11 FDA Unique Device Identification Verification and Validation

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Introduction

The Unique Device Identification (UDI) system from the Food and Drug Administration (FDA) aims to substantially reduce existing obstacles to the adequate identification of medical devices used in the US. By making it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the system could reduce medical errors that result from the misidentification of a device or confusion concerning its appropriate use. The identification system allows for more accurate reporting of adverse events by making it easier to identify the device before submitting a report.[1,2]

Concern over patient safety was the primary driver for the FDA to create its system. The mandate for the agency to develop a UDI system was required as part of the Food and Drug Administration Amendments Act of 2007. The final rule was published in September 2013 along with draft guidance on Global Unique Device Identification Database (GUDID). Subsequently, the FDA released its final GUDID guidance in June 2014.[3,4] The rule is intended to address concerns by healthcare providers and regulatory agencies about the lack of transparency in the way manufacturers and distributors assign item numbers (identifiers) to medical devices. A manufacturer typically assigns a number to its device. A distributor often assigns its own different identifier before selling that same item to the ultimate user, or Manufacturer A and Manufacturer B use the same identifier for the same type of device or completely different items. This can confuse the end user, particularly related to reporting adverse events and product recalls. The UDI system is expected to help the FDA identify product problems more quickly, better target recalls, and improve patient safety. This chapter reviews the UDI system and the corresponding verification and validation (V&V) issues facing every device labeler. Device manufacturers will learn what steps are required to comply with the FDA's UDI regulation.

FDA's UDI Regulation—The Basics

Several key aspects of the UDI final rule, 21 CFR Part 830, must be understood if an organization is to implement this regulation. Reading the entire rule is highly recommended before starting down the path of implementation. This chapter outlines some key aspects.

What Does UDI Mean?

Critically, UDI serves two distinct but related purposes, and it is important to address both as part of the implementation. Firstly, UDI adequately identifies a device throughout the supply chain. Among many benefits, this helps to control devices as they move through distribution, supports stock management, and facilitates device recalls. Secondly, UDI is used to identify devices as they are used on, or implanted in, patients. The UDI is composed of two components—a device identifier (DI) and one or more production identifiers (PIs). The DI is a global unique identifier specific to a particular device, while PIs are a dynamic component and typically include one or more of these:

- Lot number
- Serial number
- Manufacturing date
- Expiration date

Together, the DI and PI make up the UDI.

Who is Responsible for Applying the UDI Label?

The FDA has identified the "labeler" as the person responsible for applying the UDI label, not necessarily the actual (physical) manufacturer of the device (e.g., an original equipment manufacturer [OEM]). The labeler is defined as the person who secures a label to a device and places the device into commercial distribution with the expectation that the label will not be replaced or modified in any way. Further, a person who replaces or substantially modifies the original label and then places the device into commercial distribution, with the expectation that the label will not be replaced or modified in any way, is also a labeler. Distributors who simply add their name and address to the package are not considered labelers under this definition. Private-label devices present a situation where the actual manufacturer or the brand name holder can be the labeler. This would be a business decision made jointly by the manufacturer and brand-name holder. The labeler also may be a specification developer, single-use device reprocessor, convenience kit assembler, repackager, or relabeler.

Is There a Required Date Format?

All human-readable dates (manufacturing date, expiration date, etc.) printed on labels must follow a YYYY-MM-DD format to harmonize with international standard ISO 8601:2004. The day is an absolute requirement. For example, 31 March 2025 must be presented as 2025-03-31. This requirement applies to all medical device classes that use dates on their labels, whether they are subject to UDI or not.

Which "Day" Date Should be Used?

The FDA did not stipulate the "day" of the month that a labeler should use on its device labels. If a company currently uses a "day" on its device, no change should be needed other than a possible format change. If the company does not use a "day," it is suggested the same day be used for all devices. Many companies use the last day of the month. A word of caution: If a company stipulates a specific shelf life from date of manufacture in the device submission, it may not be able to use the last day of the month strategy unless its clinical trials have proven the device has an effective shelf life longer than the one used on the labeling.

How Does a Company Obtain Labeler Identification?

The FDA has accredited three agencies to operate systems to issue identifiers to device labelers:

- GS1
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Bank Automation (ICCBBA)

GS1 and HIBCC are for medical devices, while ICCBBA is for medical products of human origin regulated as medical devices.

What Additional Information Must be Printed on the Device Label?

Medical devices must follow the labeling requirements detailed in 21 CFR Part 801[5] in addition to the new requirements per the UDI rule. Specifically, the regulation requires a UDI (DI plus PI) to be printed in easy-to-read plain text, and in automatic identification and data capture (AIDC) format on the device label. The AIDC format is dictated by the issuing agency. Information printed on labels also is dictated by other governmental bodies, such as the European Commission. A company may need to seek approval of any label changes from these other bodies, particularly if the changes are major.

Does UDI Impact Existing SOPs?

The FDA expects any standard operating procedure (SOP) changes made by a labeler to be compliant with the UDI regulation. The agency also expects labelers to treat UDI the same as any other Quality System Regulation (QSR) aspect.[6] **Table 11-1** shows the sections of the QSR and related regulations that were modified to include UDI requirements—from labeling to recalls, to postmarket surveillance plans. As part of the implementation plan, the labeler will need to include SOP updating as a key milestone.

How Should Data be Submitted to the GUDID?

There are two standard-based methods to submit data to the GUDID—structured input via an FDA web interface or the Health Level 7 Structured Product Labeling (HL7 SPL) process. HL7 SPL is an extensible markup language (XML) format and uses the FDA's Electronic Submissions Gateway (ESG) as the pathway for inputting data into GUDID. To submit data to GUDID, a company must first request a GUDID user account from the FDA. Data are submitted one record at a time for both methods. There is no batch process.[3,4]

What is GMDN?

Global Medical Device Nomenclature is an international naming system for medical devices. For GUDID, a GMDN Preferred Term (PT)

Table 11-1. UDI Impact on Existing Regulations

Part	Subpart	Section(s)	Conforming Amendments
801-Labeling	A	§801.18 (a)(b)	New date format YYYY-MM-DD
	B	New section	Adds labeling requirements for UDI
803-Med. Dev. Reporting	C	§803.32, §803.33; §803.42; §803.53	Adds UDI as requirement
806-Corrections & Removals	B	§806.10; §806.20	Adds UDI as requirement
810-Med. Dev. Recall	B	§810.10	Adds UDI as requirement
814-Premarket App.	E	§814.84	Adds UDI as requirement
820-Quality System	K	§820.120	Labeling inspection—added requirement to inspect UDI
	M	§820.184	Requires adding UDI or UPC to record
	M	§820.198	Requires including UDI or UPC in investigation report
	M	§820.200	Requires including UDI or UPC in service report
821-Tracing Requirements	B	§821.25	UDI to be provided to FDA when requested (single/multi-patient use)
	C	§821.30	Adds UDI as requirement
822-Postmarket Surveillance	C	§822.9	Adds DI to information to be provided

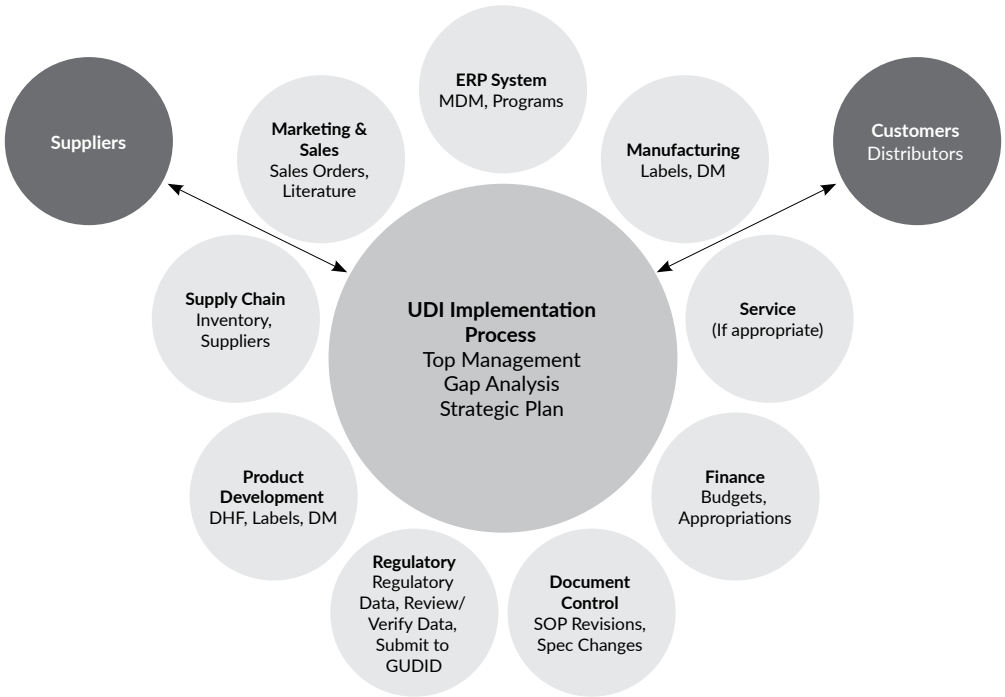
code must be entered. These codes are available from the GMDN Agency, either for free (up to 50 terms available under a basic license) or as part of a paid membership license (which offers a number of other benefits). A word of caution: As the GMDN agency continually adds and updates these codes, companies submitting data via HL7 SPL will need to subscribe to the GMDN Agency to gain access to these codes.[7]

Does V&V Need to be Planned During UDI Implementation?

Whether or not to include verification or validation in implementation planning is not a choice. At least one—preferably both—must be performed. V&V should be conducted at key implementation process points, e.g., during data compilation for GUDID submission, and for complaint-handling software, labeling software, and software for uploading DI records to GUDID. V&V's purpose is to determine whether the process is being implemented and functioning as expected. They should be included in the implementation plan as milestones. The responsible person(s) for each of these V&V milestones should sign off once a milestone has been achieved.[1,3]

Many more UDI rule facets will need to be understood to have any chance of a successful implementation. Companies often underestimate the time and resources needed for implementing and managing UDI. The more products a company has across multiple classes, the more resources will be needed; adding multiple sites increases the potential for not meeting compliance dates. A strong and knowledgeable implementation team is required to overcome the potential UDI implementation obstacles across a complex multisite organization. **Figure 11-1** shows organization departments that should actively participate in UDI implementation. Critical to successful UDI implementation is early buy-in from top management on UDI's importance to the organization. The organization's top management and all employees must

Figure 11-1. Organizational Involvement in UDI Implementation



understand that a failed implementation has the potential to stop sales in their tracks.

Companies should incorporate three steps—planning, implementation, and follow-through—to be compliant with UDI requirements. V&V is a significant component to implementing UDI. Throughout the planning, implementation, and post-implementation processes, companies need to build in and document their V&V activities to show the FDA that they are using valid data and processes to control their master data and UDI labeling.

UDI Implementation Process: Examine, Strategize, and Prepare Plan

Medical device labelers should establish an implementation team to plan for required system changes. Labelers need to develop strategic plans and schedules (details, budgets, assignments, partners, etc.) to:

- Perform gap analysis on data required for GUDID submission, software systems, labeling processes and equipment, SOPs, supply chains, and more;
- Address needed product lifecycle management (PLM) changes, enterprise resource planning (ERP) and supply chain systems, labeling and packaging equipment and procedures, and labels and packaging;
- Define GUDID gateway;
- Create V&V and compliance plans of action;
- Determine how master data will be accurately maintained going forward;
- Determine whether 21 CFR Part 11[8] revalidation will be required;
- Identify software programs that need changing (complaint handling, label printing, electronic device history record (DHR), etc.);
- Determine which existing SOPs need to be updated to meet UDI requirements; and
- Identify and verify the correct GMDN Preferred Term for each DI record.

During this UDI implementation phase, a critical aspect is identifying all the tasks that will need to be verified and/or validated. Process validation and software validation are the tools used during UDI implementation. Process validation will be used for data gathering for GUDID submission. Software validation will be used for changes made to complaint-handling software, labeling software, software for uploading DI records to GUDID, electronic DHR systems, and labeling inspection devices and/or software (see below for more information).

The FDA's QSR at 21 CFR Part 820.75(a) establishes the requirements for process validation: "Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures."[6]

A guidance document from the Global Harmonization Task Force (GHTF), Quality management systems—Process validation,[9] was written primarily for medical devices. However, this guidance's methodologies can be used for process V&V during UDI implementation. As is the case in product design, an important aspect of process design is output verification. As has been discussed, UDI implementation requires software and process V&V.

Data Gathering

This is one of the hardest tasks in implementing UDI. Before starting this process, a company should develop a Process V&V Plan (see the FDA's guidance, Reporting of computational modeling studies in medical device submissions, and the agency's draft guidance, Technical considerations for additive manufactured devices), which details the steps to be used to gather the required data and verify or validate their accuracy. The written plan should include:

- Developing an educational document to train staff on GUDID attributes and processes to be used for data gathering, data verification or validation, controlling spreadsheets (if used) and designating who will have signoff responsibilities;
- Creating a repository for the gathered data with identified columns for the required data elements to be collected, i.e., attribute spreadsheet;

- Verifying the data gathered, including GMDN Preferred Term codes;
- Identifying the parties (titles) responsible for collected data signoff;
- Outlining all the steps needed to gather required data;
- The process to be used to upload the data into GUDID, including how the data will be controlled and verified or validated;
- Documenting any changes to the original plan; and
- Managing changes to the device or its data attributes.

If a company has multiple labeler sites, plans will need to be developed for each site. It is necessary to determine who will verify or validate the attribute data from each site and whether the corporate location will be in the V&V flow and have signoff responsibilities. Attribute spreadsheets, if used, need to be controlled during the entire process, and the control method used needs to be documented.

UDI Implementation Process: Construct and Enact

During the implementation, construction, and enactment phase, medical device labelers will need to:

- Compose, establish, administer, and verify or validate software system changes;
- Rehearse connectivity with GUDID and validate that all systems are functioning correctly; and
- Create or revise SOPs as needed and conduct process validations.

Software Changes

The FDA's QSR under 21 CFR Part 820.70(i) defines "automated processes" as such: "When computer systems or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.[6]

Labelers should familiarize themselves with the requirements of 21 CFR Part 11 and its corresponding guidance, Part 11 electronic records; electronic signatures—scope and application,[8] which further delineates a tightened scope and describes the requirements for which compliance is most important.

Two requirements are needed for Part 11 to be applicable:

- Records whose maintenance is mandatory (under predicate rules—that is, the UDI rule) or submitted to the FDA
- Records kept in electronic format rather than paper

The FDA says in its rule that the UDI must be included in several quality management system areas, such as complaint handling, labeling, device history records, and servicing systems (see the GHTF document, Quality management systems—process validation guidance). Many manufacturers have changed their complaint-handling systems from paper-based to software-based. These systems would be validated under 21 CFR Part 820.70(i). The UDI rule requires changing the software to include a device's UDI, so it "shall be validated before approval and issuance." Likewise, DHRs should store UDI or universal product code (UPC) and other required data elements, which, if electronic, again will require software validation. And because UDI requirements call for changes to information printed on a device's label, modifications to the software that provides changeable data to the label printer also will need to be validated.

Further, each label needs to be inspected per 21 CFR Part 820.120(b), "Labeling inspection": "Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct [UDI or UPC], expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR."[6]

Two issues need to be addressed with any new labeling applications employing AIDC technology:

- Authenticating the format of the encoded information against application requirements, and
- Confirming the barcode meets quality requirements—that is, barcode verification—to assure reliable "reading" at the point of use.

Labelers may use 1D or 2D symbology on labels. The symbols need to be verified to determine whether they are correctly configured, the label information is accurate, and the information corresponds to the human-readable text. It is not practicable to inspect each label as it is printed. Machine-vision software is available that allows labelers to "read" the labels, segregate the fields within the barcode, interpret the human-readable text, and verify the form and content of both are correct.

Printing barcodes is one thing; being able to read them is another. Symbol quality is critical to the ability to verify barcodes. Barcode symbols must be printed at the highest possible quality level to maximize their ability to be successfully decoded by the variety of barcode scanners and cameras available today. High-quality 1D and 2D barcodes can be validated through verification when labels are printed. They must also be "graded" at the same time (barcode verification). The minimum acceptable grade to guarantee meeting industry standards and reliable decoding throughout the supply chain is "C," or 2.0. Labelers need to understand barcode print quality. Topics such as "edge determination," "minimum reflectance," and "quiet zone" are explained in The Layman's Guide to ANSI, CEN, and ISO bar code print quality documents.[10]

In addition to label requirements, medical devices intended by manufacturers to be "reprocessed" (cleaned and disinfected, or cleaned and sterilized) must have the UDI "direct marked" permanently on the device itself. Laser marking is one such method. The UDI in these cases will be very challenging to verify and will necessitate the use of an automated process to confirm the label information.

Software V&V[11] is critical to successful UDI implementation. For more information on how to validate software, be sure to read Chapter 11 on software validation.

Global Unique Device Identifier Database

Managed by the FDA, the GUDID serves as a reference catalog for every medical device with a DI; meanwhile, the public site—AccessGUDID—is maintained by the National Institutes of Health. The UDI rule requires the labeler of every device with a UDI to submit data on each to the GUDID, unless there is an exception or alternative. There are 60-plus attributes that need to be entered for each device (see **Table 11-2**).

There are two standard-based methods to submit data:

- Structured input via an internet interface
- HL7 SPL

HL7 SPL is an XML format and uses the FDA's ESG as the pathway to upload data to the GUDID. Both submission methods are one DI record at a time. No batch option is available. For HL7 SPL, there is one DI record per XML file.

The web-based tool will work well for up to 200 total DI records. Any more than that becomes overwhelming; companies with that records volume should use HL7 SPL instead. Experience has shown it can take anywhere from three to six minutes to enter each DI record manually into the online interface. Third parties also can be used to submit data. Companies also can build their own submission tools.

The only validation in the GUDID is based on what the database does intrinsically or through business rules designed into the entry program. Both submission methods mentioned above use standardized controlled vocabularies and business rules to validate each attribute entered. Controlled vocabularies are:

- Data Universal Number System (DUNS) number
- GMDN code
- FDA product codes

Table 11-2. 62 Attributes for Each Device Identifier

FDA GUDID Data Fields			
Labeler	**Regulatory**	**Production**	**Characteristics**
Labeler DUNS Number^	Publish Date	Lot/Batch Number (Y/N)	Single Use (Y/N)
Company Name*	Distribution End Date	Manufacturing Date (Y/N)	Combination Product#
Company Physical Address*^	Distribution Status*	Serial Number (Y/N)	HTP/C#
Customer Contact Phone	Premarket Exempt#	Expiration Date (Y/N)	Contains Rubber (Y/N)
Customer Contact Email	Premarket Submission No.	Donation ID Number (Y/N)	Labeled 'Not Made With Rubber'#
Device Identification (DI)	Supplement Number	**Packaging**	MRI Safety
Issuing Agency	FDA Listing Number	Device Count	Size Type
Primary DI Number	FDA Product Code	Unit of Use DI Number	Size Value
Brand Name	FDA Product Code Name*	Kit#	Size Unit of Measure
Version/Model Number	GMDN Code	Package DI Number	Size Type Text
Catalog Number	GMDN Name*	Quantity per Package	Storage & Handling Type
Device Description	GMDN Description*	Package Contains DI Number	S&H Low Value
Second DI Issuing Agency	Prescription#	Package Type^	S&H High Value
Secondary DI Number	Over-the-Counter#	Package Discontinue Date	Storage & Handling Unit
Subject to DM, but exempt#		Package Status*	Special Storage Conditions
DM DI Different (Y/N)#			Sterile Package (Y/N)
DM DI Number			Sterile Required (Y/N)
Previous DI Issuing Agency			Sterile Method
Previous DI Number			

^Data elements not released to public
*FDA GUDID System completes these fields
#Checkbox

Source: RSQM Associates LLC

Examples of business rules used by the GUDID are:

- All required data elements must be provided;
- Validating specific elements (structure and size of DI, FDA listing number, etc.);
- Data constraints on specified elements (publish date must always be ≥ TODAY); and
- System rules, which determine available user actions based on the status of the DI record (e.g., only unpublished and published DI records can be copied).

When using HL7 SPL, whether using company-developed software or a third-party solution, the software must be verified and validated before final DI data can be uploaded to the GUDID. When using third-party submitters, it is the device labeler's legal responsibility to ensure the third-party solution meets the records

requirement for 21 CFR Part 830.360 and the requisites of 21 CFR Part 11. Should the labeler desire to develop its own solution, it also will need to follow 21 CFR Part 11, which details the process companies should use for software validation. This document also points to 21 CFR 820.70(i) (see above). Because GUDID SPL submissions do not require a signature, Part 11 requirements specific to electronic signatures do not apply. Instead of an electronic signature, the FDA requires the use of a digital certificate that serves to authenticate the submitter. Digital certificates are requisites for all data uploaded to the FDA's ESG, including the GUDID.

DI records successfully uploaded to the GUDID using SPL will allow labelers to view and edit data attributes via the web interface. Labelers need to be aware that editing uploaded SPL data via the web interface can lead to discrepancies between their source data and GUDID data. It is incumbent on labelers to create and follow SOPs for data management to control the quality of their device data.

UDI Post-Implementation Follow-Through (Change Management)

Managing the UDI process does not end once labelers have made sure their devices comply with FDA expectations. They must maintain not only their systems, making changes as needed; they also must address changes to the device or its data attributes, and continue to update and keep current the data in GUDID. This includes verifying and validating new product listings and changes to existing devices in the GUDID.

Introducing a new device subject to UDI into commercial distribution requires the labeling to comply with the FDA's UDI rule. It also requires submission of the DI record for the new device to be entered into the GUDID before distribution.

Relabeling or changing an existing device required to have a UDI necessitates assigning a new DI. In addition, 21 CFR Part 830.60 stipulates keeping a record of the relationship of the prior device identifier to the new DI.

There are 12 GUDID attributes (see the FDA's Design control guidance for medical device manufacturers—new DI triggers) that, if changed, require a new DI to be assigned to the device (model or version) and a new GUDID submission. Changes to GUDID data attributes not requiring a new DI must be made within 10 business days. Companies will need to have tight controls and processes in place to monitor these attributes for changes. Changes not resulting in the requisite new DI and GUDID submission will result in the device being out of compliance, and it may be misbranded.

Maintaining the System

The FDA under 21 CFR Part 830.360[1] expects the labeler to maintain, retain and make available to the agency upon request "records showing all [UDIs] used to identify devices that must bear a UDI on their label." The UDI rule stipulates that device labelers keep these records for three years from the date they have stopped marketing the model or version.

Making System Changes

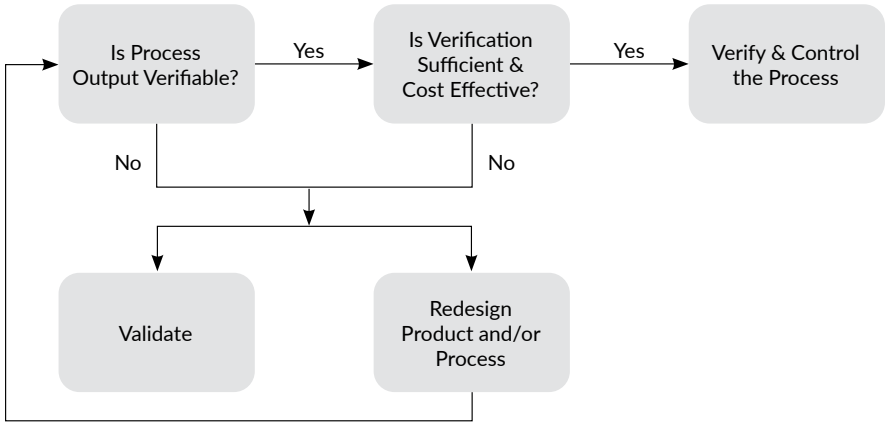
Changes to any of the systems maintaining the GUDID data, modifications to the labeling software or equipment, or changes to software used for complaint handling or electronic DHRs will need to go through verification and revalidation.

Updating GUDID

21 CFR Part 830.330[1] requires submitting any changes to the information required by the UDI rule to the FDA's GUDID database whenever necessary. The changed information must be entered into GUDID no later than the date the changed information is printed on the device's label for the first time. Should the modified information not be printed on the label, the changes must be entered into GUDID no later than 10 business days after the changes go into effect. Companies should have SOPs in place to manage this change process. The SOP should delineate the process for verifying and validating changed data, including the titles of those responsible for signing off on the changes.

The FDA also has the right to notify labelers if it determines information in the GUDID appears to be incorrect or misleading. If this occurs, the labeler is responsible for either

Figure 11-2. GHTF Process Validation Decision Tree



correcting the information or providing adequate justification to the agency as to why the information is correct within 30 days of receiving FDA notification. Labelers cannot ignore this notification. Should a labeler not respond to THE FDA within the 30 days post-notification, the agency may either delete or correct the wrong information. This FDA action does not relieve the labeler from providing corrected information or an explanation as to why the original information is correct.

New DI Records

There are several reasons new DI records and corresponding labels need to be implemented using V&V, including:

- New device introduction
- Relabeling an existing device
- Changes to key GUDID attributes (see the FDA's Design control guidance for medical device manufacturers)

Summary

UDI implementation is complex and requires constant attention. Many company leaders appear to be underestimating the impact UDI will have on their organizations and the amount of time it will take to implement and manage. Top management must understand UDI is here to stay and should commit the necessary resources needed for successful implementation. The FDA will not be the only regulatory authority to implement UDI. It will become a worldwide standard.

Manufacturers that have implemented unique identifiers have seen increased revenues and decreased costs. Their hospital and GPO customers view them as "easy" companies with which to do business, resulting in a sales increase for both contracted and noncontracted devices. Hospitals need to implement systems that will reduce their costs, and UDI is such a system. It permits hospitals to manage their inventories better by reducing or eliminating duplication and providing improved inventory tracking. Barcodes on products allow hospitals to charge patients more accurately for the devices they use while hospitalized. Manufacturers also have been able to increase the speed to market for a new device compliant with unique identification standards by adding the device to existing GPO contracts. This can increase the new device's market exposure very quickly.

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12 Equipment Validation

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Equipment Validation—Its Purpose

When searching for the word "validation," many definitions are found. Essentially, however, validation breaks down into addressing basic expectations, stated or unstated (all requirements and expectations in regulated industry must be in writing), that led to the initial acquisition of the equipment.

Thus, validation involves proving all expectations and requirements have been met by observation, checking, testing, and performing similar quantifiable activities, and are sustainable and reproducible over time, given expected (allowed) variation in all foreseeable inputs.

Understanding equipment validation requires the definition of validation inputs, i.e., requirements and specifications (**Figure 12-1**).

A "requirement" can be any system or discrete equipment need or expectation. Requirements reflect the customer's stated or implied needs, and may be market-based, contractual, or statutory, or included in an organization's internal requirements. Applicable standards provide requirements. Many different requirement types may exist (e.g., design, functional, implementation, interface, performance, or physical requirements). Equipment requirements' specifications typically are derived from the requirements needed for it to function as part of a production or test environment.

Documenting such requirements accurately and completely is crucial in successful equipment validation because the requirements' specifications form the basis for all verification steps (test cases or scripts).

A "specification" is defined by the US Food and Drug Administration as a "document that states requirements."[1] It may refer to or include drawings, patterns, or other relevant documents and usually indicates the conformity means and criteria with the requirement can be checked. Many kinds of written specifications (e.g., use, function, or system requirements' specifications; equipment design specifications; test specifications; and integration specifications, etc.) establish "specified requirements," and are design inputs for which various forms of verification are necessary.

Such "expectations, requirements, and specifications" also could include any of the following:

- Resulting equipment meets predetermine expectations (requirements);
- Challenge the equipment to its "allowable worst case" inputs;
- Verify all requirements have been met per a "requirements specification" (one or