The GUDID DI Record with Indira Konduri

Slide 1
Hello, my name is Indira Konduri and I am the Program Manager for the Global Unique Device Identification Database, the GUDID. Today's presentation will focus on The GUDID DI Record.

Slide 2
In today's presentation, I'll start with an overview of the GUDID, which we call the GOOD-ID for short. Next, we'll delve into the device identifier record, the DI record --- so you understand what the DI record is, and learn about the data elements in a DI record. Then I'll talk about how to manage your DI record through the life of your device so your information stays updated. And I'll also cover best practices for better GUDID data

Slide 3
Let's review some basics. UDI, the Unique Device Identifier, is composed of two parts. The Device Identifier or DI, highlighted in yellow on the slide, and the Production Identifier or PI, shown in green on the slide. The Device Identifier is the fixed portion of the UDI and identifies a given version or model of a device AND the labeler of that device. The Production Identifier is the variable portion of the UDI. It identifies the Lot or batch number, Serial number, Expiration date, Manufacturing date, and, for Human Cellular and Tissue based products regulated as devices, the distinct identification code, when included in the UDI.

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The GUDID is the repository of key device identification information. GUDID only contains the DI. We do not collect the actual PIs, such as the lot or batch number in GUDID. What we do collect are PI flags, which are Yes or No answers that indicate which PIs are in the UDI.

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Here's a high level view of GUDID. On the right hand side is AccessGUDID. Data that labelers submit to GUDID is made available to patients, health care providers and any member of the public through AccessGUDID.

The top blue box shows the two ways labelers can submit information to GUDID - the GUDID HL7 SPL Submission option and the GUDID Web Interface option. The GUDID HL7 SPL submission option allows labelers to send their information as XML files via the FDA Electronic Submissions Gateway. You will hear more about this in the session following this.

<u>Slide 6</u>
The GUDID Web Interface submission option is a secure web application. Labelers can enter device information one record at a time using manual data entry. The web interface is suitable for labelers with small volume of submissions.

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Let's move to the GUDID DI Record and Data Elements

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Again, the DI is the fixed part of the UDI. It identifies a given version or model of a device AND the Labeler of that device. A DI Record in GUDID is the Device Identifier + GUDID Data Element values.

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Here you see a physical label of a fictitious device. Most of the values for the DI record data elements come directly from the device label. For example, on the top left you see Brand Name. In the middle you see the UDI, which has the DI and PI. Further down, you can find storage and handling, a single use designation and the labeler name and address.

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Getting into the GUDID DI record itself, remember there are two ways labelers can submit DI record information - Web Interface and the HL7 SPL. Now, if you're using the Web Interface, the Labeler Data Entry (LDE) user will be entering the records. Those using the HL7 SPL submission option will submit them as xml files.

Over the next few slides I'm going to walk through the GUDID Data Elements. The screen shots will be from the GUDID Web Interface application. But the information about these data elements applies to both submission options.

To start out, we have 3 groups of GUDID data elements - Device Information, Device Status and Device Characteristics. Let us take a look at each grouping.

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Device Information. These data elements cover basic device identification information. From the top and moving left to right, Issuing Agency. Choose from one of the FDA-accredited Issuing Agencies. For this DI record it is HIBCC.

Primary DI Number - this is the DI on the base package, the lowest level of a medical device package containing a full UDI.

Device Count is the number of medical devices in the base package.

Unit of Use is an unmarked DI and is applicable when the device count is greater than 1.

I'm skipping Labeler DUNS Number, Company Name and Address for now. We'll come back to it later.

Brand Name, Version or Model, Catalog Number and Device Description should be self-explanatory. Let us skip DI Record Publish Date for now, we will come back to it later.

On to Commercial Distribution End Date; this is the date after which the device is no longer offered for sale by the labeler on record. Commercial Distribution Status is automatically updated by the system. When an End Date has been entered, the status will change to show "No Longer in Commercial Distribution" after that date.

Let's now talk about Labeler DUNS Number. In GUDID, the DUNS number is used to pull Company name and Address from the DUNS database. It's important to make sure that the company name associated to the Labeler DUNS number matches the company name on the physical label of the device. On this fictitious label, the company name and address are circled in red. The DI record in GUDID should reflect the same company name as the one on the label. The company address in GUDID should also match what's on the label, if possible.
We know that some of you use the DUNS Doing Business As or the DBA name. You may use the DBA name associated to your Labeler DUNS in GUDID if that is what's shown on the label.

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Here's how the Company Name and Address associated to your Labeler DUNS looks in a GUDID DI record.

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Here's why this is important. AccessGUDID is the portal where we make GUDID information publicly available. If someone has a device label in hand, and searches for the device record using the company name on the label, the record that's retrieved should show the same company name as the one on the label.

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Let's go back to the Data Elements, and continue on with the Device Information group of elements. Next come Alternative and Additional Identifiers for a device. Direct Mark DI is a DI marked directly on the device itself. You only need to provide this in GUDID if the direct mark DI is different from Primary DI. If your device has a DI issued by an Issuing Agency that is different from the Primary DI Issuing Agency, you would enter it under Secondary DI. Package DI - These are DIs assigned to higher level packages. More on packages in just a minute.

So as you see, all Device Identifiers for a for a given version or model are part of the same DI record. Customer Contact information is in the bottom - phone and email information that customers can use to contact you if they need more information on a device.

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Now let's talk a little more about packages. A device package contains a fixed quantity of a particular version or a model of a device. Each level of package requires a different DI.

On the left side of the slide, we have a catheter in a base package with DI 1001. Going across the top, 30 catheters with DI 1001 are put into a box. The box is the second level of package; it is assigned a Package DI of 2001. Moving right from package 2001, 12 boxes with package DI 2001 are put into a larger box. The larger box is the next level of package with Package DI 3001. At the bottom is another package level. In this case, 50 catheters with DI 1001 are put into a box, and gets a Package DI of 2002.

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Here's how this package configuration would be entered in GUDID. On the top you see that Base package DI 1001 is the Primary DI. In the bottom you see the higher level packages are all entered as part of the same DI record. So from our example, package DI 2001, 2002, and 3001 are all part of the same DI record.

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Let's move to the second grouping of data elements and that is Device Status. This group of elements primarily captures regulatory type information. On the top you see check boxes to indicate if the device is a Human Cellular or tissue based product, a Kit or a Combination Product. Next, you provide Premarket Submission, FDA Product Code, and FDA Listing Number. The GMDN code is circled in red. GMDN stands for Global Medical Device Nomenclature.

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GMDN is an international nomenclature used to group devices into broad, high level categories. It consists of GMDN Code, Preferred Term Name and Preferred Term Definition. GMDN codes are created and maintained by the GMDN Agency. You need to be a member of the GMDN Agency to obtain GMDN codes.

The FDA has developed FDA Preferred Term codes, to allow companies to select a GMDN Preferred term, but it is preferable for companies to obtain a code from the GMDN agency. The FDA Preferred Term codes are available when labelers login to GUDID. If your device requires a new GMDN code it may take time to obtain one, so please make sure you allocate enough time to identify and obtain GMDN codes for your devices.

Slide 20
Now to the third grouping of data elements, Device Characteristics. Going clock wise from top right, you see For Single Use, Latex, MRI information, and Prescription Status. Finally, you see the PI flags mentioned earlier. The PI or Production Identifier may contain the lot or batch, serial number, expiration, manufacturing date, and Donation Identification Number. In GUDID, the actual Lot or Batch or the Serial Number isn't captured. Instead, you enter YES or NO to indicate which PIs are in the UDI.

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And finally you see Size, Storage and Handling, and Sterility information. That completes the data elements in a DI record. While I've shown you screen shots from the GUDID Web application, remember that these data elements are applicable to both submission options: the GUDID Web Interface where you manually type in your device record and the GUDID HL7 SPL Submission option where information is sent as XML files.

Slide 22
Now that we've covered what a DI record is, let's understand how to manage your DI record.

Slide 23
The GUDID DI record life cycle helps you manage the entry and edits of information in your DI record throughout the life of the device. There are 3 DI record states in GUDID: Draft, Unpublished and Published.

Slide 24
Starting with the Draft DI record state. A draft DI record is simply that, a draft. If you are a GUDID web interface user, creating draft DI records is a way to test or learn about GUDID and DI records. The Draft DI is entered and "saved" into the system. It is not "submitted" to the system. Stay with me, I will explain what submitted means in a minute. You may edit a draft DI record as much as you like. Draft DI records with no activity will be deleted from GUDID after 180 days.

Once you enter a GUDID Draft DI record, you can click the "Review" button as shown circled in red to your right, to see if your DI record passes all the GUDID business rules. If the record doesn't pass business rules, you CANNOT submit. What do I mean by that?

Slide 25
Here you see when Review you click review, the system says there are errors. You cannot "submit" a record with errors, there is no Submit button for you to click. You can now resave as a draft. Or, fix the error and click "Review" again to see if you passed this time. Or you may cancel.

Slide 26
Let's say I've fixed the error and clicked review. Now the DI record passed because the record was entered correctly! So SUBMIT is available as one of blue buttons on the right side. At this point, you can resave as a draft, submit the record, re-edit the record or cancel and exit.

Slide 27
Once your record is "submitted", it is no longer in the draft state. You now have "Submitted" the record by passing all the business rules. After the record leaves the draft state, the DI record Publish Date determines whether the record is in the Unpublished or Published state.

Slide 28
DI record Publish Date is a critical concept. The Publish Date determines when a DI record is saved in the "published" state. The system requires the Publish Date to be today or in the future. Your GUDID submission requirements are met the date the DI record is saved in the "published" state.

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Let's use this picture to depict the relationship between the 3 record states. Starting from the top, you start with a Draft DI record. Walking down the left arrow, you click the "Review" button, and pass all the business rules. The Publish Date is in the future, so the record will be in the Unpublished State. Walking down the right arrow, you click the "Review" button, and pass all the business rules. The Publish Date is today, so the record is in the Published State.

Slide 30
So let's get into the Unpublished DI record a little more. As you just saw, an Unpublished DI record is a DI record that has passed "Review", meaning it has passed all the business rules AND has been submitted to GUDID by clicking the Submit button AND has a future publish date.

Unpublished records can be edited an unlimited number of times. These records are not released to AccessGUDID, because they are "not published", yet. Now here's a key feature: any record that has passed business rules can be "copied". That means an unpublished DI record can be copied to create new DI records. This can help reduce data entry burden if you're using the manual data entry option because if you copy records that are very similar, the only changes you need to make would be to update information that would be specific to a given version or model --- for example, the primary DI of the record would have to change for a different version or model.

Slide 31
Let's take a look at an unpublished DI record. On the top right hand side you see the buttons for Copy, Edit, and Cancel. At the bottom you see the DI record Publish date set to a future date.

Slide 32
Let's talk about what happens when a record goes from Unpublished to Published, in other words, moving across the bottom of the slide. Unpublished records have a future publish date. Every day, after mid-night, the GUDID system checks to see if there are Unpublished DI records with Publish Date = today. If there are, then the system changes the record to Published status automatically. So if you have a record with Publish Date tomorrow, then tonight after midnight, the automated check would change the status of your record from Unpublished to Published.

Slide 33
Now let us understand the Published DI Record state. A DI record that has passed "Review", meaning it has passed all the business rules AND has been submitted to GUDID by clicking the Submit button AND has a publish date of today or in the past, is a Published DI record

Editing is limited on published records. These records are released to the public on AccessGUDID. The records on AccessGUDID must be accurate and dependable, so they can't be changing constantly. This is one of the reasons for limited editing. Since a Published record has passed business rules, it may be "copied" to create new DI records. And to emphasize from earlier, your GUDID submission requirements are met the date the DI record is saved in the "published" state.

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Here's how a published DI record appears in the database. At the top right, you see the buttons for Copy and Edit. At the bottom left, you see the DI record Publish date set to a date in the past.

Slide 35
These next two slides provide high level summaries of the DI record life cycle and the points we have covered for the Draft, Unpublished and Published states. The DI record state determines the applicable business rule. This slide can be used as a quick reference tool.

Slide 36
This second summary slide is for those of you who like flow charts. You can use it to follow the path of your DI record through its life cycle. You can also find this flow chart in the GUDID Guidance Document. Please take a look at your leisure.

Slide 37
I've talked about how draft and unpublished records have unlimited editing, but some edits are restricted for Published records. Let's look at editing Published DI records a little closely.

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I want to introduce another concept to you, the New DI Trigger Data Element. If you change a GUDID data element that is designated as a New DI Trigger, you won't be able to simply edit a Published DI record to change that element once edit restrictions go into effect. Instead, you will need to assign a new DI to your device and submit a new DI record to GUDID.

Here is a page from the GUDID Data Elements Reference Table. The table lists all the GUDID Data elements, along with other features for each element. The last column indicates whether a data element is a new DI trigger. The top data element is "For Single Use". It's a new DI trigger, so the column says YES. That's because a device that's intended for single use is not the same as a device that can be used multiple times. Since it is no longer the same device, if you have to change this data element, AND your DI record is in the published AND has edit restrictions, you need to assign a new DI and enter a new DI record in GUDID. Similarly, "Device Packaged as Sterile" is a new DI trigger. If the device was originally packaged and used as sterile, but is then provided non-sterile, it's not the same device and can't be identified by the original DI. To change this data element value once your device record is in the Published state with edit restrictions, you would need to provide a new DI and a new GUDID record.

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What if you make a mistake on one of the new DI trigger data element and did not catch it until after the record is published?

The Grace Period exists for just this type of a situation. The grace period is currently 30 calendar days. If you have a record with Publish Date of January 15, 2016, the Grace Period starts the day after, which would be January 16, 2016 and ends on February 15, 2016.

During the Grace Period, the only data element you cannot edit is the DI record Publish Date. Other than that, unlimited editing still applies to your records. So if you did make an error, even on a data element that is a new DI trigger, you may edit that record.

After the end of the 30-day Grace Period, the record is released to AccessGUDID, for any member of the public to see and use. Other data elements also have certain limits on editing. So the bottom line is: PLEASE use the grace period! Take the time to review your records, make any edits or corrections before the record is available for public view.

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And that leads us to GUDID Data Quality. GUDID serves as a master repository for device identification information. We think of it as the gold standard for device identification!

So start with good data! Bake in data quality into all your processes as you prepare for GUDID. Do everything you can to ensure that your records are accurate when they are submitted, and be sure to make full use of the grace period. GUDID has an "export" feature that can be used to export all the DI records you have entered into GUDID. This is a great tool to use to review and validate against your source system data. If you find problems, be sure to correct those records as necessary during the grace period.

Finally, please don't wait to review your information until after your records are publicly available on AccessGUDID, because by then, the grace period has passed and your records have limited editing.

Slide 41
This slide provides best practices for better data. Device Identifier - ensure your DI is built correctly, and validate DI check digits. Version or Model - do not include the word "version" or "model" - if you have version 2, just put "2" in the field. If no version or model number is available, you may enter catalog number. Device Description - please do not leave this field blank. We recommend you base your description on the approved or cleared indications for use. Clinically Relevant Size - Use this field to enter the device size; don't put size in device description or brand name, and please use the List of Values when they apply to the size of your device. If you need a new size value, send us a request through the UDI help desk. GMDN Code - one code is sufficient for most medical devices. Remember it is a way to categorize devices into broad groupings, it is not very granular. Donation Identification Number is only applicable to devices that use the ICCBBA Issuing Agency.

Slide 42
Here are steps that we think will lead to successful GUDID submissions. Start with the many resources on our website. They provide greater detail on many of the concepts we've touched on today. So take the time to review and use them. Select your Issuing Agency and label your devices with UDI. Determine primary submission option - GUDID Web Interface or HL7 SPL.

Gather your data, and "bake in" data quality from the beginning. Understand the GUDID Account Structure. Identify/Obtain your DUNS numbers. Get a GUDID Account. Submit your DI records. And finally, subscribe to get notified about GUDID System Status. So how do you do that?

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We make every effort to notify users in advance when we have planned GUDID system downtimes for enhancements and maintenance. So be sure to subscribe to get GUDID System Status email alerts by visiting our website.
The email alert is also used to notify users of any system related updates such as document updates.

Scheduled downtimes will also be posted on www.fda.gov/udi. Look for GUDID System Status web page. If you notice that the system's down during a time it wasn't scheduled, first check the GUDID system status on our web page. If there's no information, we ask that you report the issue via Help Desk.

Slide 44
So it is time to get started. You now have the basics. If you need more information, please visit our website and take advantage of the resources we have available. Do not forget to "bake-in" data quality from the beginning, make sure your source system data is correct. Understand the GUDID DI record edit rules so you are effective in managing your records throughout the life of the device. Use the grace period to review your information and make any edits. Subscribe to the GUDID System Status notification so you can be alerted of system down-times and any system updates we communicate to our users. Thank you….

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