UDI – Final rule

It´s already here…and more is coming.

Ferenc Dahnér
QAdvis AB
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QAdvis key competence areas

- Turn key quality systems
- Sharepoint based
- Digital signatures
- Efficient and lean
- Validated and compliant

QMS in-the cloud

- Project management
- Product software validation
- Regulated software validation
- Requirement management
- Risk management
- Verification and validation
- Process validation

System development

- Interim management
- Expert advise
- Audits/Mock audits/assessments
- Warning letter, compliance projects
- PMA, 510k, CE-mark
- Global regulatory support
- Vigilance, recall, post market surv.
- Clinical evaluation/clinical study

QA&RA/Clinical Consulting

- CE-marking
- ISO 13485
- IEC 62304 & IEC 82304-1
  - SW life cycle
  - SW risk management
- FDA's QSR
- Risk management
- Etc

Training/ courses

- Training and Consulting
- In cooperation with Oriel Stat-A-Matrix

Lean and Six Sigma

- Providing European representation for non-EU MedTech companies
- Active member of EAAR: European Association of Authorised Representatives

European Authorised Representation

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History

- The Unique Device Identification (UDI) System was signed into US-law on September 27, 2007
- Proposed Rule July 2012
- Final Rule presented September 2013
- FDA established the UDI system September 24, 2013

Purpose

- To adequately identify medical devices through their distribution and use.
- A key component of the National Medical Device Post Market Surveillance System proposed in September 2012

Requirements

A UDI must appear on the label in a human readable format, as well as in a manner that can be read by automatic identification and data capture (AIDC) technology.

Specified data about UDI-labeled medical devices is required to be uploaded to a new Global Unique Device Identification Database (GUDID).This database is publicly accessible.

Automatic Identification Data Capture (AIDC)

- Linear bar codes
- Two-dimensional barcodes,
- RFID tags
- ……

FDA has not specified nor prohibited any technology.

What comprises an UDI?

UDI is made up of two parts:

- **D**evice **I**dentifier
  - Identifies the model of the device and the manufacturer.
  - Each level of the package requires a different UDI

- **P**roduction **I**dentifier
  - May include for example lot/batch, serial number, expiration date, date of manufacture. (Information required is dependent of the class)

UDI Issuing Agencies

FDA has accredited the following agencies:

- **GS1**

  Web Site: **http://www.gs1.org**

- **Health Industry Business Communications Council (HIBCC)**

  Web Site: **http://www.hibcc.org**

- **ICCBBA** (medical products of human origin only)

  Web Site: **http://www.iccbba.org**

UDI = DI+PI

Machine readable format

Device Identifier (DI)

Production Identifier (PI)

Human readable format

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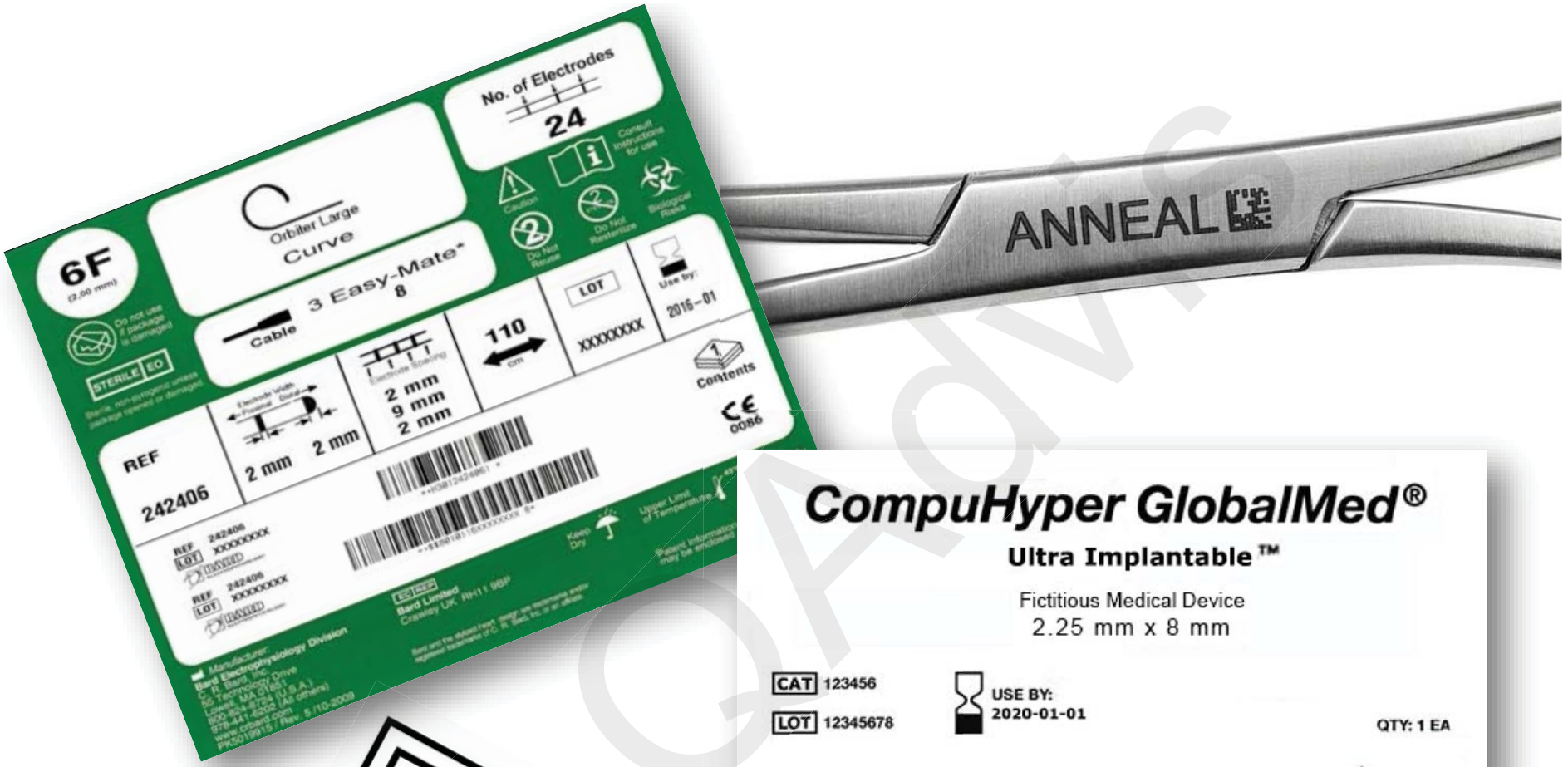

(01) 09504000059118
(17) 141120
(10) 7654321D
(21) 10987654d321

(01) 09504000059118
(17) 141120
(10) 7654321D
(21) 10987654d321

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Unique Device Identification in GS1 terms

UDI Unique Device Identification	**GS1 Standards** Product Identification
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (if applicable)	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	**GTIN or GTIN + AI(s) = UDI**

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Package levels

Each designated package level must have its own DI.

Base package = 1 Syringe

00857674002010

Second level package = 10 Syringes

10857674002017

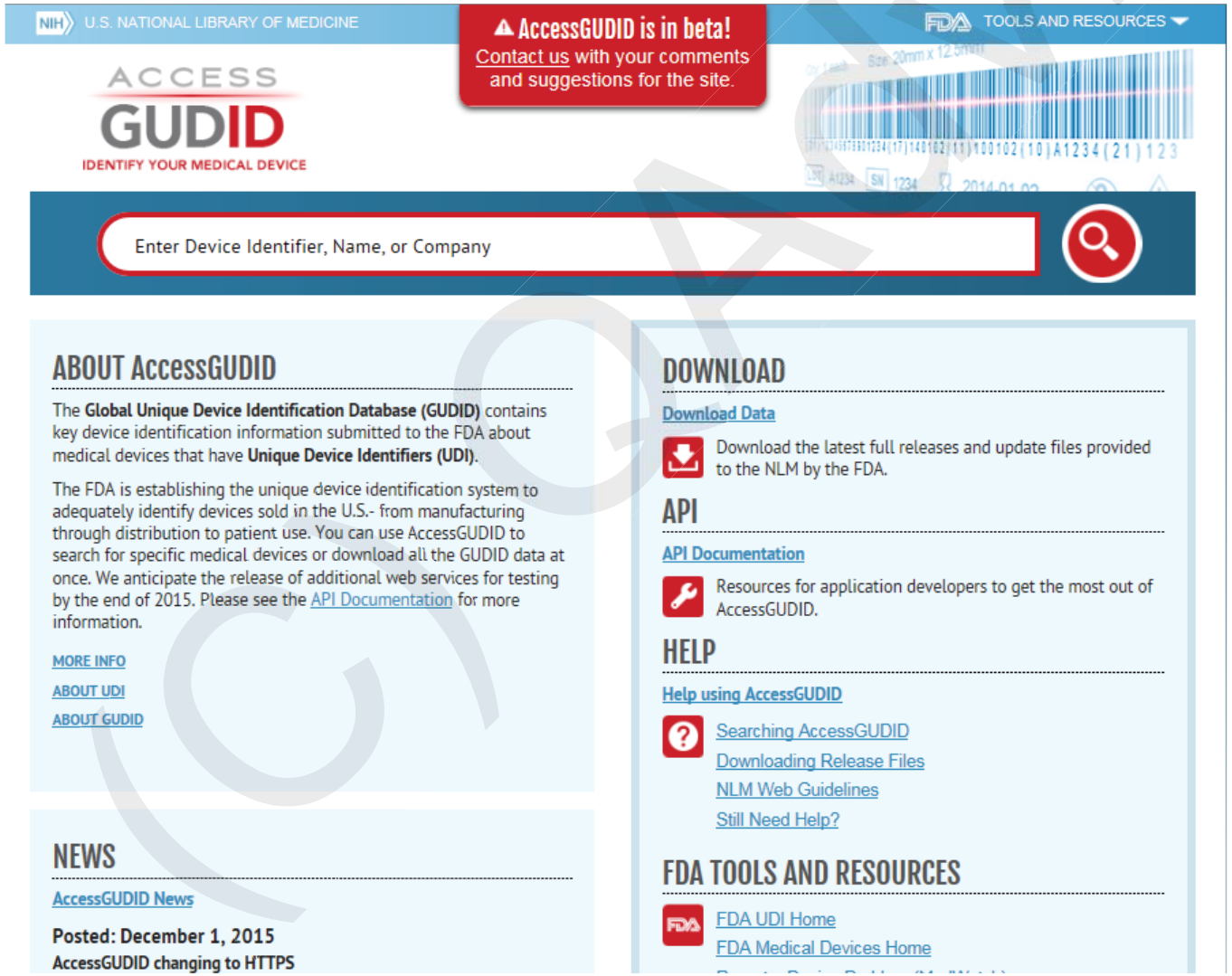
Third level package = 100 Syringes

40857674002018

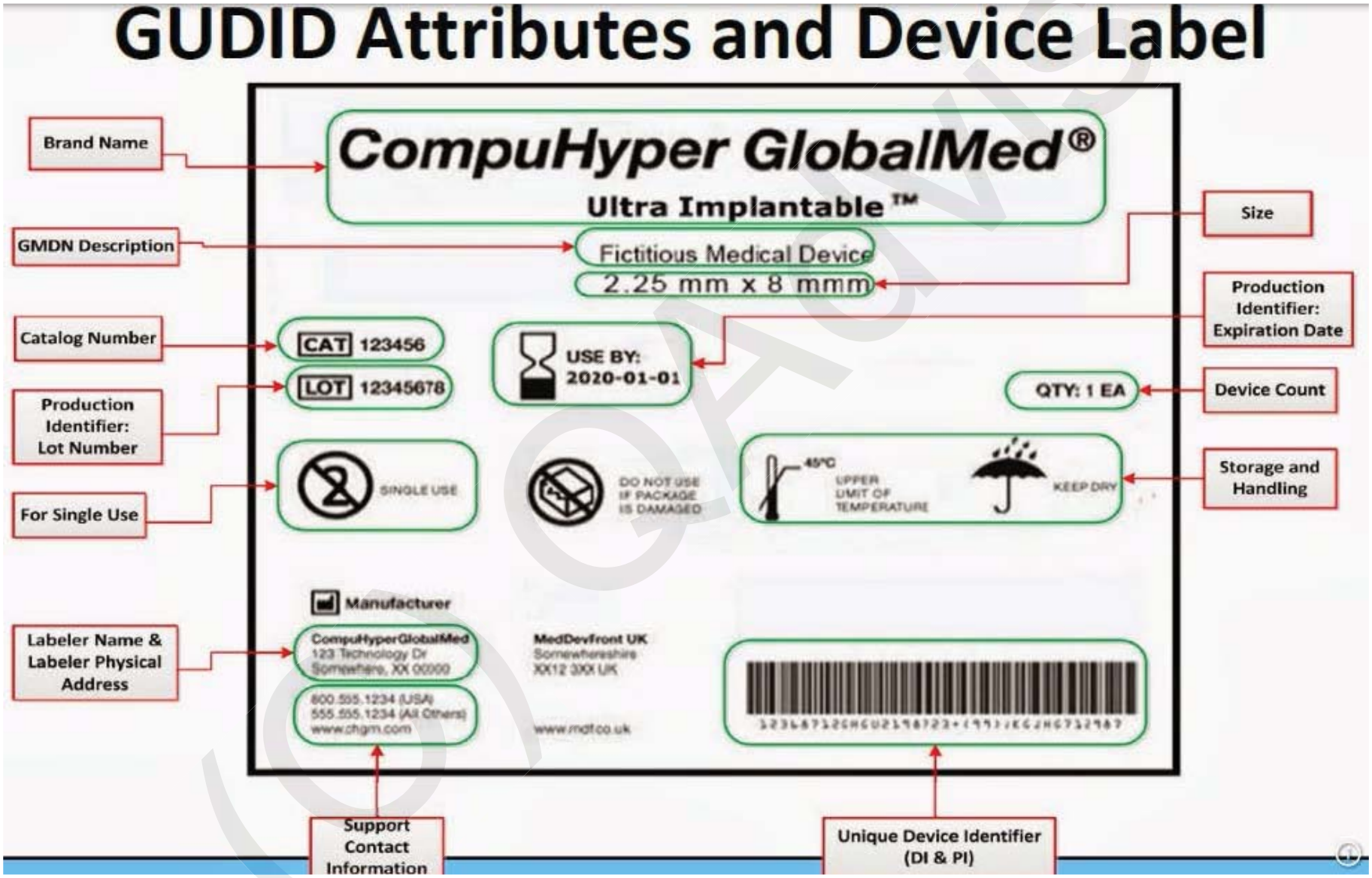
The Global Unique Device Identification Database (GUDID)

http://accessgudid.nlm.nih.gov/

The Global Unique Device Identification Database (GUDID)



GUDID Attributes and Device Label



The Global Unique Device Identification Database (GUDID)

55 different parameters needs to be submitted for each ref or model

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
DI Record Publish Date
Commercial Distribution End Date
Commercial Distribution Status
Direct Marking (DM)
Device Subject to Direct Marking (DM), but Exempt
DM DI Different from Primary DI
DM DI Number
Secondary DI
Issuing Agency

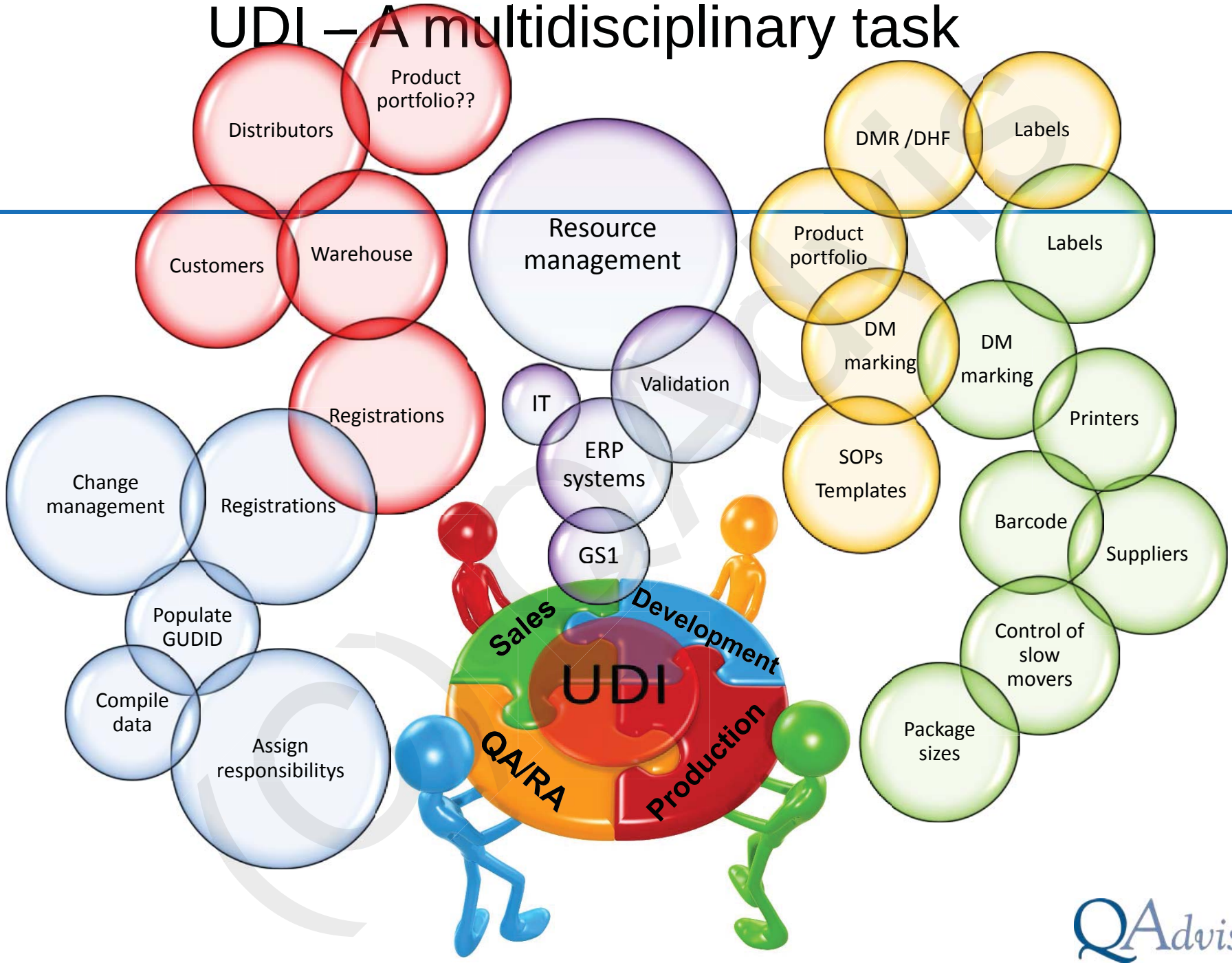
Secondary DI Number
Package DI
Package DI Number
Quantity per Package
Contains DI Package
Package Type^
Package Discontinue Date
Package Status
Customer Contact Phone
Customer Contact Email
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
Kit
Combination Product
Device Exempt from Premarket Submission
FDA Premarket Submission Number
Supplement Number
Product Code
Product Code Name
FDA Listing Number^
Code^

Name
Definition
For Single-Use
Lot or Batch Number
Manufacturing Date
Serial Number
Expiration Date
Donation Identification Number
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).
Device labeled as "Not made with natural rubber latex"
Prescription Use (Rx)
Over the Counter (OTC)
What MRI safety information does the labeling contain?
Size Type
Size Value
Size Unit of Measure
Size Type Text
Storage and Handling Type
Low Value
High Value
Unit of Measure
Special Storage Conditions
Device Packaged as Sterile
Requires Sterilization Prior to Use
Sterilization Method

Implementation timeline for FDA UDI

- Class III licensed under the Public Health Service Act (PHS Act)
  - Implantable, life-supporting, and life-sustaining devices
    - Class III (Used more than once and reprocessed before each use => DM)
      Class II
      Class II Stand-Alone Software
      - Class II (Used more than once and reprocessed before each use => DM)
        Class I (or unclassified)
        Class I Stand-Alone Software
        - Class I (or unclassified) (Used more than once and reprocessed before each use => DM)

UDI – A multidisciplinary task



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Recommendations for next steps

1. Get management commitment, manage any resource limitations.
2. Assign project resources. Understand the need for a team work.
3. Learn the UDI requirements.
4. Gap Analysis
5. Strategic Plan, Create Project plan, Quality plan, Checklists
6. Identify responsible functions. Assign resources and manage any resource limitations.
7. Get personnel trained
8. Assign adequate timelines for transition

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GUDID

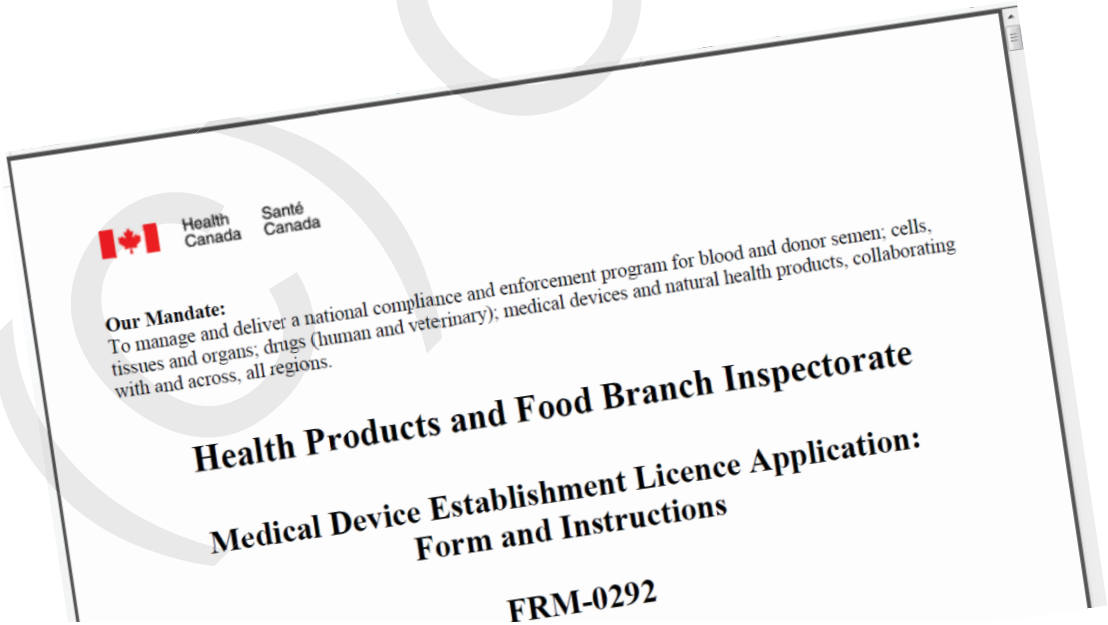
1. Acquire all the relevant data from various sources and documents.
2. Confirm data with responsible departments.
3. Submit data to GUDID
4. Wait for the acknowledgement of acceptance……
5. Maintenance throughout product lifecycle.

Coming requirements - EU

- European Commissioners published recommendations for an EU-wide Unique Device Identification (UDI) system in 2013.
- EUDAMED European Databank on Medical Devices
- Enhanced requirements for traceability! ” one-step-up/one-step-down" approach.

Coming requirements - Canada

Health Canada says they will follow the International Medical Device Regulators Forum (IMDRF) guideline and not plan to add any additional requirements “at this time” .



Health Canada Santé Canada

Our Mandate:
To manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across, all regions.

Health Products and Food Branch Inspectorate

Medical Device Establishment Licence Application: Form and Instructions

FRM-0292

Coming requirements

- Australia closely watches what happens in the US as does Brazil.
- China has a local UDI system for pharmaceuticals. Not clear if this will be used for medical devices or they will use the GS1 standard.
- Japan has already implemented the GS1 product identifiers. They have a database with this information and plan to use it as the UDI database
- Turkey has a UDI database already in place. Similar to the IMDRF-requirements.
- Korea are in the process of considering the outline of their UDI regulations.

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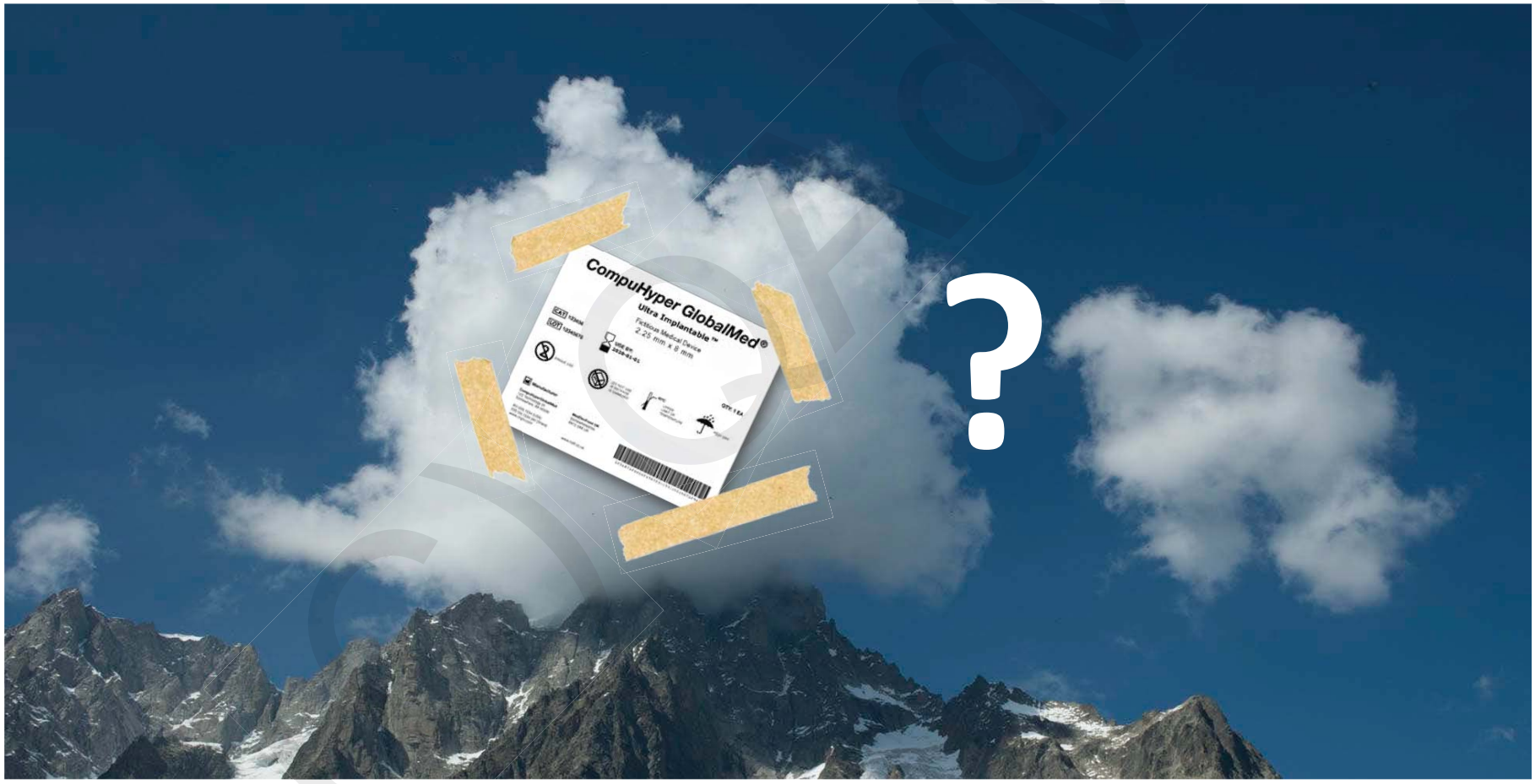
Software as a Medical Device



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Software as a Medical Device

21 CFR 801.50

Labeling requirements for stand-alone software

(1) An easily readable plain-text statement displayed whenever the software is started, and/or

(2) An easily readable plain-text statement displayed through a menu command (e.g., an ‘‘About * * *’’ command).

and/or

Software as a Medical Device

Device Identifier (DI)	**Production Identifier (PI)**
Company + product	Version number coded as batch number For example, version 1.2.3 =
(01)XXXXXXXXXXXXX	**(10)001002003**

Software as a Medical Device

Packaged software still needs a UDI label

QAdvis can support you with UDI roll-out

Services

- UDI-Coach for management
- UDI readiness – Gap analysis
- Hands-on guidance on worldwide UDI requirements
- Setup of local UDI database
- Validation of local UDI database

- Courses and Training

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Questions & Answers

Thank You!

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