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Radiological Health

Introduction to the Unique Device Identification System

December 18, 2013

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Unique Device Identification System

- 2007 FDAAA – the system

- 2012 FDASIA – the timelines

- 2012 Proposal – 77 FR 40736

- 2013 Final Rule– 78 FR 58786

CDRH Learn **Unique Device Identification (UDI) System – The Final Regulation** www.fda.gov/CDRHLearn

CDRH Device Advice–UDI   www.fda.gov/udi

Key Benefits of the UDI System

- More accurate adverse event reports

- More rapidly and precisely identify a device

- Enhance analysis of devices on the market

- More robust postmarket surveillance system to support premarket clearance and approval

- More effectively manage device recalls

- Support a secure global distribution chain

Establishing the UDI System

Step 1 Develop a standardized system to create unique device identifiers (UDI).

Key Players

FDA accredits the Issuing Agencies

Issuing Agencies develop unique labeler codes for use in UDIs, using ISO 15459

Labelers select Issuing Agencies to work with

Establishing the UDI System

Step 2 Place the UDI in human readable (Plain Text) and machine readable (AIDC) on label and packaging, and for certain devices, on the device itself.

Key Players

Labelers –   Label with intent to commercially distribute

September 24, 2014	• Class III devices, incl. class III stand alone software
	• Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software
	• Direct Marking of I/LS/LS for certain intended uses
September 24, 2016	• Class II devices
	• Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses
September 24, 2018	• Class I devices and devices not classified class I, II or III
	• Direct Marking of class II devices for certain intended uses
September 24, 2020	• Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses

Conforming Amendments

- 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

Establishing the UDI System

Step 3 Create, maintain, and use the UDI Database (GUDID).

Key Players

FDA creates and maintains GUDID

Labelers enter data into GUDID

Public access data in the GUDID

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GUDID Overview
December 18, 2013

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Presentation Outline

- GUDID Overview
- GUDID Key Concepts
  o GUDID Account
  o DI Record
- How to Get Started
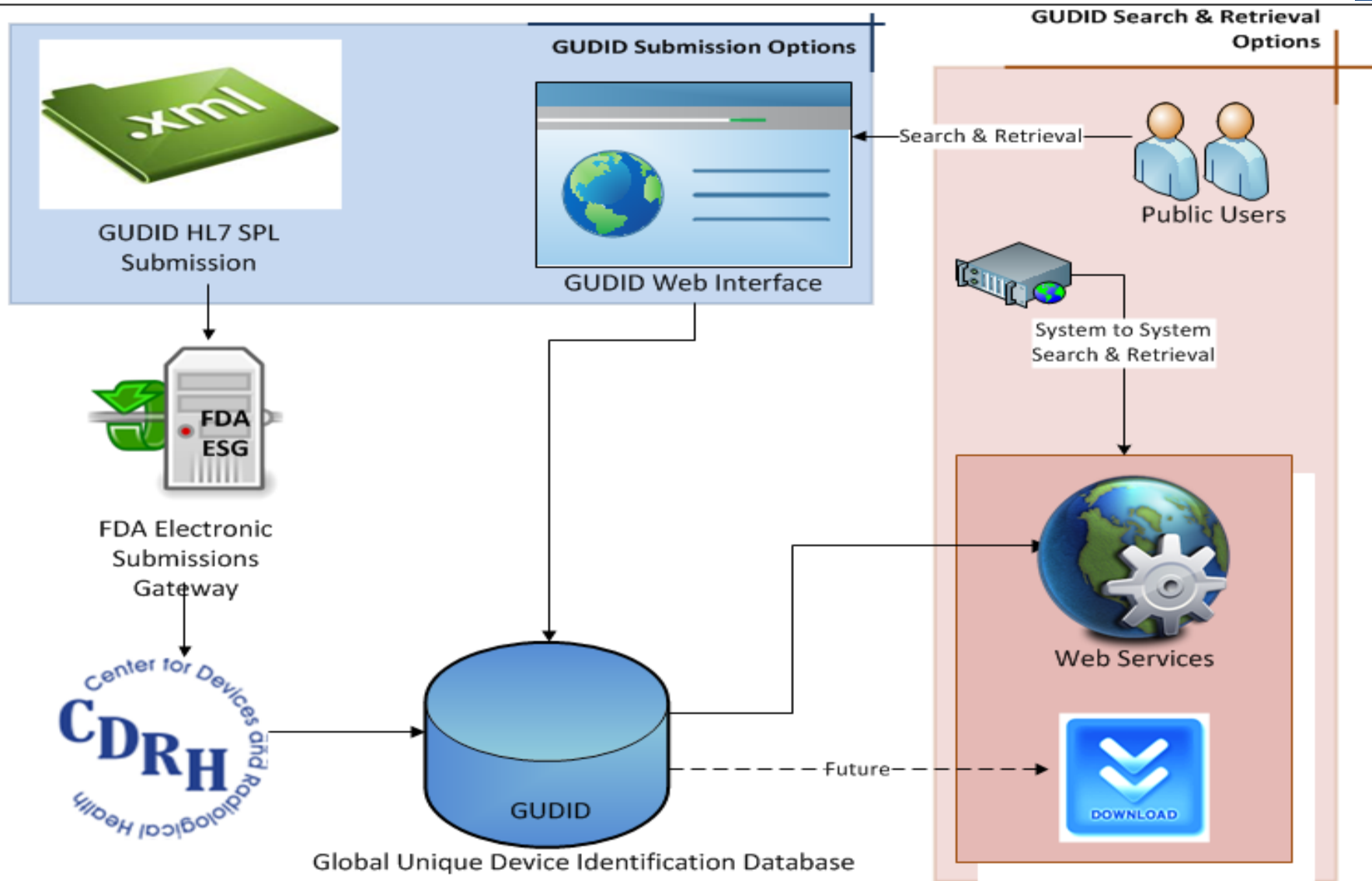- How to Contact Us

UDI = Unique Device Identifier

- Device Identifier(**DI**) + Production Identifier(s)(**PI**)

- **DI**= mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device
  o Issued by FDA-accredited Issuing Agencies

- **PI**= a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
  o Lot or batch number
  o Serial number
  o Expiration date
  o Manufacturing date
  o For an HCT/P regulated as a device, the distinct identification code

GUDID Global Unique Device Identification Database

- Repository of key device identification information
- Contains ONLY the DI; PIs are **not** submitted to or stored in the GUDID
  - o Contains only PI flags to indicate which PI attribute(s) are on the device label

GUDID Overview

GUDID Submission Options

GUDID Search & Retrieval Options

GUDID HL7 SPL Submission

GUDID Web Interface

Search & Retrieval

Public Users

System to System Search & Retrieval

FDA ESG

FDA Electronic Submissions Gateway

Center for Devices and Radiological Health
CDRH

GUDID

Web Services

Future

DOWNLOAD

Global Unique Device Identification Database

GUDID Web Interface

GUDID Web Interface

- Secure Web Application

- Submission of device information one record at a time by Labelers

- Search and Retrieval of published device information by public users

GUDID HL7 SPL Submission Option

GUDID HL7 SPL Submission

- HL7 = Health Level 7
- SPL = Structured Product Labeling
- Submission of device information as xml files – one record at a time
- Technical specifications available on the UDI website
- Uses the FDA Electronic Submissions Gateway (ESG) to transmit the file www.fda.gov/esg
- Testing required prior to production submission

GUDID Search and Retrieval

Two Search and Retrieval Options *will be* available:

1) Web Interface Search and Retrieval
   – Quick Search – enables search on Device Identifier, Company Name, Brand Name, Version or Model Number.
   – Advanced Search – additional attributes available for searching.

2) System to System Search and Retrieval
   – Web Services – accepts a DI Number and returns published attributes.
   – Database Download capability – planned for the future.

GUDID and Data Quality

- Review submissions
- Use lessons learned for program and database improvements; refine instructions
- Provide assistance and work collaboratively with labelers

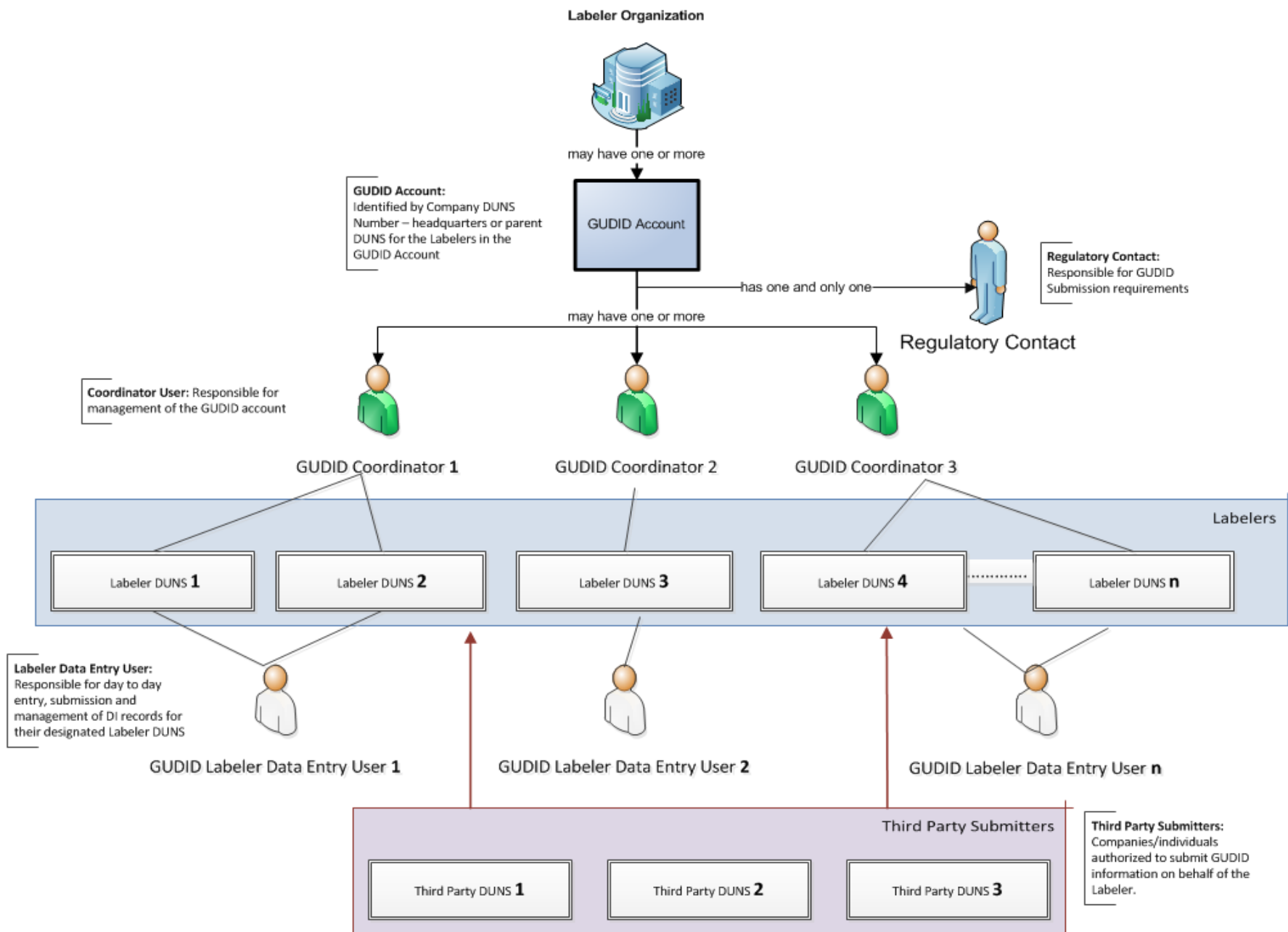- "Bake-in" Data Quality as you work on GUDID

GUDID Key Concepts
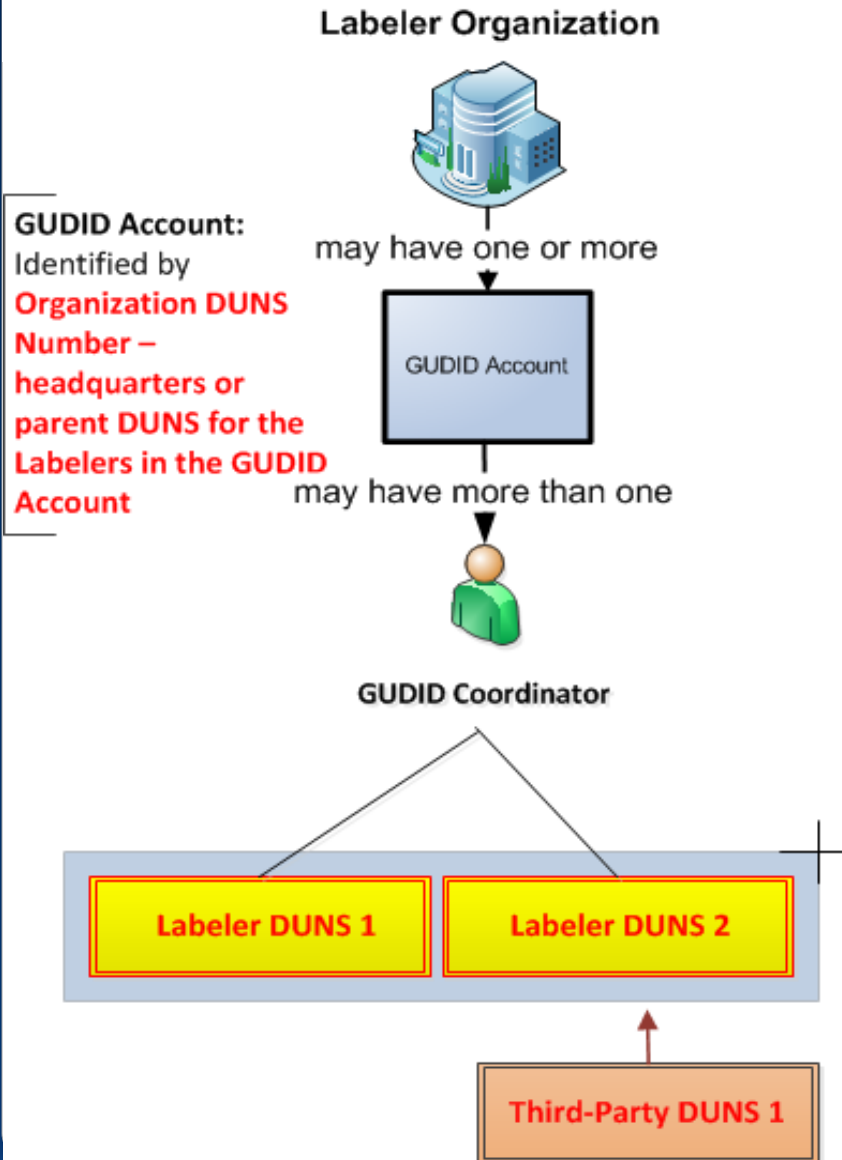
- GUDID Account
- The DI Record

GUDID Account

- Required for submission to GUDID
- Identifies Labeler organization – DUNS Number
- Enables labelers to manage access to GUDID within their organization
- GUDID account is created by FDA Staff

- GUDID account user information is not made public

DUNS Number

- Used to identify labeler organizations in GUDID
- DUNS = Data Universal Numbering System
- 9 digit number assigned by Dun & Bradstreet (D&B)
- Labeler name and address pulled from DUNS database

GUDID DUNS Numbers

Labeler Organization

GUDID Account:
Identified by
Organization DUNS Number –
headquarters or parent DUNS for the Labelers in the GUDID Account

may have one or more

GUDID Account

may have more than one

GUDID Coordinator

Labeler DUNS 1   Labeler DUNS 2

Third-Party DUNS 1

- Organization DUNS
  - identifies the labeler organization for a GUDID Account

- Labeler DUNS
  - identifies the Labeler as shown on the medical device label

- Third Party DUNS
  - identifies the individual/company authorized to submit information to GUDID on behalf of labeler

Labeler DUNS and the DI Record

GUDID User Roles

- # Regulatory Contact
  - o Responsible for GUDID submission requirements

- # Coordinator
  - o Manages the GUDID account for assigned Labeler DUNS numbers

- # Labeler Data Entry (LDE) User
  - o Responsible for day to day entry, submission and management of device identification (DI) records
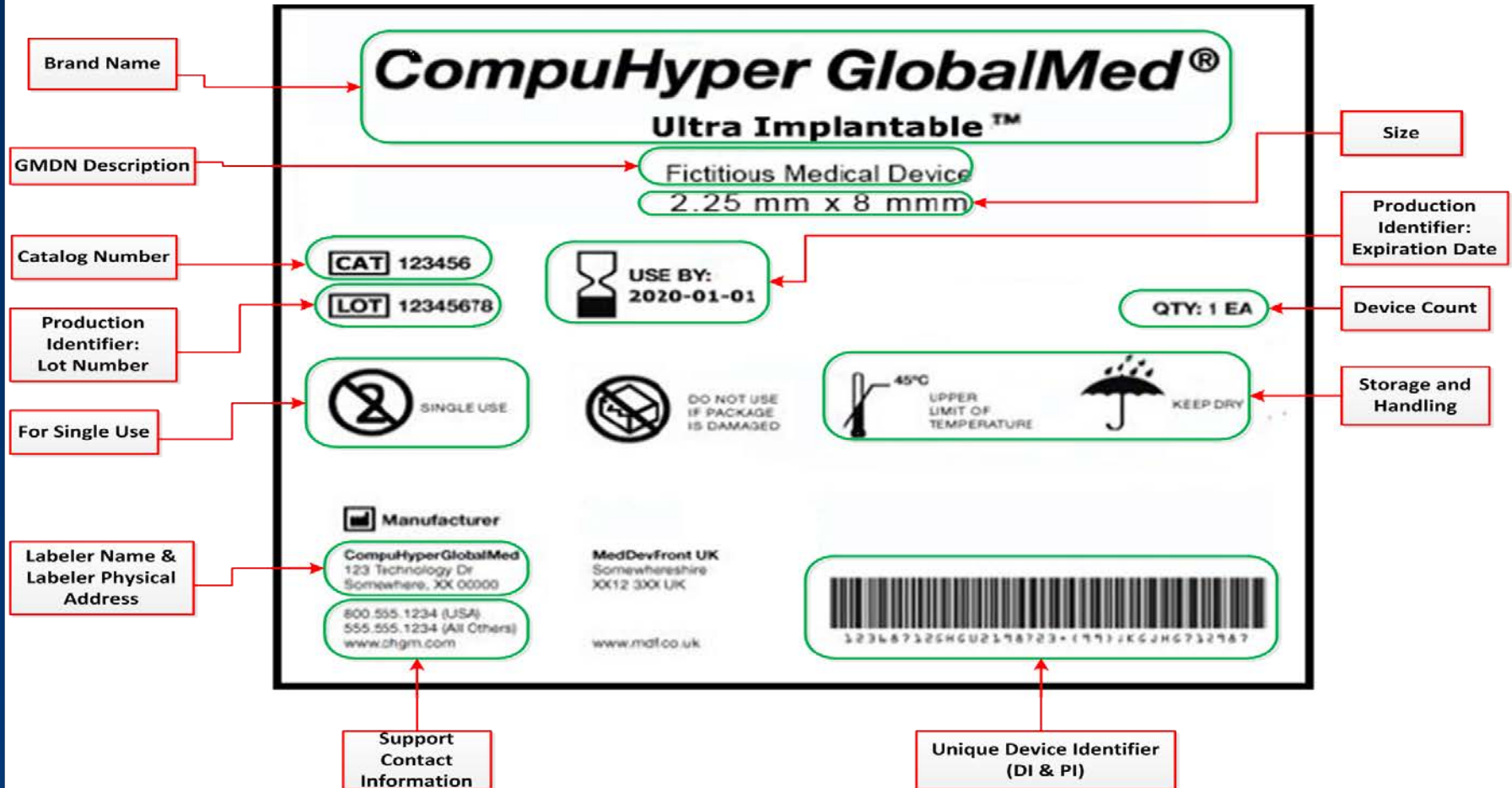
Third-Party Submitter

- Company/Individual authorized to submit to GUDID on behalf of the labeler

- Web Interface Submitters – Labeler may designate third-party as Coordinator or LDE User.

- HL7 SPL Submitters –
  o Labelers must identify third-parties on their GUDID Account Request
  o Only those identified will be allowed to submit on behalf of labeler

GUDID Account – TO DO

- Understand GUDID Account structure and User Roles
- DUNS Numbers
  - Identify/obtain appropriate DUNS numbers
  - Verify information in the D&B database is correct; update if needed
- GUDID User Roles
  - Identify individuals for the different GUDID User Roles
  - Ensure they understand GUDID functionality and responsibility for their user role

Note: You need a GUDID Account regardless of the submission option you choose.

DI Record

- DI Record = Device Identifier (DI) + GUDID attributes

DI Record – Key Concepts

- New DI Trigger Attributes –when changed, no longer represent the same device and require a new DI.
  - *"Device Packaged as Sterile?"*

- DI Record Publish Date – determines when a DI record gets "published" and is available via public search.

DI Record – Key Concepts

- Grace Period – Starts the day after the DI record Publish Date and ends after 7 calendar days

Publish Date	Grace Period Start Date	Grace Period End Date
Friday, Sep 20, 2013	Saturday, Sep 21, 2013	Friday, Sep 27, 2013 11:59 PM

- Within Grace Period
  - All attributes are editable, **except Publish Date**
  - Edits must take place via the same submission option used to initially submit the record
- After Grace Period
  - New DI trigger attributes – not editable
  - Limited editing of certain attributes

DI Record Life Cycle

- DI Record Life Cycle = DI record states + business rules
- DI record state determines applicable business rule

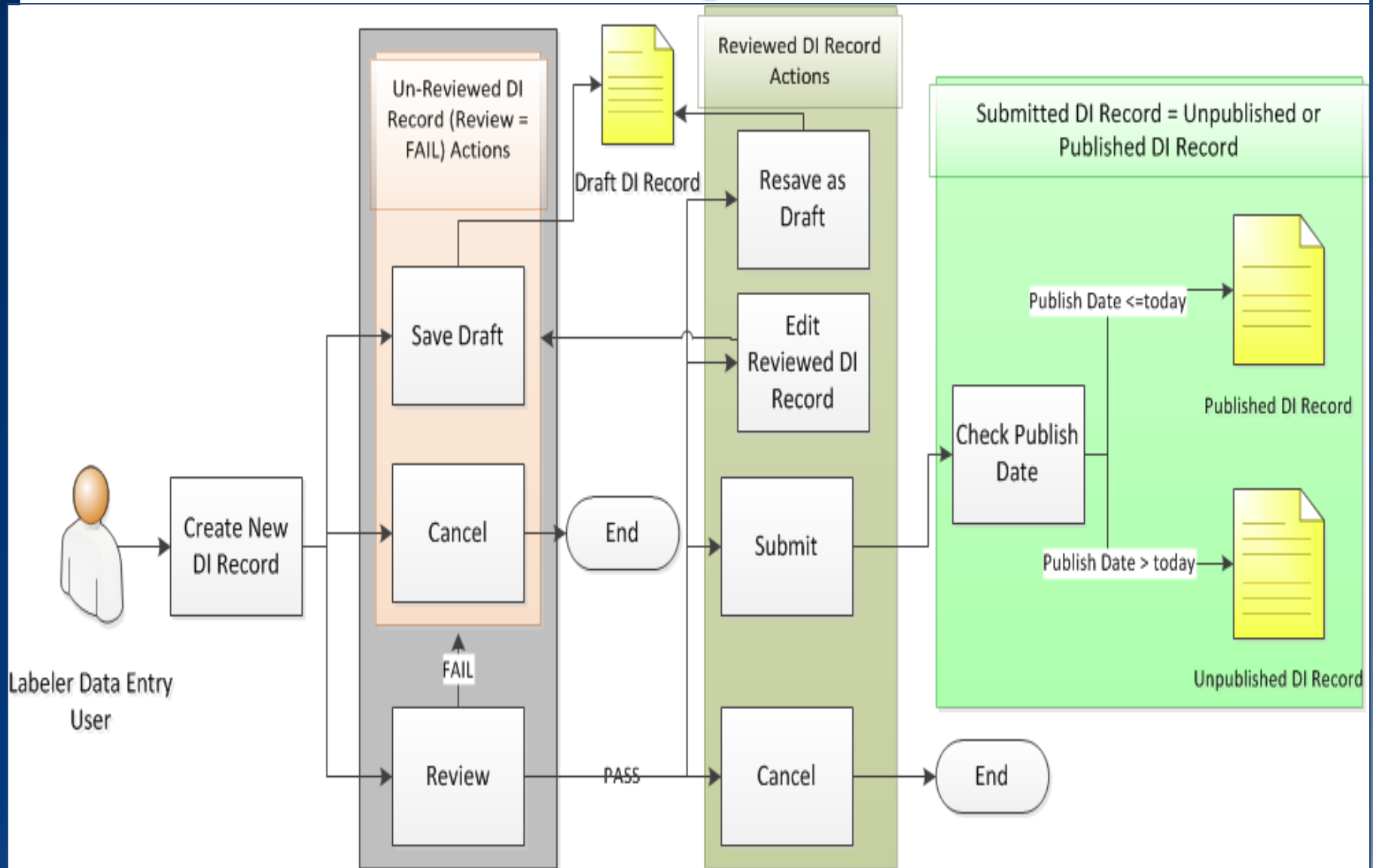| Draft DI Record	Unpublished DI Record	Published DI Record
• Business rules = N/A • Publish Date = N/A • Public Search = NO • Editing = unlimited • *Not available via HL7 SPL	• Business rules = pass • Publish Date > today • Public Search = NO • Editing = unlimited	• Business rules = pass • Publish Date<=today • Public Search = YES • Editing = limited

Moving between states

Draft DI Record

Business rules = pass,
Record Submitted &
Publish Date > today

Business rules = pass,
Record Submitted &
Publish Date <= today

Unpublished DI Record

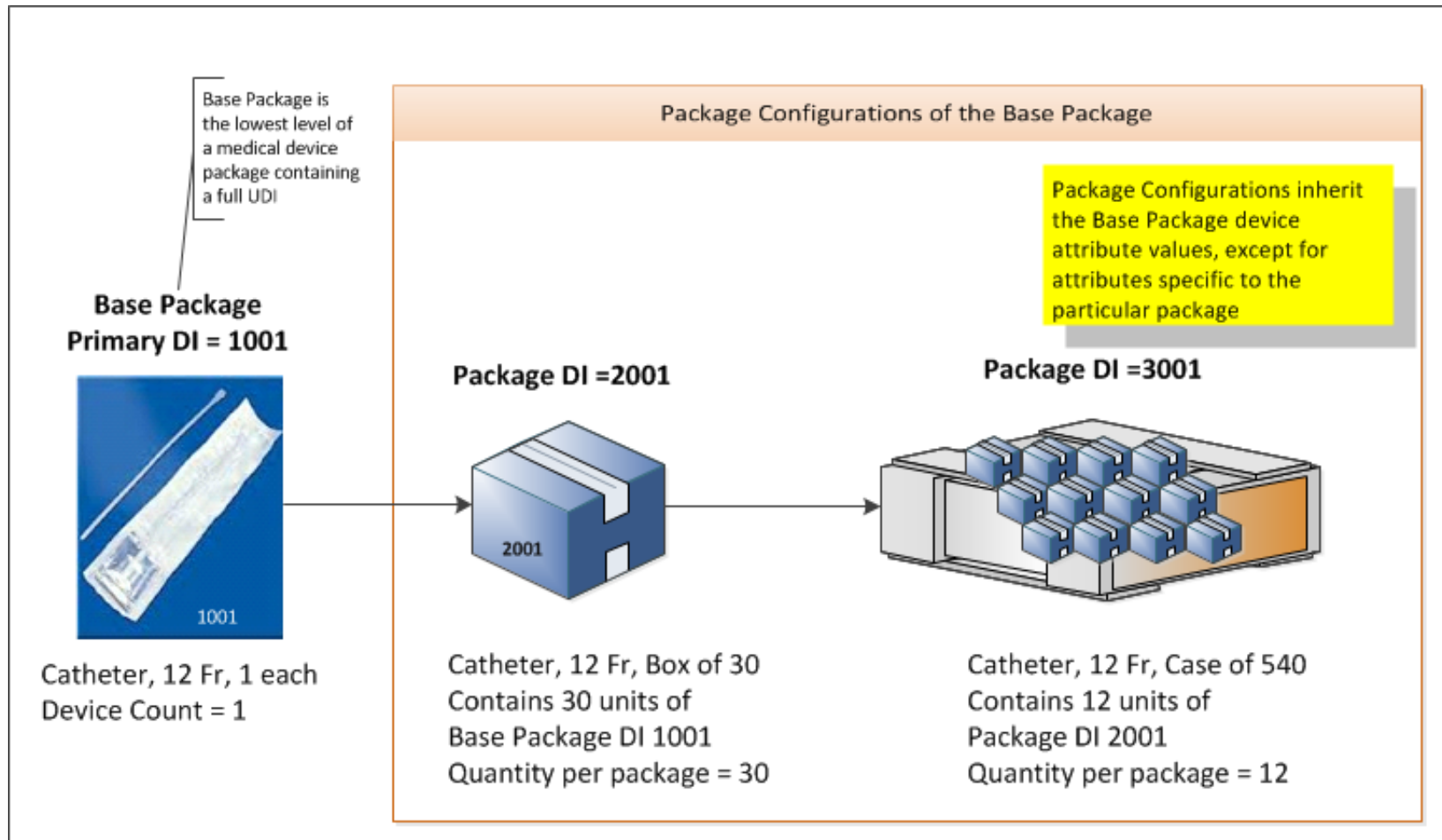**Published DI Record**

Nightly automated check
If Publish Date = today

DI Record Life Cycle

Device Packages

- Package configurations of a device are part of the same DI record.

Base Package is the lowest level of a medical device package containing a full UDI

Package Configurations of the Base Package

Package Configurations inherit the Base Package device attribute values, except for attributes specific to the particular package

Base Package Primary DI = 1001

1001

Catheter, 12 Fr, 1 each
Device Count = 1

Package DI =2001

2001

Catheter, 12 Fr, Box of 30
Contains 30 units of
Base Package DI 1001
Quantity per package = 30

Package DI =3001

Catheter, 12 Fr, Case of 540
Contains 12 units of
Package DI 2001
Quantity per package = 12

Packages in GUDID

DI Record – TO DO

- Gather your data
  - Attribute list in Appendix B of GUDID Draft Guidance Document
  - Global Medical Device Nomenclature (GMDN) Preferred Terms – *Required
    - Identify/obtain active GMDN preferred terms for your devices, www.gmdnagency.org
  - FDA Listing Number – *Required
    - Identify/obtain correct Listing Number for your devices
- "Bake-in" data quality processes

GUDID Status

- Accepting submissions from:
  - Labelers of Class III medical devices
  - Labelers of devices licensed under the PHS Act

- GUDID Search and Retrieval temporarily disabled – will be enabled when the database is populated.

- Production Accounts – 12*
- Number of Published DI records – 0*

*Data as of December 17, 2013

What should you do to get started?

- Read up!
  - Visit www.fda.gov/udi
  - GUDID Draft Guidance for Industry
  - GUDID HL7 SPL Implementation Files

- Determine your submission option

Web Interface Submitters– TO DO

- Request and obtain a GUDID Account
  - No required testing
  - Submit GUDID Account Inquiry at www.fda.gov/udi
- Get familiar with the system
  - Create Draft DI records – only visible to the user who created the records
  - May submit DI records with a "future" publish date, i.e., Unpublished DI records – not available via public search
- Submit and publish DI Records

HL7 SPL Submitters – TO DO

- Register with the FDA ESG and complete ESG testing
  - Existing test accounts can be used
- Request a GUDID Account for testing
  - Submit GUDID Account Inquiry at www.fda.gov/udi
- Complete HL7 SPL testing
- Request and obtain a GUDID Account for production submission
- Submit DI records
  - Note: "Draft" DI Record state is not available via HL7 SPL

Third-Party Submitters – TO DO

- Verify information in the DUNS database is correct; update if needed
- May test HL7 SPL submission option independently of Labelers
  - Request a GUDID Account – indicate it is for HL7 SPL testing
    - Submit GUDID Account Inquiry at www.fda.gov/udi
  - Dummy data for certain required attributes will be provided for testing purposes ONLY, upon request

How to Contact Us

- HL7 SPL submitters with FDA ESG questions –
  – ESGHelpDesk@fda.hhs.gov

- All other inquiries via **FDA UDI Help Desk**
  o GUDID Account Request – production and test
  o Regulatory questions
  o Technical questions

FDA UDI Help Desk

- Submit question via the web, www.fda.gov/udi
- Please complete all fields on the web form!

FDA UDI Help Desk

The FDA UDI Help Desk is the primary way to obtain information and assistance on the UDI program and the GUDID. Labelers and GUDID users are encouraged to use the help desk to submit all questions related to UDI and the GUDID. Please complete the information below to submit a UDI support question/comment. Once the question is received, an FDA UDI Help Desk analyst will respond to you as soon as possible.

First Name:*

Last Name:*

Organization:*

Email:*

Phone:*

Subject:*

Question:*

Type:* Technical

Fields marked with * are REQUIRED

Submit Question

Reset

FDA UDI Help Desk

- Question becomes a "case" in help desk tool
- Response will be sent to the email you provide
  - Ask follow-up questions by responding to the email, will append the "case"
- Please ensure you can receive emails from help desk – check your spam folder
- Monitored during business hours, EST

GUDID System Status

- Scheduled downtimes will be posted on www.fda.gov/udi, look for GUDID System Status

- Unscheduled downtimes
  - Visit www.fda.gov/udi for information
  - If no information, report issue via Help Desk

- Subscribe to GUDID Email Alerts

We are here to help!

- Please submit complete and correct information
  - Help Desk questions
  - Account Requests
  - DI Records
  - Build-in data quality into all tenets of your process as you get organized for GUDID submission

- Be patient with us as we learn/grow as a program