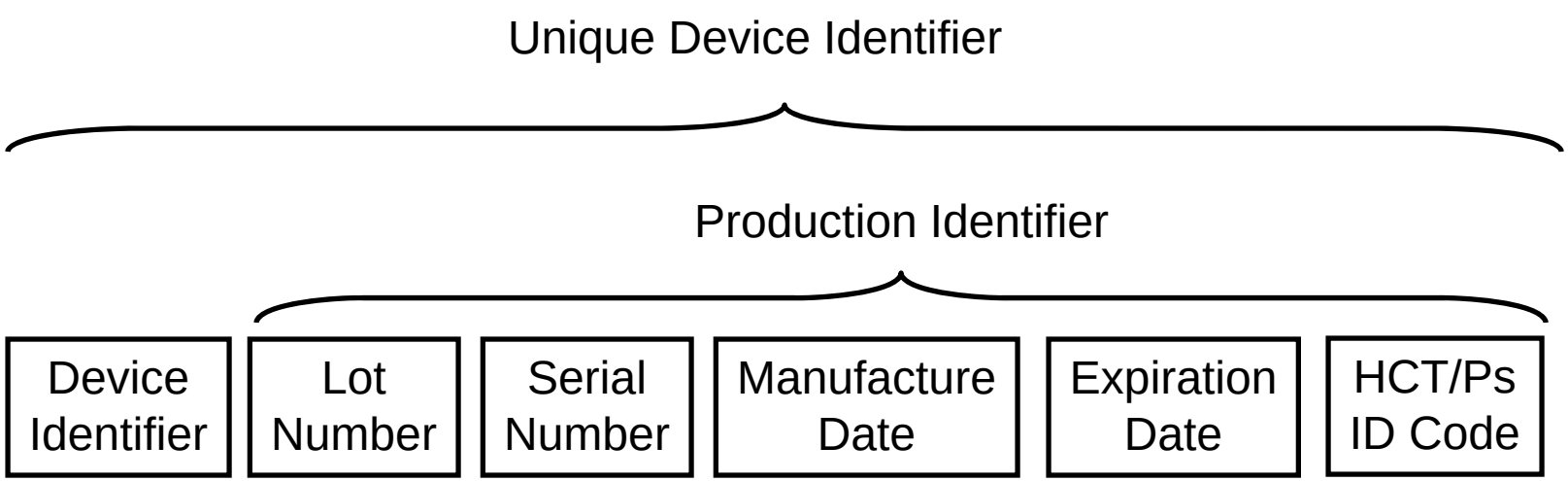
With the DI, your customer has access to the FDA-CDRH database



The Basic Concept

- The manufacturer assigns a unique Device Identifier (DI) to each version or model of a device.
- The manufacturer loads a database with specified device attributes
- The public can enter the database with the DI and retrieve the loaded attributes

Overview – UDI Elements



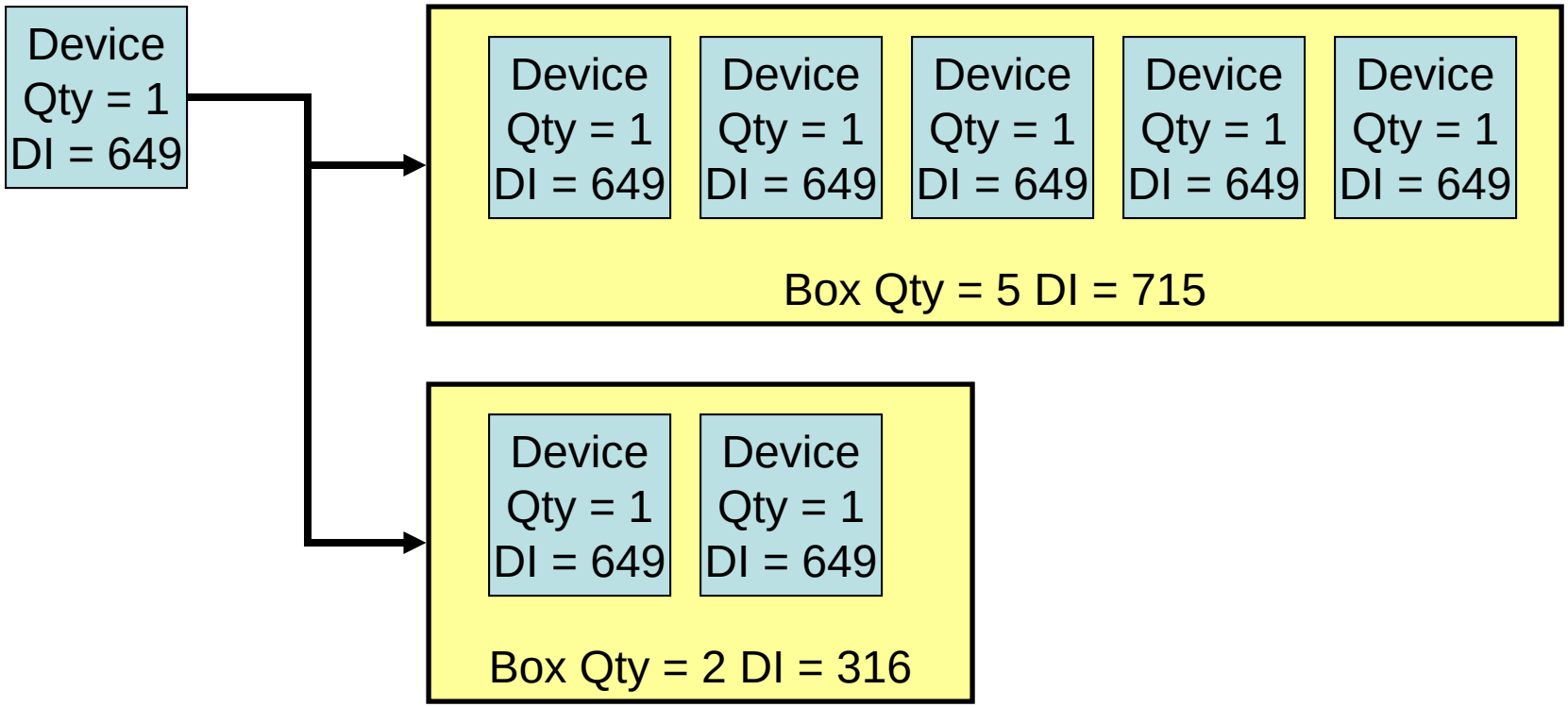
The elements of the Production Identifier are optional. If they are on the label, they must be part of the UDI.

The elements of the UDI must be shown in both easily readable plain text and automatic identification and data capture (AIDC).

Stand-alone software has a different format.

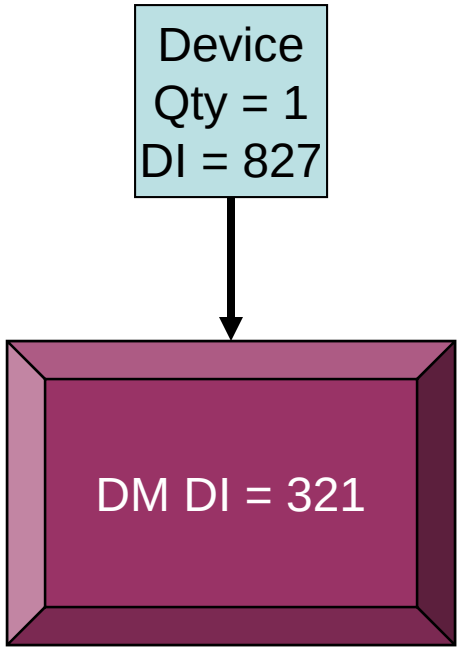
Overview – Package Level

- The concept extends upward from the device label to the package configuration



Overview – Device Level

- The concept may extend downward from the device label to the device using a Direct Marking Device Identifier (DM DI)



Overview – GUDID Elements

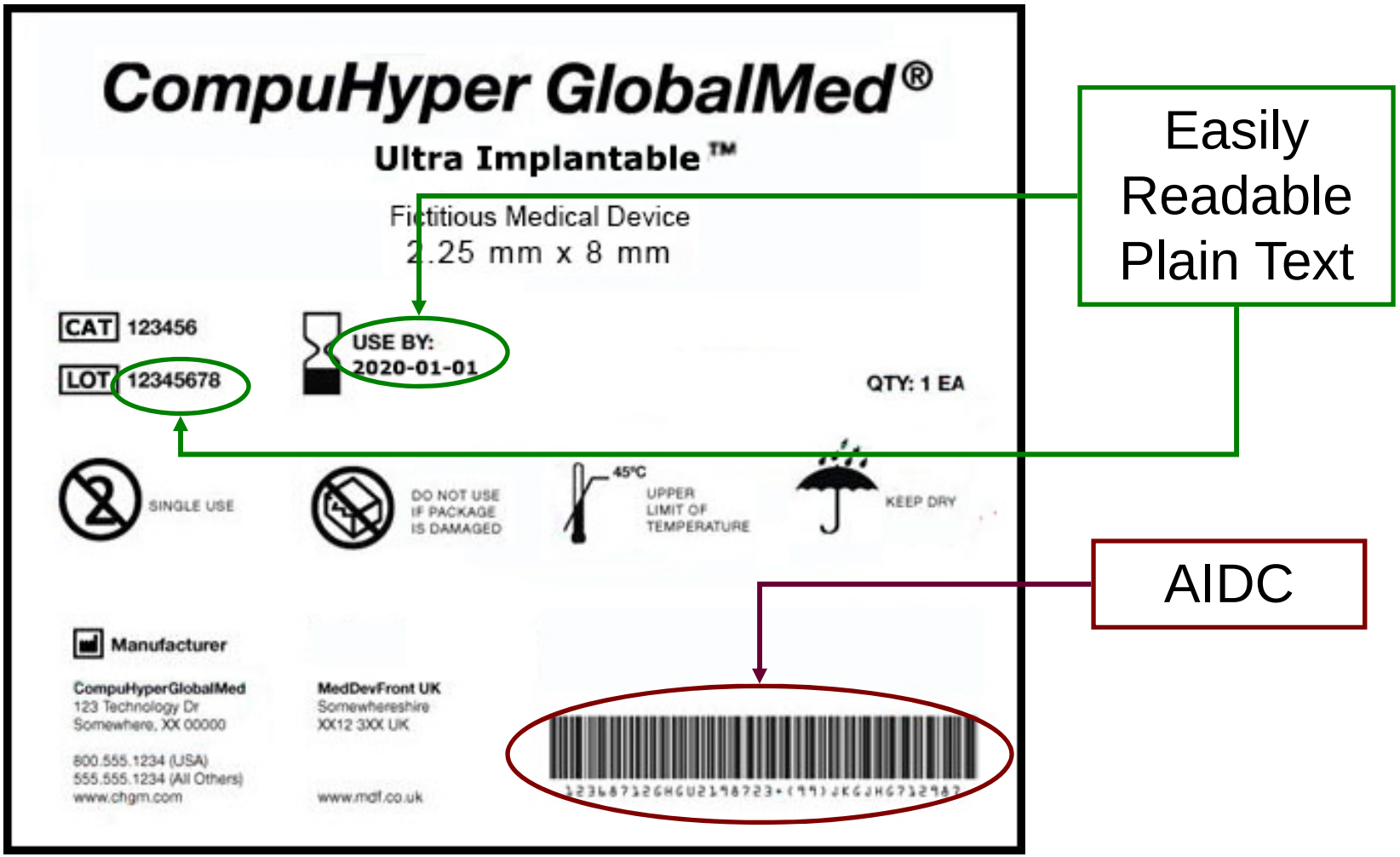
- The GUDID has about 60 data elements
- Some data elements are required.
- Some data elements are conditional, triggered by specific entries and business rules.
- About 6 data elements are for each package configuration
- About 10 data elements would, if changed, require a new DI

GUDID

Device Identifier (DI) Information	Issuing Agency	Primary DI Number	Device Count
Unit of Use DI Number	Labeler DUNS Number	Company Name	Company Physical Address
Brand Name	Version or Model	Catalog Number	Device Description
Commercial Distribution	DI Record Publish Date	Commercial Dist. End Date	Commercial Dist. Status
Alternate or Additional Identifiers	Direct Marking but Exempt	DM DI Different from Primary DI	
DM DI Number	Secondary DI Issuing Agency	Secondary DI Number	Package DI Number
Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
Customer Contact	Customer Contact Phone	Customer Contact Email	
Device Status	HCT/P	Kit	Combination Product	Premarket Exempt	Premarket Submission Number
Supplement Number	Product Code	Product Code Name	FDA Listing Number	GMDN Code
GMDN Name	GMDN Definition		
Device Characteristics	For Single Use	Lot or Batch Number	Manufacturing Date	Serial Number
Expiration Date	HCT/P Number	Labeled as “contains latex”	Labeled as “not made with latex”	Rx	OTC
MRI Safety Label	Size Type	Size Value	Size Unit of Measure	Size Type Text
Storage & Handling Type	Low Value	High Value	Unit of Measure	Special Storage Conditions
Device Packaged as Sterile	Sterilize Before Use	Sterilization Method	

Label Issues

Example Label



Considerations

- The initial view phases-in UDI by risk class: Class III, Class II, and Class I

- However, there are complexities:
  - Implantable, life-supporting, or life-sustaining
  - Intended to be used more than once and intended to be reprocessed before each use
  - Stand alone software

Compliance Date – Simple Table

Compliance Date	Device Type
Sep. 24, 2014	Class III devices & devices licensed under the PHS Act
Sep. 24, 2015	Implantable, life-supporting, and life-sustaining devices Direct marking for life-supporting or life-sustaining device
Sep. 24, 2016	Class II devices Direct marking on Class III devices
Sep. 24, 2018	Class I and unclassified devices Direct marking on Class II devices
Sep. 24, 2020	Direct marking on Class I and unclassified devices

A finished device manufactured and labeled prior to the compliance date has a 3 year grace period before the labeler must apply the UDI.

Compliance Dates

- Standard
  - Put the AIDC on the labels
  - Change date formats to YYYY-MM-DD
  - Load GUDID
- Direct Marking
  - Put UDI on the device itself

AIDC

- The AIDC comes from an FDA Accredited Issuing Agency.
  - Their standards tell the manufacturer how to form the AIDC

- FDA has, to date, accredited 3 agencies:
  - GS1
  - Health Industry Business Communications Council (HIBCC)
  - ICCBBA

GUDID

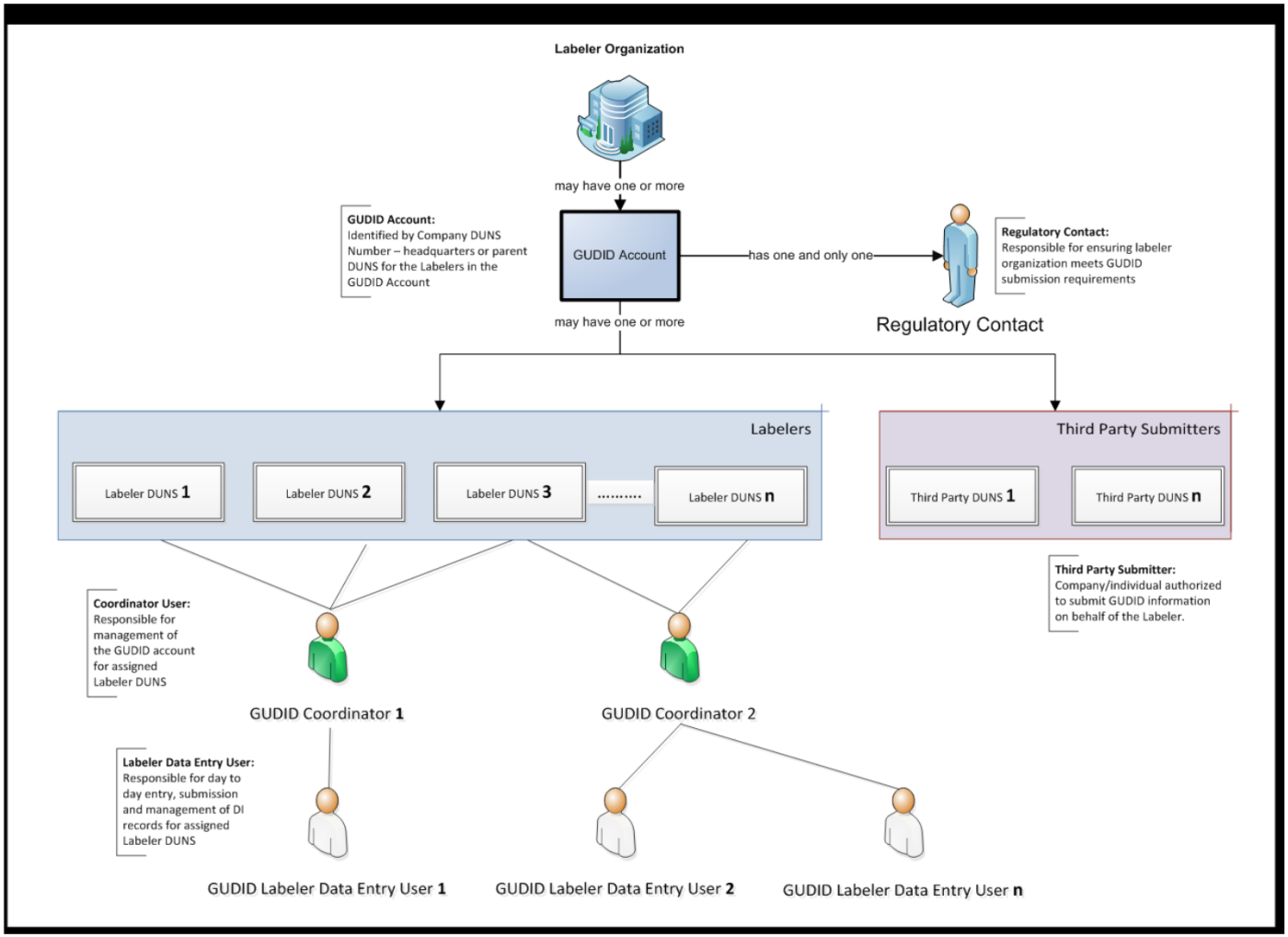
GUDID Concept

- The Device Identifier (DI) is a unique “number” assigned to each different version or model of a manufacturer’s device.
- It is also the key to a DI Record, that the manufacturer loads.
- The DI Record contains a large amount of information about the device.

DI Record Examples

- Is this a single use device? (Yes/No)
- Is the device required to have labeling for latex? (Yes/No)
- Does the device come in sizes?
  - Size type (length, diameter, volume, *etc*.)
  - Size value (a number)
  - Size unit of measure (centimeter, inch, cup, French, etc.)
- Does the device have storage or handling requirements?
  - Storage type (temperature, humidity, atmospheric pressure, etc.)
  - Low value (a number)
  - High value (a number)
  - Unit of measure (degrees C, % rel. humidity, kilopascals, etc.)

Organizational Structure



Creating an Account

- A manufacturer needs to set up an account for the data

- The manufacturer fills out a form on the FDA website.
  - This will trigger a new form by e-mail, which the manufacturer completes
  - The manufacturer must submit a DUNS number as well as the identity of the people in the required organization

Submission Methods

- The manufacturer needs to pick a method to load the DI Records

- Web-based Interface
  - FDA provides a web-based interface where the manufacturer can key-in the data
  - It also allows a record to be copied and modified

- XML Data
  - The HL7 SPL option allows a manufacturer to submit one DI record at a time as an HL7 SPL xml file
  - HL7 is a data exchange format, Health Level 7
  - Structured Product Labeling (SPL) is a HL7 standard for the exchange of product information using extensible markup language (XML)

QMS Issues

Effective Date

- The UDI regulations went into effect on December 23, 2013.
- They may not have practical effect until the compliance date
- One issue for some manufacturers is multiple compliance dates
- The QMS changes should be in effect now, *i.e.,* all of the QMS procedures and work instructions should have been updated by now.
- For device manufacturers with multiple compliance dates, there is an implementation strategy question.
  - Some manufacturers may follow the FDA's compliance dates
  - Some manufacturers may decide to have one large implementation
  - In some cases, the customer may drive the implementation schedule

Labels

- Correct labels are critical to medical device regulations
  - A designated individual must inspect labels for use.
  - The inspection includes expiration date, control number, storage instructions, handling instructions, and any additional processing instructions
  - The UDI rule adds the correct unique device identifier (UDI)
    - This means the designated individual must read both the “easily readable plain text” and the AIDC

Databases

- Some records must now include UDI.
  - When a manufacturer receives a complaint, the record now includes the UDI
  - When a manufacturer services a device, record now includes the UDI

- When a manufacturer uses “computers or automated data processing systems … as part of production or the quality system” the application must be verified
  - Changes, such as adding the fields for UDI, require another validation before use

Device Changes

- When a manufacturer changes a device, such as adding new features or making an improvement, the manufacturer must follow design controls, 820.30(i).

- When the change creates a new version or model, the manufacturer must create a new DI.
  - A new DI means a new AIDC on the device, label, and package
  - It also requires a new DI Record

Reports to FDA

- Manufacturers report to FDA when:
  - an adverse event occurs (MDR)
  - there is a change to device already shipped (C&R)

- These reports now include the UDI

Summary & Conclusion

Summary

- The UDI rule is a major change for all device manufacturers

- There are three major components:
  - Changes to the device, device label, and package label (including date formats)
  - Loading the DI Records into GUDID
  - Revising the QMS procedures, work instructions, forms

Conclusion

- Medical device regulations, especially QSR, are generally static
- UDI is a major change that will impact all parts of the medical device regulations
- Manufacturers face a major project that will take years to implement and require significant resources

QUESTIONS