QTS Medical Device Outsourcing

How to Implement UDI With QTS, Your Outsourcing Partner.

Part I: Background of UDI and Preparing for Impacts

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Prominent Legal Disclaimer

What follows is based on the presenter's personal and QTS' collective knowledge regarding UDI requirements. QTS is not qualified, accredited nor competent to provide regulatory services or advice. The intent of this presentation is to share our interpretation and best practices with our Customer partners.

You are strongly encouraged to research and implement UDI in a manner supported by your Quality System(s) and Regulatory resources.

Unique Device Identification

- Final Rule issued as revisions to 21CFR Parts 16 and various 8xx, including:
  - 801 Labeling
  - Various reporting sections
  - Part 830 added

Unique Device Identification

- § 801.55 Request for Exemption
  - This section outlines the exemption and alternative process.
  - Class III (only) may request a one year extension.

Unique Device Identification

- § 801.3 Definitions [new section]
  - **AIDC**: any technology that conveys the UDI [to] computer system

Strictly speaking, labeled UDI not limited to "barcodes".

Unique Device Identification

- § 801.3 Definitions
  - **Labeler**: … who causes the label to be applied to a device

You (the QTS customer) are the Labeler

Unique Device Identification

- § 801.30 Definitions
  - **Issuing Agency**: [An] organization accredited by FDA to operate a system for the issuance of unique device identifiers.

Unique Device Identification

- § 801.3 Definitions
  - **Unique Device Identifier (UDI)**: Composed of:
    1) Device Identifier; and
    2) Production Identifier(s) (when included on the label)
       i. Lot
       ii. Serial
       iii. Exp. Date
       iv. Date of Mfg

Unique Device Identification

- § 801.3 Definitions

  Expiration Date: "…the date by which [the] device must or should be used"

Why is FDA discussing Dates in a UDI standard?

Format of Dates

- Per new § 801.18, this is the **ONLY** allowed format of (printed label) dates.

YYYY-MM-DD

YYYY-MM-DD

Not the same format as the barcoded date(s)

Implementation Timelines

For the following timelines, note these specific exemptions per § 801.30

- 3-year grandfather clause for existing labeled Finished Goods; from applicable compliance date.
- Class I that carry a UPC code
- Class I GMP-exempt devices
- Individual single-use, not-implantable devices [SUDs]
- *Contents* of convenience kits
- Shipper labels
- Custom, IDE or intended for export
- *and a few more…*

Timeline

[1 Year after publication]
September 24, 2014

Class III Devices and Software

- Labels and Packages to bear a UDI
- Date(s) formatted as YYYY-MM-DD
- GUDID data submitted

Timeline

[2 Years after publication]
September 24, 2015

Implantable, Life-supporting and Life-sustaining Devices and Software

- Labels and Packages to bear a UDI
- Date(s) formatted as YYYY-MM-DD
- GUDID data submitted

Timeline

[3 Years after publication]
September 24, 2016

Class II Devices and Software

- Labels and Packages to bear a UDI
- Date(s) formatted as YYYY-MM-DD
- GUDID data submitted

Timeline

[5 Years after publication]
September 24, 2018

All Devices and Software

Class I and unclassified devices

- Labels and Packages to bear a UDI
- Date(s) formatted as YYYY-MM-DD
- GUDID data submitted

Location and Form of UDI *§ 801.40*

UDI Appear on the Device Label(s)

"label" per § 201 (k); "... immediate container"

UDI appears as "easily readable plain-text" and AIDC technology.

UDI must contain a Device Identifier

UDI must replicate Production Identifier(s)

Complete UDI
[using GS1 standard]

Device Identifier + Production Identifiers

(01) GTIN

(17) Exp. Date x(YYMMDD)

(10) Lot Number

"easily readable plain-text" and AIDC technology.

Creating Device Identifiers | Which Issuing Agency?

§ 830.100

GS1 [GTIN] [UPN] (ICCBBA)

- ISO 15418
- Annual fee
- ⇧$ = ⇧Capacity
- Broad supply chain acceptance

HIBCC

- ANSI/HIBC 2.4
- One time expense
- "unlimited" capacity
- alpha-numeric; UPN directly related to REF
- Supports SN & Lot in 2D only
- Supports Date of Mfg. in 2D only

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

- Device Identifiers are "built", by you, per the requirements defined by your Issuing Agency
- Device Identifiers incorporate:
  i. Identification of the Labeler
  ii. An single digit indication of the quantity contained in the labeled package.
  iii. A reference to Model or version of the Device
  iv. Checksum [GS1 only]

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

i. Identification of the Labeler

Example

GS1:	0890091001
HIBCC:	M555

This alpha-numeric string is uniquely associated with your organization. But that's all you get for your money; you have to "build" the actual DI yourself.

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

ii. A single digit indication of the quantity contained in the labeled package.

Qty indicator is "level" 0-9, not actual quantity contained (!).
Generally, zero [0] or one [1] is employed for unit of use.

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

iii. A reference to Model or version of the Device.

This is an internal, on-going obligation. GS1 shown; the "cross-reference" between DI and Model Numbers may not be "one and done".

Spec.	Model	X-Ref
25-9800	TR1-2200	01
25-8505	TR1-2309	02
25-2202	TR1-2301	03
25-2201	TR1-2700	46

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

iv. Calculated checksum [GS1 only]

- Is used for automatic verification of the decoded message.
- This trailing character is calculated from the preceding letters and numbers.
- Since the DI is not variable, the checksum is static.

Complete DI
[using GS1 standard]

Device Identifier

0	Pkg Level
0890091001	Surgical, Inc
46	TR1-2700
4	checksum

Complete DI
[using GS1 standard]

Device Identifier

0	Pkg Level
0890091001	Surgical, Inc
46	TRI-2700
4	checksum

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

GS1 [GTIN-14] Example of Device Identifiers

Spec.	REF	GTIN-14
25-9800	TR1-2200	0 0890091001 01 3
25-8505	TR1-2309	0 0890091001 02 0
25-2202	TR1-2301	0 0890091001 03 7
25-2201	TR1-2700	0 0890091001 46 4

The development and control of these "static" DI is a customer obligation.

UDI Implementation

Creating Device Identifiers

§ 801.3, 830.3

HIBC Example of Device Identifiers

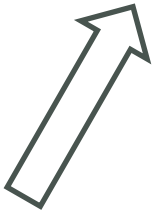
Spec.	REF	UPN
25-9800	TR1-2200	M555 TR12200 0
25-8505	TR1-2309	M555 TR12309 0
25-2202	TR1-2301	M555 TR12301 0
25-2201	TR1-2201	M555 TR12309 0

The development and control of these "static" DI is a customer obligation.

UDI Implementation

DI checksums for GS1, revisited

REF	GTIN-14	
TR1-2200	0 0890091001 01	3
TR1-2309	0 0890091001 02	0
TR1-2301	0 0890091001 03	7
TR1-2700	0 0890091001 46	4



Calculated up-front and become part of the static DI.

Checksum algebra is convoluted, suggest online tools, spreadsheet or other "automated" solutions.

UDI Implementation
Creating Device Identifiers
§ 801.3, 830.3

So, how static are these DI anyway?

§ 830.40; Use and discontinuation* of a DI

§ 830.50; Changes that require use of a new identifier (i.e. "change triggers")

** UDI may not be reused or reassigned*
GS1 customers also see, "Healthcare GTIN Allocation Rules"

Uses for the Device Identifier

- "1st Half" of any UDI
- Key field for FDA's GUDID (database) *§ 830.310(b)(1)*
- Periodic reporting *§ 814.84*
- Post-market submissions *§ 822.9*

Complete UDI
[using GS1 standard]

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Device Identifier + Production Identifiers

UDI Implementation

Production Identifiers *§ 801.3, 830.3*

These are Lot-specific data, generally assigned by QTS. In part:

A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

UDI Implementation

Production Identifiers *§ 801.3, 830.3*

a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

[HIBC: Accommodates Date of Mfg, and/or Lot + SN in 2D barcode only]

UDI Implementation

Production Identifiers *§ 801.3, 830.3*

Regarding date format in Production Identifiers, the structure is defined by the Issuing Agency, and in all cases are a different format than the "labeled" date.

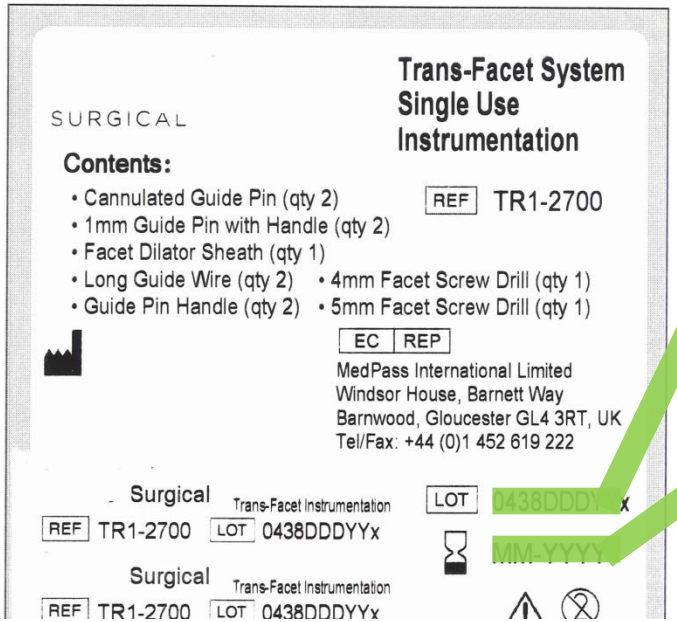
YYYY-MM-DD

GS1 barcoded format: **YYMMDD**

HIBC: **YYMMDD**, MMDDYY and five other choices

UDI Implementation

Production Identifiers *§ 801.3, 830.3*



LOT 043814314A

2018-04-15

Complete UDI
[using GS1 standard]

Device Identifier (GTIN-14) + Production Identifiers

(01) GTIN For Model TR1-2700, unit of use

(17) Exp. Date x(YYMMDD)

(10) Lot Number

Complete UDI
[using GS1 standard]

- UDI: a combination of the static Device Identifier, supplied by the Customer, and one or more Production Identifiers, typically assigned by QTS
- This alphanumeric string, structured per the Issuing Agency's standard, is called the *Message*.
- The barcode itself is the AIDC, formatted per ISO standards and rendered on-demand by QTS' validated label printing system.

Uses for the UDI

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Reporting

- Adverse Event *§ 803.32,33,42,52*
- Corrections and Removals *§ 806.10,20*
- Recalls *§ 810.10*
- DHR *§ 820.184*
- Complaint Files *§ 820.198*
- Servicing *§ 820.200*
- Device Tracking *§ 821.25,30*

The Manufacturer's Other UDI Obligation

- There exists a public database, called the GUDID, sponsored and controlled by FDA. § 830.310 - .360
- This data repository is considered an extension of your labeling and requires the same care and controls as the label content itself.
- This data, keyed by your (self-assigned) DIs, contains dozens of Device attributes, including:
  - Size
  - GMDN term
  - Listing Number
  - Corporate information

Permanent Marking [DPM] § 801.45

If the device is intended to be used more than once and intended to be reprocessed before each use

- Marked UDI can be different than the labeled UDI
- Marked UDI can be *either or both*:
  1. "Easily readable plain-text"
  2. AIDC technology

- If you self-exempt from DPM, the rationale must be documented within the design history file; exemption is not directly "approved" by FDA.

Timeline for Direct Part Marking

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If the device is intended to be used more than once and intended to be reprocessed before each use

Life-supporting and Life-sustaining Devices

September 24, 2015 [2 years after publication]

Class III Devices

September 24, 2016 [3 years after publication]

Class II Devices

September 24, 2018 [5 years after publication]

Class I and unclassified Devices

September 24, 2020 [7 years after publication]

In Summary

- There are significant compliance obligations on the part of *QTS' **Customers***, including
  - Engaging with an FDA-accredited Issuing Agency
  - Assignment and management of Device Identifiers
  - Uploading and maintenance of the GUDID attributes
  - Communicating DIs to QTS
  - Incorporating resultant UDIs in records.
- QTS' role in creating, verifying and controlling UDI will be covered in Part 2.

Additional Information

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- www.fda.gov/udi
- www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
- www.hibcc.org/udi-resources/

Questions?

QTS Medical Device Outsourcing

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