UDI Regulatory Overview

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Hello, my name is Linda Sigg, and I am the Associate Director of Informatics for CDRH. I lead the team that implements the Unique Device Identification, or UDI program, and today I will provide a regulatory overview of the UDI system.

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The Learning Objectives of this session are to:

Recognize the four steps of the UDI System,

Understand the labeler requirements,

Know the UDI compliance dates, and

Identify some of the UDI adoption benefits

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What is the UDI System and why do we need it? Congress directed the FDA to establish a UDI system to adequately identify medical devices through distribution and use, with the goal to realize many important public health benefits.

The UDI system was signed into law in 2007, as part of the Food and Drug Administration Amendments Act. The FDA Safety and Innovation Act was signed into law in 2012, and required FDA to impose specific compliance time frames for certain devices. FDA published the final UDI Rule on September 24, 2013.

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The UDI system's objective is to enable medical devices to be identified through distribution and use, with specific goals:

Facilitate the rapid and accurate identification of a device and prevent incorrect identification.

Enable access to important information concerning the device such as the company name, brand name, description and important safety information

And provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries

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The UDI Program is essentially a four step process.

First, the FDA built the regulatory and technical framework for the UDI System in the final rule that was published on September 24, 2013.

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Next, the medical device industry needs to comply. A UDI is required on device labels and device packages, and in some cases on the devices themselves, unless there is an exception or alternative granted by the FDA.

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Then, additional data about each device is required to be submitted to the Global UDI Database, which we call the GUDID for short. The GUDID serves as the repository of key device identification information.

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Finally, the success of the UDI system depends upon adoption and implementation of the UDI System by the health care community.

Step one, the standardized system, has been established.

Today's discussion will focus mainly on Steps two and three and the labeler's responsibilities.

And for the last step, I will briefly describe several of the UDI benefits at the end of this presentation. These benefits can only be realized through successful adoption and implementation of the UDI system.

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As part of the UDI system, a UDI is required on device labels. What is a device Label? Section 321(k) of the Food, Drug, and Cosmetic Act defines "label" as a display of written, printed, or graphic matter upon the immediate container of any article. For retail devices, the UDI is required to appear on the outside container or wrapper of the retail package or be easily legible through the outside container or wrapper. This means the UDI can be on the retail package and the package can be enclosed in a clear container or wrap.

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What is the UDI? It is a unique string of characters on a device label, package or in some instances on the device itself. It is both in human readable plain text and machine readable formats. Here are some examples of the Automatic Identification and Data Capture, or AIDC, machine readable formats, including the 1D barcode that is on the label,

the 2D barcode that is to the left of the label, and the symbol at the bottom left, which is an abstract of Radio Frequency Identification, or RFID, technology. All are acceptable machine readable formats for UDI purposes, and for this presentation, I will use the 1D barcode for the examples.

If you go back to the 1D barcode, the numbers below the bar code are the human readable plain text form of the UDI. The UDI is composed of the Device Identifier, or DI, and the Production Identifiers, or PI. The DI is the yellow portion of the plain text on the left, and the PI is the green portion of the plain text on the right.

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Now let's parse the different parts of the UDI. The DI is the mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device. Once the DI is assigned to a specific version or model of a device, the DI never changes. If a different version or model is made available, a new DI is required. The DI serves as the primary key used to look up information about the device in the GUDID. Only one labeler can be associated with each DI.

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The PI is the variable portion of the UDI. Except for Class 1 devices, when certain information is on the label it should be in the UDI as well. This information includes lot, batch, serial number, expiration date, date of manufacture, and for human cell and tissue products, or HCT/P's regulated as devices, the distinct identification code. This data will change for each lot or batch, or in the case of some devices like implantables, for each serialized device.

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The UDI regulations define device package as a package that contains a fixed quantity of a particular version or model of a device. Each package level requires a different UDI.

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Here is an example of package levels.

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The base package is the lowest level of a device package containing a full UDI. In this example, the base package is a single wrapped catheter. The UDI is on the individual device wrapper and the base package DI is 1001.

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The individually wrapped catheters are packaged in a box of thirty. That box of thirty is related to the base package and is the next package level that requires a different DI -2001.

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If the catheters are also packaged in boxes of fifty, that would also be a next package level with a DI that is different from the DI on the box of thirty but still related to the base package DI - 2002.

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Multiple boxes can also be packaged together in a case, a third package level. If boxes of thirty catheters are packaged twelve to a case, that case is a third package level requiring a new DI, but again related to the base DI - 3001.

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Here are examples of what are not considered packages and do not require a UDI. Any type of wrapping intended to protect the device from damage during shipping. As seen in the picture on the left, this includes inner linings, bubble wrap, and other protective material. The middle picture is a pallet. Pallets are another example of a package that does not require a UDI, especially when the number of units differs from pallet to pallet. In the picture on the right, any shipping containers used to transport devices when the contents vary from one shipment to another do not require a UDI.

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Let's talk about Direct Marking. In addition to including the UDI on the label and package, the UDI needs to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed between uses. This permanent UDI may be in plain text, AIDC technology, or both. The direct mark UDI may be identical to the UDI on the label or it may be different to distinguish the packaged device from the unpackaged device.

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What is a Labeler? The labeler is responsible for compliance with the UDI requirements. The UDI rule created the term "Labeler", and in 21 CFR 801.3 the labeler is defined as the one who causes a label to be applied to a device, or who causes the label to be replaced or modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label.

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A device manufacturer is usually the labeler, but not always. The term labeler can include contract manufacturers, private label distributors and

convenience kit assemblers, as well as device repackagers or device relabelers. However, distributors who only have their name and contact information added to an existing label may not be considered labelers.

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At this point, we have covered the UDI and the DI and PI portions of the UDI. In addition, we have talked about the labels, packages, and who are the labelers. Now, let's discuss how UDIs are created.

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The UDI rule requires all UDIs to be issued under a system operated by an FDA-accredited Issuing Agency. The Rule also requires the Issuing Agencies to create systems that conform to international standards.

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The FDA has accredited several Issuing Agencies, and labelers are required to work with at least one accredited Issuing Agency. For more information on how to build your UDIs, first make sure you understand the basic UDI requirements, and then follow the guidelines and use the tools provided by the Issuing Agency. The list of FDA-accredited Issuing Agencies is available on the FDA website.

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To bring date formats in line with international standards, dates on the label intended to be brought to the attention of the user, such as expiration date and date of manufacture, must be in a specified format to harmonize with international standards. This format starts with four digits for the year, followed by two digits for the month, and then two digits for the day, separated by hyphens. For example, January 30, 2014 will be written as 2014 hyphen 01 hyphen 30. The date format compliance date is the same as the compliance date for the UDI.

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Let's review the basic UDI requirements. We just covered that a UDI is required on every device label and device package, and in some cases on the device itself, unless there is an exception or alternative granted by FDA. Next, we will talk about the key information that must be submitted to the Global UDI Database, or the GUDID.

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The GUDID serves as the repository of key device identification information. The GUDID contains only the Device Identifier, or DI, which serves as the primary key to obtain device information in the database. Production Identifiers, or PIs, are not submitted to nor stored in the GUDID. The GUDID contains only production identifier flags to indicate which PIs are in the device UDI. The GUDID does not contain any patient identifying

information. There is much more information on our FDA UDI website, and there are modules that explain the GUDID data submission process in detail.

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Can anyone see the data that is submitted to the GUDID? The answer is a qualified yes. One of the key objectives of the UDI system is to enable health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device. Therefore, once the labeler has verified their data, most data from the GUDID is made public via AccessGUDID. AccessGUDID launched in May 2015 through a partnership with the National Library of Medicine. The main features of AccessGUDID are the public search capability, the database download capability and the web services. Please check the site often, as new features and functionality are being added to improve AccessGUDID.

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To give everyone enough time to prepare and ensure orderly compliance with the regulation, the compliance dates for UDI requirements are phased in over a seven year period based primarily on the device classification with the compliance dates for higher risk devices occurring first. Here are the key compliance dates. There are more details on compliance dates on the UDI website which you can access using the link on this slide.

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All medical devices must be in compliance with the requirements of the UDI Rule by the applicable compliance dates, unless an exception or alternative has been granted by the FDA. Some key general exceptions include Class 1 devices that are exempt from current Good Manufacturing Practices, or cGMP, individual single use devices of a single version or model that are sold and intended to be stored within a single device package until removed for use, devices under premarket investigation or intended solely for nonclinical use, devices intended for export from the US, and individual devices in a convenience kit. In addition, a device packaged and labeled for sale prior to its compliance date is excepted from UDI requirements for three years after the compliance date. This is not an exhaustive list of the general exceptions. All the general exceptions are listed in 21 CFR 801.30.

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There is also a provision that allows FDA to grant individual exceptions or alternatives. FDA may grant exceptions or alternatives either on its own initiative or in response to a request from a labeler. Labelers submit such requests to the UDI Help Desk.

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If you recall from the four steps of the UDI system, the last step is adoption. The UDI will clearly and unambiguously identify the device. The availability of the UDI in electronic health information allows connections to different sources of data to easily link information that was once difficult or impossible to link. With the UDI, there is now a key that unlocks the data. A specific version or model of a device could be linked to an adverse event, or to a recall. And better data means better analysis of the data for faster and more accurate reporting and decisions.

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With the UDI as the unique key, and electronically available on devices, device data for patient care can be rapidly and accurately captured and retrieved. The GUDID contains several device safety fields that help providers at the point of care. And once the UDI is available, patient safety could be improved by tracking the device through the supply chain to the point of use and beyond. For example, if the UDI is on the device and the UDI is in the EHR then recalls can be connected to patients.

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FDA is working with several different partners to ensure the UDI is in Electronic Health Records, Claims, and Registries. FDA also works with standards organizations to ensure there is interoperability between the data sets so that the data can be linked and integrated in systems.

With more specific device information it is possible to improve patient safety, identify poor performers in the marketplace and facilitate device innovation. UDI is one of the cornerstones of National Medical Device Evaluation System, and adoption is necessary to reap the benefits.

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I hope you found the information presented very informative. Remember, there are four steps to the UDI system, and steps two and three are the labeler requirements for labels and data submission. I would like to encourage labelers to be aware of your compliance dates, and please start the label and data submission processes early to ensure your requirements are met prior to the compliance date. If you would like more information about the UDI benefits, there are several listed in the preamble of the UDI Rule. Thank you for your time today, if you have any questions about UDI you can access information on our website at www.fda.gov/udi

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This presentation and other helpful videos and educational resources can be found at CDRH Learn. For text based information on premarket and post market topics including how to bring a medical device to market please visit device advice. For additional information on these or any other

medical device regulatory topics feel free to contact the Division of Industry and Consumer Education.

Thank you!