

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 Oriol 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

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:

- **Device Identifier**
 - Identifies the model of the device and the manufacturer.
 - Each level of the package requires a different UDI
- **Production Identifier**
 - 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>

$$\text{UDI} = \text{DI} + \text{PI}$$

Machine
readable
format



Device Identifier (DI)

Production Identifier (PI)

Human
readable
format

6F
(2.50 mm)

Do not use if package is damaged

STERILE EO

Blanks, non-potassium unless package opened or damaged

Orbiter Large Curve

3 Easy-Mate®
8

Cable

Electrode Width
2 mm 2 mm

Electrode Spacing
2 mm
9 mm
2 mm

110 mm

No. of Electrodes
24

Caution

Do Not Reuse

Do Not Autoclave

Biological Risk

Consult Instructions for Use

LOT

XXXXXXXX

Use by

2016-01

REF

242406

REF 242406 LOT XXXXXXXX

REF 242406 LOT XXXXXXXX

Manufacturer:
Bard Electrophysiology Division
Bard, Bard Inc.
35 Technology Drive
Lanett, AL 36043 (U.S.A.)
800-637-9724 (All others)
978-441-4030
www.credent.com
1-800-991-9119 / Fax: 978-441-3009

Bard Limited
Cranney UK RH-11 989P

Keep Dry

Upper Limit of Temperature

Special Information may be followed

CE 0086

Contents



CompuHyper GlobalMed®

Ultra Implantable™

Fictitious Medical Device
2.25 mm x 8 mm

CAT 123456
LOT 12345678

USE BY:
2020-01-01

QTY: 1 EA

SINGLE USE

DO NOT USE IF PACKAGE IS DAMAGED

45°C
UPPER LIMIT OF TEMPERATURE

KEEP DRY

Manufacturer

CompuHyperGlobalMed
123 Technology Dr
Somewhere, XX 00000
800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com

MedDevFront UK
Somewhereshire
XX12 3XX UK

www.mdf.co.uk



123456789012345678901234567890

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



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

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) <ul style="list-style-type: none">• Expiration Date AI(17) - e.g. 141120• Lot/Batch AI(10) - e.g. 1234AB• Serial Number AI(21) - e.g. 12345XYZ
<i>Production Identifier data will vary by medical device type and manufacturer current practice.</i>	
DI + PI = UDI	GTIN or GTIN + AI(s) = UDI

Package levels

Each designated package level must have its own DI.



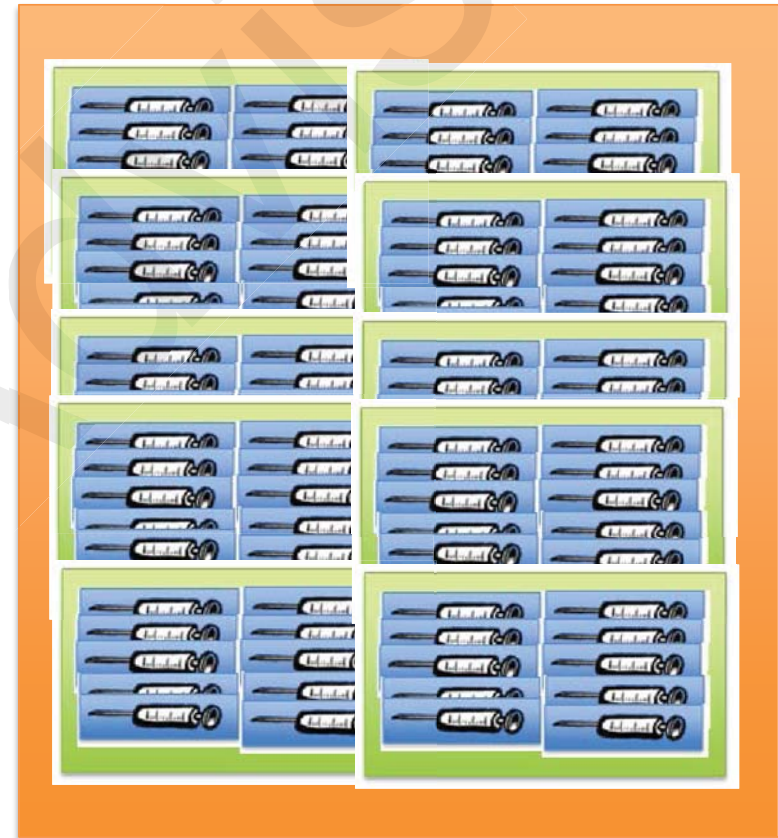
Base package
= 1 Syringe

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)

NIH U.S. NATIONAL LIBRARY OF MEDICINE

AccessGUDID IDENTIFY YOUR MEDICAL DEVICE

AccessGUDID is in beta!
Contact us with your comments and suggestions for the site.

FDA TOOLS AND RESOURCES

Enter Device Identifier, Name, or Company

ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. We anticipate the release of additional web services for testing by the end of 2015. Please see the [API Documentation](#) for more information.

[MORE INFO](#)
[ABOUT UDI](#)
[ABOUT GUDID](#)

NEWS

[AccessGUDID News](#)

Posted: December 1, 2015
AccessGUDID changing to HTTPS

DOWNLOAD

[Download Data](#)

Download the latest full releases and update files provided to the NLM by the FDA.

API

[API Documentation](#)

Resources for application developers to get the most out of AccessGUDID.

HELP

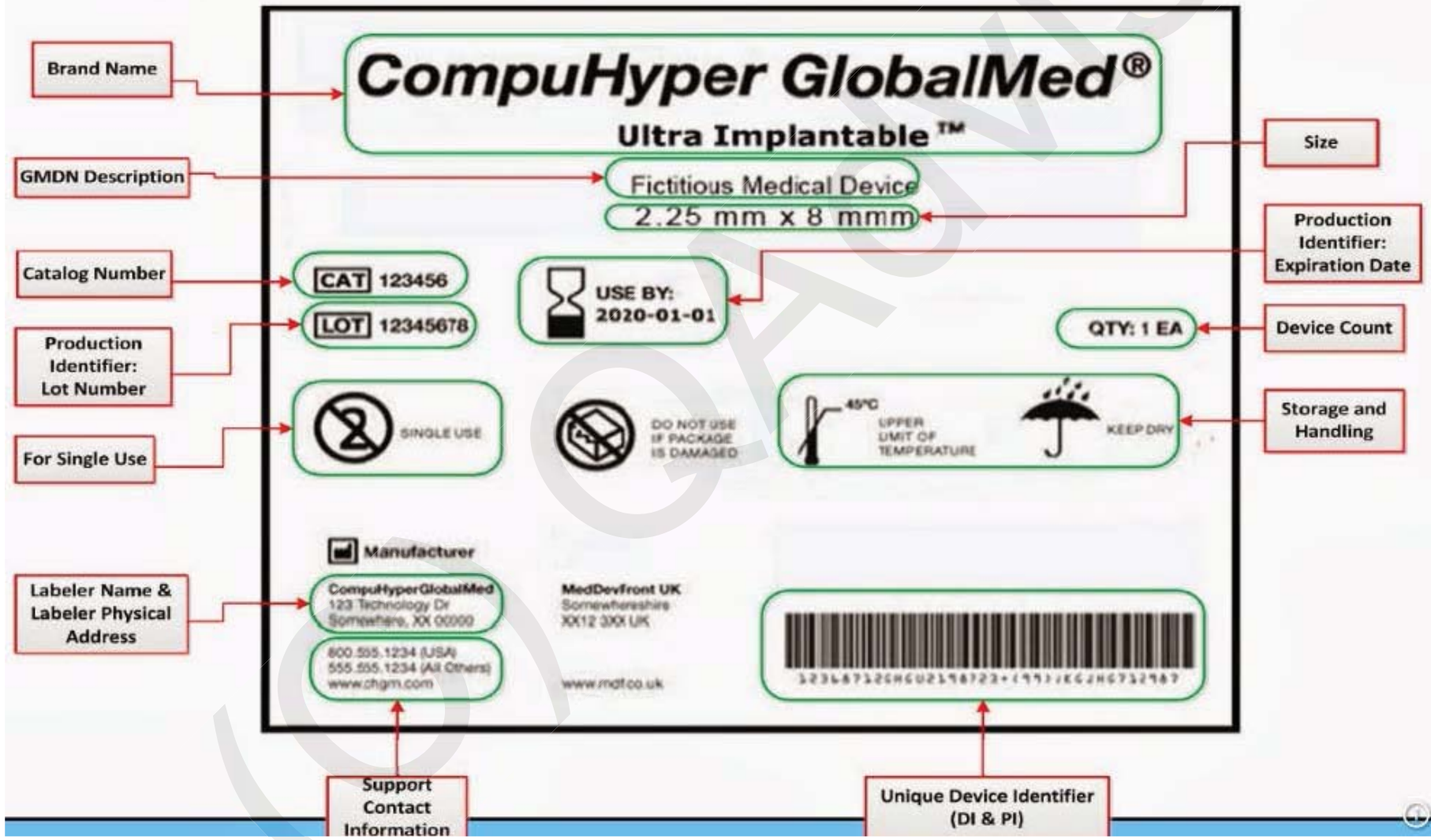
[Help using AccessGUDID](#)

[Searching AccessGUDID](#)
[Downloading Release Files](#)
[NLM Web Guidelines](#)
[Still Need Help?](#)

FDA TOOLS AND RESOURCES

[FDA UDI Home](#)
[FDA Medical Devices Home](#)

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	Secondary DI Number	Name
Primary DI Number	Package DI	Definition
Device Count	Package DI Number	For Single-Use
Unit of Use DI Number	Quantity per Package	Lot or Batch Number
Labeler DUNS Number ^	Contains DI Package	Manufacturing Date
Company Name	Package Type ^	Serial Number
Company Physical Address ^	Package Discontinue Date	Expiration Date
Brand Name	Package Status	Donation Identification Number
Version or Model	Customer Contact Phone	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).
Catalog Number	Customer Contact Email	Device labeled as "Not made with natural rubber latex"
Device Description	Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Prescription Use (Rx)
DI Record Publish Date	Kit	Over the Counter (OTC)
Commercial Distribution End Date	Combination Product	What MRI safety information does the labeling contain?
Commercial Distribution Status	Device Exempt from Premarket Submission	Size Type
Direct Marking (DM)	FDA Premarket Submission Number	Size Value
Device Subject to Direct Marking (DM), but Exempt	Supplement Number	Size Unit of Measure
DM DI Different from Primary DI	Product Code	Size Type Text
DM DI Number	Product Code Name	Storage and Handling Type
Secondary DI	FDA Listing Number ^	Low Value
Issuing Agency	Code ^	High Value
		Unit of Measure
		Special Storage Conditions
		Device Packaged as Sterile
		Requires Sterilization Prior to Use
		Sterilization Method

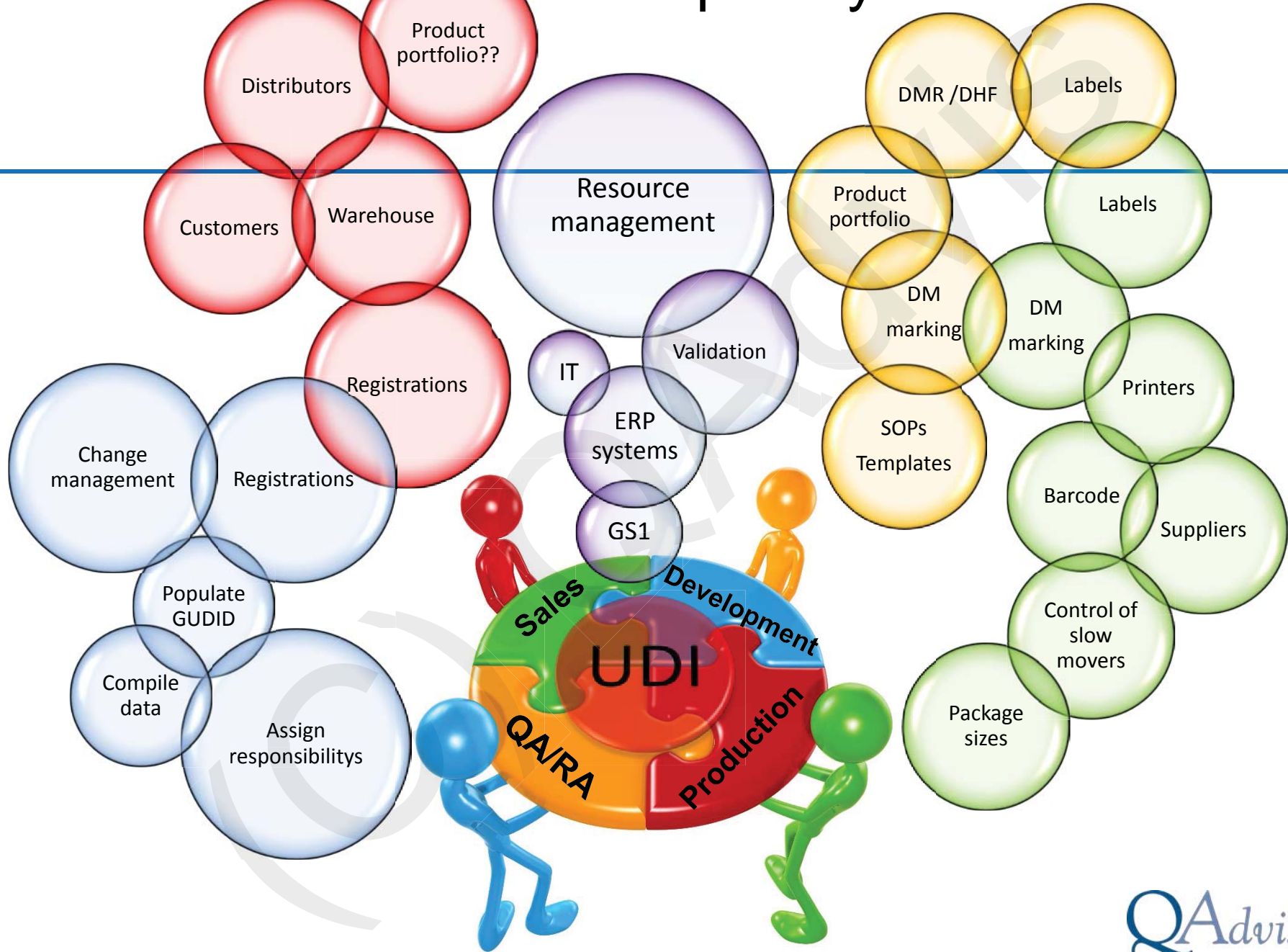
Implementation timeline for FDA UDI

September 24



- 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





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

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



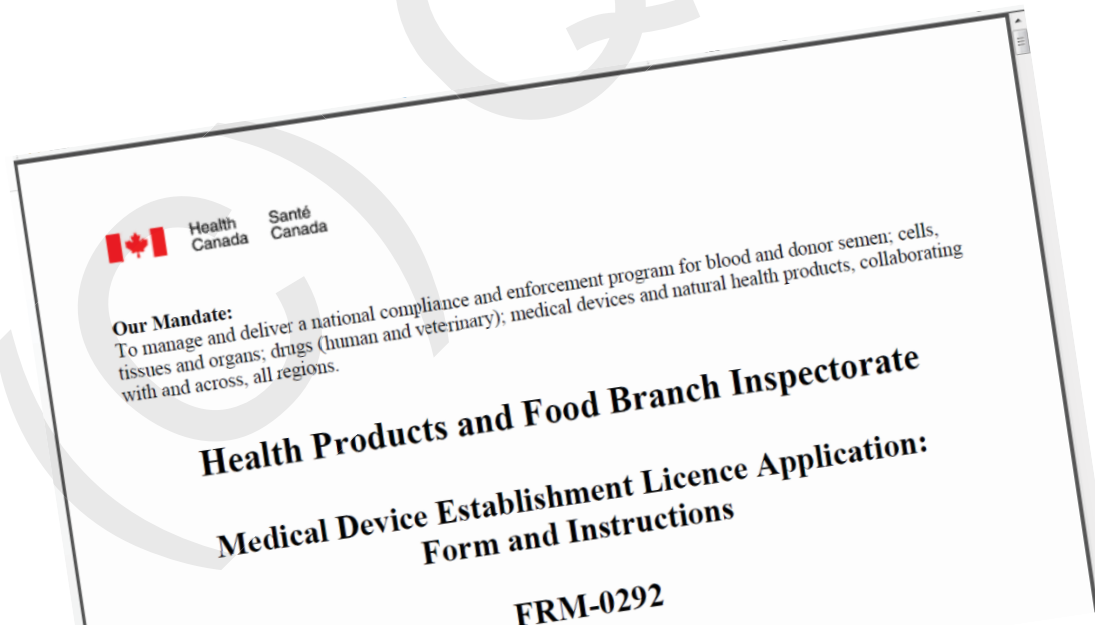
- European Commissioners published recommendations for an EU-wide Unique Device Identification (UDI) system in 2013.
- EUDAMED European Databank on Medical Devices
- Enhanced requirements for traceability! "one-step-up/one-step-down" approach.



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” .



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.

Software as a Medical Device



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).

A blue, multi-pointed starburst graphic with a white outline. Inside the starburst, the text "Startup splash screen" is written in bold black font, and "Version 1.2.3" is written in a smaller black font below it.

Startup splash screen
Version 1.2.3

and/or

A white rectangular box with a blue border. Inside the box, the text "About..." is written in bold black font at the top, and "Version 1.2.3" is written in a smaller black font below it.

About...

Version 1.2.3

Software as a Medical Device

Device Identifier (DI)

Company + product

(01)XXXXXXXXXXXXXXXX

Production Identifier (PI)

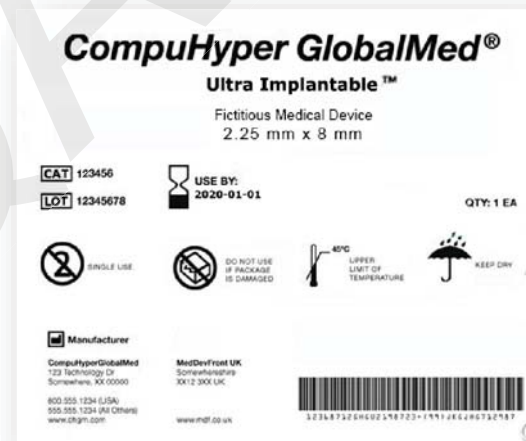
Version number coded as batch number

For example, version 1.2.3 =

(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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QAdvis

Questions & Answers



Thank You!

QAdvis