

Preliminary Implementation Requirements

1. A comprehensive commitment to compliance:

- a. UDI is a required label element in the US (FDA) Market.
Note: This is just as important as date of expiration, catalog number, etc.
- b. Direct Part Marking (DPM) is a UDI requirement for re-usable and re-processed devices.
- c. Creation and maintenance of UDI attributes in the public database (GUDID); this is not simply a one-time submission, it implies an active and ongoing database administration activity.
- d. Compliance to the above (Items 1. a - c) implies an ongoing commitment.
- e. All of the above (Items 1. a - d) must be fully incorporated into your Quality System.

Manufacturer Requirement

2. Partner with a UDI "Accredited Standard Organization"

- a. Choose from three available Accredited Standard Organizations.

These Accredited Standards vary by:

- Initial and ongoing membership fees.
- Acceptance and integration with existing supply chain.
- Scalability for change.

Research is required for this step.

- b. Purchase Unique Identification Prefix from your selected Accredited Standard.

Research is required for this step. This decision should include executive level input. This will set direction for all tactics to follow.

- c. Implement in Quality System, including: Risk Management, Qualification, Quality Assurance, etc.

Manufacturer Requirement

System Implementation

Manufacturer Requirement

(QTS can consult on customer behalf for item 1. a)

- 1. Create a Quality System procedure (controlled process) for the assignment and maintenance of device identifiers for your products. Create a device identifier log.

This scope of this process includes:

- a. Initial assignment of device identifier(s).
- b. Evaluation of "change triggers" that may dictate an assignment of a new identifier.
- c. Assignment of identifier(s) for new products.
- d. Administration and maintenance of device attributes in the GUDID.

- 2. Make initial assignment of UDIs.

- a. Create a mapping of catalog numbers to device identifiers.

Manufacturer Requirement
(QTS can consult
on customer behalf)

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System Implementation (Cont.)

- b. Gather your related product data.
- c. Identify triggers for when to change the device IDs.

Manufacturer Requirement
(QTS can consult on customer behalf)

3. Determine which production identifiers to include within your UDI.

When these identifiers are expressed on your label, they also need to be incorporated into UDI.

4. Determine the internal and external attribute data for the UDI database.

Manufacturer Requirement

5. Develop and implement formal acceptance criteria for printed UDI and DPM. Quality System Procedures establish the structure and requirements for printed barcodes and DPM.

Manufacturer Adopts QTS Criteria,
which incorporates regulations.

6. If necessary, develop and implement formal controls within the labeling process.

Manufacturer Requirement

Actionable Tasks for Implementation

Labeling and Marking

QTS Capability
(Items 1-3, with exception for study
safety and efficacy)

1. Evaluate current hardware (printers), software (label printing and rendering software) and consumables (label stock and printing media).

Do these support the printing of barcodes (linear or 2D)?

2. Develop and/or implement UDI within a controlled label system, this may include verification and validation of imprinted UDI.

3. The above also applies to Direct Part Marking (DPM).

- a. Have you evaluated and safety or efficacy concerns related to physical part marking?
- b. Do you have necessary software and equipment to create UDI marking on devices?
(ex. laser etching or dot peening, or other)

Database Implementation

Manufacturer Requirement

1. Upload relevant device information to the GUDID.

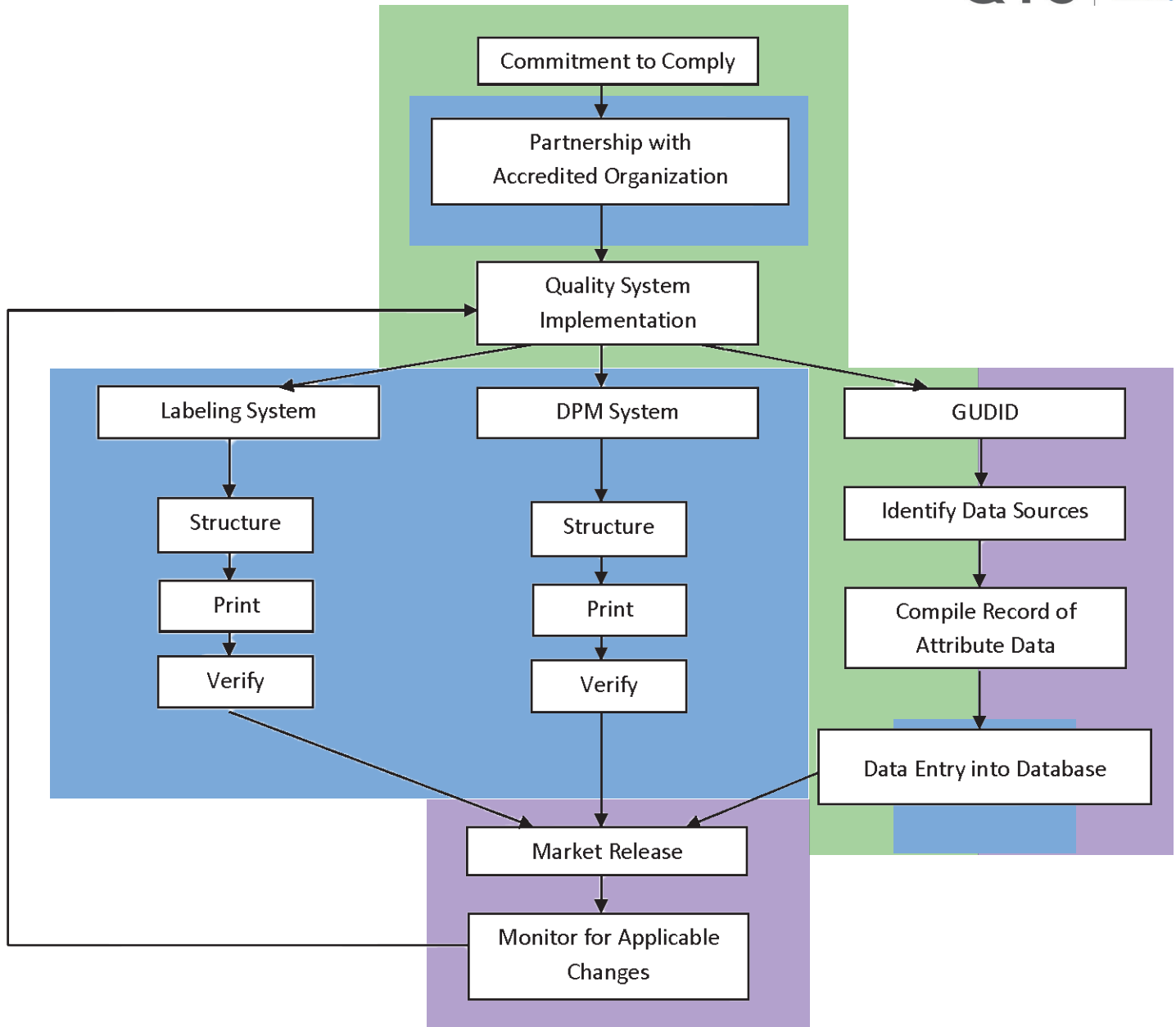
Quality System to provide instructions on where to get this information (data source), what to do with the data, and how to react when the data changes.




Notes:

- Both package barcodes and database updates are required for market release.
- Any changes in your device? Go back to top for implementation due to changes.
- Other change triggers may require updates.

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Unique Device Identification (UDI) Best Practices for Implementation



-  Manufacturer
-  QTS Involvement
-  Third Party Resources may be involved

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