QTS Medical Device Outsourcing

How to Implement UDI With QTS, Your Outsourcing Partner.

Part II: Implementation of UDI

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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.

Scope

- Scope of discussion
  - Labeling
  - Supply chain transactions
  - Records and Certs
  - [DPM]
- Semi-Scoped
  - Creation and maintenance of DIs
- Out of Scope
  - GUDID upload and maintenance
  - Changes to Customer's Quality System

(Unique) Device Identification

Recall:

- Device Identifier [DI]
  - "Static" value, assigned by Labeler (you)
  - Combination of
    - Manufacturer ID
    - Catalog/REF number; reference or abstract
    - Packaging level
    - Checksum [GS1 only]
- UDI
  - DI + Production Identifiers [PI]
  - Used in DHR and Reporting

Creating Device Identifiers

Regarding your choice of Issuing Agency, QTS has direct experience with

- GS1
- HIBC

ICCBBA, [ISBT 128], associated with Medical Products of Human Origin, is another currently accredited issuing agency.

GS1 "Capacity" Limitation

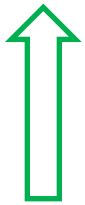
REF	GTIN-14
TR1-2200	0 0890091001 01 3
TR1-2309	0 0890091001 02 0
TR1-2301	0 0890091001 03 7
TR1-2700	0 0890091001 46 4

1 + **10** + 2 + 1 = 14

Note that DIs cannot be reused (true of HIBC as well)

DI Creation – GS1 Example

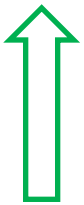
REF	GTIN-14
TR1-2200	0 0890091001 01 3
TR1-2309	0 0890091001 02 0
TR1-2301	0 0890091001 03 7
TR1-2700	0 0890091001 46 4



Packaging Level, not Qty Contained !
Use zero (0) or one (1) for Unit of Use

DI Creation – HIBC Example

REF	UPN
TR1-2200	M555 TR12200 0
TR1-2309	M555 TR12309 0
TR1-2301	M555 TR12301 0
TR1-2700	M555 TR12700 0



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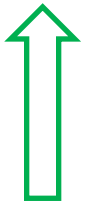
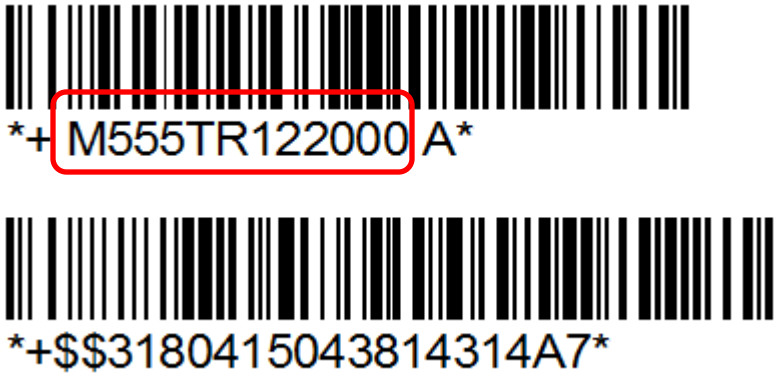


For GS1 only, checksum is actually a static part of Device Identifier; calculated and controlled "up-front".

DI Creation – HIBC Example

REF	"+" & UPN & checksum
TR1-2200	+ M555 TR12200 0 ~~A~~
TR1-2309	+ M555 TR12309 0 ~~K~~
TR1-2301	+ M555 TR12301 0 ~~C~~
TR1-2700	+ M555 TR12700 0 ~~B~~



Production Identifier(s)

Examples of typical QTS-Assigned Production Identifiers

- Lot Number 

- Serial Number 

- Expiration Date 
- Date of Manufacture 

Date Format

Recall the new mandatory Date format:

 **YYYY-MM-DD**

FDA definition § 801.3

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

ISO 15223-1 (2012)

"…device should not be used after the end of the [date] shown"

Date Format

YYYY-MM-DD

For Expiration Date,

- Let QTS manage based on date multiplier,
- consider arbitrarily assigning day 01 or 28 in the expiring month.

Date Format

Regarding Date of Manufacture (if present)

 **YYYY-MM-DD**

- FDA says Date of Mfg *is* a PI § 801.3

  "The date a specific device was manufactured is a [variable] portion of a UDI *[when] included on the label"*

Date Format

Regarding Date of Manufacture (if present)

 **YYYY-MM-DD**

- The GS1 AIDC will be relatively larger/longer
- HIBC solution is limited to 2D barcodes

Production Identifier(s)

Examples of typical QTS-Assigned Production Identifiers

- Lot Number 

- Serial Number 

- Expiration Date 
- Date of Manufacture 

HIBC Limitations re. PIs

If your label contains both, HIBC supports *only* in a 2D barcode:

- Lot Number LOT
- Serial Number SN

Re. Date of Manufacture, 

HIBC supports *only* in a 2D barcode.

Complete UDI

[using GS1 standard]

Device Identifier + **Production Identifiers**

(01) GTIN

(17) Exp. Date (YYMMDD)

(10) Lot Number

Complete UDI
[using HIBC standard]

Device Identifier + **Production Identifiers**

(+) UPN / ($$3) Exp. Date (YYMMDD)

Lot Number

Complete UDI
[using GS1 standard]

(01) 12345678901234
(17) 180415
(10) 043814314A
(11) 140415

Device Identifier + **Production Identifiers**

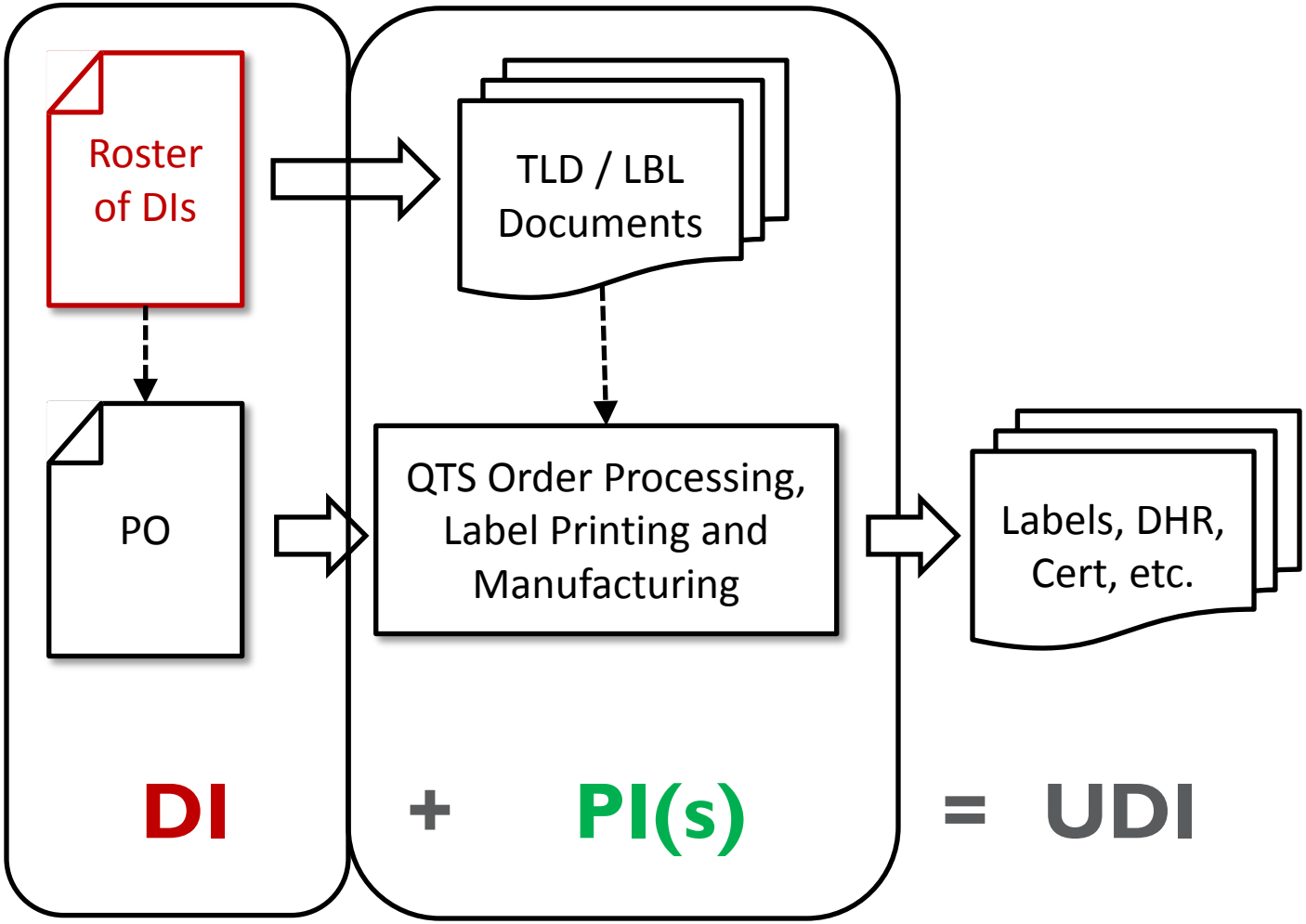
(01) GTIN

(17) Exp. Date (YYMMDD)

(10) Lot Number

(11) Date of Mfg. (YYMMDD)

Partnership in Creating UDI



Partnership in Creating UDI

- QTS recommends no changes in how PI are calculated or assigned
- QTS relies on customer for accurate DIs, via specification, which we incorporate into our LBL document
- Customer may choose to order by DI

DI + PI(s) = UDI

Adding UDI to Labeling

- QTS can render any of the set of 1D (linear) or 2D barcodes per the applicable standard.
- QTS relies on validated label software and systems to render these UDI on-the-fly.
- Controls (AIDC, size, position, which PIs) are incorporated into your LBL document

UDI Design Considerations

- Labels must display both AIDC and "easily readable plain-text"
  (But, which Labels?)
- Be aware of label copy's "Prominence" requirement per § 801.15
- In a pinch, GS1 and HIBC allow stacked 1D code pairs

UDI Size Considerations

- GS1 and HIBC each define (strongly recommend?) minimum barcode size, in terms of the "element" dimension.

  (ex: HIBC 1D barcode,
  X-dim ≥ 0.17mm)

Engage QTS Engineering for layout and barcode compliance requirements.

UDI Validation & Verification

- The UDI message, the alphanumeric string structured per either GS1 or HIBC standard, is *Validated*.
- The AIDC carrier (barcode) is "built" per ISO requirements, and is *Verified*.

For both, the rules and acceptance criteria are set by the Issuing Agency, not *directly by FDA.*

UDI Message Validation

- The UDI message can be validated by visual review, using the GS1 or HIBC standards.
- The checksum included in the GS1 DI can be validated using on-line tools provided by GS1.

ANSI/HIBC 2.4 - 2013; *The Health Industry Supplier Labeling Standard*

GS1 Version 14, Jan-2014; *GS1 General Specifications*

UDI Message Validation

QTS has extensive experience formulating compliant UDI messages using our Quality System documents and controlled labeling software.

UDI AIDC Verification

- The barcode, on the other hand, cannot be visually qualified or approved. Modern barcodes are no longer like Morse code.
- This important task requires a purpose-built optical tool calibrated to traceable standards.
- The ideal verifier serves both roles; validating the message while verifying the AIDC.

UDI AIDC Verification

QTS' Verifiers are able to validate GS1 and HIBC messages while verifying printed linear and 2D barcodes.

Use & Communication of UDI

- UDI will be captured at Label printing, and recorded within the QTS DHR
- *QTS will communicate UDI via packing slip or Cert.*

Summary of UDI Impacts within QTS

UDI integration is most evident within *existing* label creation, control, printing and reconciliation processes.

- QTS uses validated label software and printing systems. These systems are controlled by Documentation, and validated to "build" compliant AIDC.
- QTS maintains calibrated Verifiers at label printing stations.

Summary of UDI Impacts within QTS

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- In label production, QTS verifies printer settings, and controls for material variability, via spot-check verifications throughout the printing run.
- Retains of printed labels (and assigned UDI) are included within the QTS DHR

UDI Roadmap
1 of 2

Customer

- Select and engage with Issuing Agency [GS1 or HIBC]
- Create system to assign, control and maintain Device Identifiers
  - Packaging Levels
  - Checksums for GS1 GTIN-14
  - Change-trigger evaluation
- Document and communicate DIs to QTS for label development and QTS' documentation

UDI Roadmap 2 of 2

QTS

- AIDC development and placement
- Creation of UDI messages
- Verification and Validation of UDI

Customer

- Accommodate the GUDID process within your QS
- Determine the use of DI and UDI in supply chain activities
    - Contracts and Purchase Orders
    - Recording of "received" UDI
- Ensure compliance via specification and audit

Additional Information

QTS Medical Device Outsourcing

- 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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