HL7 SPL Submissions to the GUDID with Linda Sigg

Slide 1

Hi, my name is Linda Sigg, and welcome to the Global Unique Device Identification Database, or GUDID, HL7 SPL Submission Option session. This module covers HL7 SPL submissions to the GUDID. There is another submission option, the Web Interface, that is covered in a separate module.

Slide 2

In today's presentation, we will:
- Start off with an overview of the GUDID HL7 SPL Submission Option,
- Talk about the required testing that is necessary before you send Production GUDID submissions,
- Examine the FDA Electronic Submissions Gateway or ESG, which is what you will use to send your HL7 - SPL submissions to GUDID,
- Explain the three acknowledgements you will receive and the purpose of each of them,
- Share with you some helpful pointers on using the HL7 SPL submission option, such as how to edit and manage your DI records and how to use third party submitters,
- And provide information on whom to contact, and when, for help.

Slide 3

Let's start with the basics, which includes a few acronyms. HL7 is Health Level 7, a standards development organization that works in the health care domain - they develop messaging standards that facilitate seamless exchange of health care information. SPL is Structured Product Labeling, and, as the name implies, SPL captures label information.

The FDA has taken the HL7 SPL standard and constrained it to the GUDID use case. Labelers must gather their medical device information and format it as an HL7 SPL XML message. Each XML file contains one DI record, and the technical specifications you need to create the XML file, are available on our website.

Slide 4

Once you have your GUDID HL7 SPL XML file, you then send it to us using the FDA Electronic Submissions Gateway, or ESG - we will talk more about the ESG in a few minutes. We want to make sure the information is formatted correctly, and loads to the GUDID correctly. Therefore, testing is required prior to sending files to the GUDID Production system, and we will talk more about that as well.

The HL7 SPL submission option is resource intensive, so it is suitable for those with a large volume of submissions.

Slide 5

Let's learn about the FDA Electronic Submissions Gateway. The ESG enables secure receipt and authentication of FDA electronic regulatory submissions. The ESG serves the entire Agency, and it routes submissions to the appropriate Center - this is important because if you already have an ESG account for other submissions to CDRH or one of the other FDA Centers, you do not need a new account to use the ESG to submit your information to the GUDID.

Slide 6

The ESG offers two submission options: Web Trader and AS2. Remember we said each XML file contains one DI record, and that is true no matter which ESG option you choose.

WebTrader is a web portal where the user logs in and uploads one submission, or file, at a time. AS2, or Applicability Statement 2, is a communications protocol, and this option is a Gateway-to-Gateway connection. The labeler's Gateway communicates directly with the ESG. The Labeler sends their submissions through their gateway to the ESG using the AS2 protocols, and the ESG picks up the submissions and processes them.

If you are considering using WebTrader as the primary mode for your ESG submissions, then we suggest you consider using the GUDID Web Interface instead of HL7 SPL submissions. The resources necessary for you to submit using HL7 SPL and upload one XML file at a time with WebTrader may not provide you with any payoff. With AS2 you can load many files at once to send to the ESG. Also note that GUDID does not use the eSubmitter Tool used for eMDR submissions.

Slide 7

Acknowledgements are sent for each stage of ESG report transmission, and we will look at that in detail in a minute.

The ESG website shown on the slide has a wealth of in-depth information on all of the ESG topics. Please go to www.fda.gov/esg to access user guides, checklists, and tutorials. It's very important to remember that the ESG needs to know the Center and Submission Type for every submission that comes through the ESG. For GUDID, make sure to specify the Center as CDRH and the Submission Type as GUDID.

Slide 8

Here is how the Acknowledgements work.

Slide 9

The labeler sends an HL7 SPL submission through the ESG, and specifies the Center as CDRH and the Submission Type as GUDID.

Slide 10
The ESG receives the submission and sends the Acknowledgment or Ack1 back to the labeler to indicate the ESG received your file - the file does not get opened, validated or reviewed at this point.

Slide 11
The ESG sees the Center specified as CDRH and sends the submission to CDRH.

Slide 12
The ESG then sends the Ack2, telling the labeler that the Submission has been sent to CDRH.

Slide 13
CDRH then routes the submission to GUDID, where it gets processed.

Slide 14
And GUDID sends the Ack3, telling the labeler the submission passed or failed validation.

Slide 15
As you can see, Ack1 and Ack2 are sent by the ESG, and all questions related to Ack1 and Ack2 must go to the ESG helpdesk at esghelpdesk@fda.hhs.gov.

Slide 16
Ack3 issues should be sent to the UDI Help Desk at gudidsupport@fda.hhs.gov.

Slide 17
If you open the Acknowledgements, they will look something like this. The Ack1 is your receipt for your submission, or your Message Disposition Notification. The ESG sends this, and it just tells you that the ESG received your file, and a messageID is provided.

Slide 18
Ack2, again, the ESG sends this, and it tells you that the file was sent to the right center. A messageID and a coreID are provided.

Slide 19
And as you can see at the bottom of the message, the Ack2 states that CDRH has received your submission.

Slide 20
Ack3 is sent by GUDID, and it tells you if your submission passed or failed validation. The Ack3 contains the same coreID from the Ack2.

Slide 21

If the submission fails validation, you may also see an Ack called "unidentified or unparseable submission type."

Slide 22

Unidentified means we don't know what kind of submission it is, so we can't route it to the right place in CDRH. It could be an MDR or a GUDID. Remember to indicate Submission Type as GUDID in the ESG submission header.

Unparseable means we are unable to parse your submission because it failed validation against the GUDID schema that is provided in our HL7 SPL Implementation Package. Be sure to validate your submission before you submit it. This is the most commonly seen error when users first start testing.

Slide 23

For all questions on your submissions or missing Acknowledgements, you need to contact the correct helpdesk, and you need to provide us with some information.

If you have issues with Ack1 and Ack2, or if they are missing, please contact the ESG Helpdesk and provide the MessageID. If you did not receive the Ack1 and you do not have a MessageID then provide as much information as possible.

If you have issues with Ack3 or you are missing the Ack3, please contact the GUDID Helpdesk and provide the CoreID. Please do not automatically retransmit submissions if you are having issues. It is better and issues can be resolved faster if you contact the appropriate helpdesk first and work with them to figure out if there is a problem with the submission or the acknowledgements.

Slide 24

Here we lay out the various steps and the process required to get ready to submit HL7 SPL production submissions to GUDID. On the top you see that the first step is to begin gathering your data using the HL7 SPL implementation guide and work on your XML file generation. While you work on that, you can start the ESG and the GUDID Account processes. Remember you need an account for both ESG and GUDID. Once you have your HL7 SPL formatted data and your accounts, you may begin testing.

On the left you see the steps for ESG testing.
On the right you see the steps for the GUDID testing.
Before we go into the details of each, let's talk about timing. Please be sure to allocate plenty of time, the expectation is that you may need as long as 12 weeks depending on the number of testing iterations you need to reach success.

Slide 25

Here is more detail on the ESG Testing process. Just like the GUDID, the ESG starts with a test account. To request and obtain an ESG test account you need to: obtain a digital certificate; exchange the public key with ESG; and send a letter of non-repudiation, which indicates who can submit on behalf of your organization and that your digital signature is the same as your wet signature. To complete your ESG testing, the ESG requires a Connectivity test and a Load test. You should allocate a total of 2-4 weeks for the ESG Testing process.

As we said before, if you have an existing ESG test account from another program in the Agency or in CDRH, you may use the same account. If you already have an existing ESG test account, no additional ESG testing is necessary, but GUDID testing is still required. When you send your GUDID test submissions through the ESG, be sure to specify the Center as CDRH and the Submission Type as GUDID.

Slide 26

Hopefully, while you have been obtaining an ESG test account and performing ESG testing, you have also been putting together the GUDID HL7 SPL XML files.

When you generate the XML file for the DI record, be sure to validate your file against the GUDID schema.

Remember, I mentioned the unparseable error, this is the most common error we see during the GUDID Testing process, so it will save you time if you validate your file before submitting.

Slide 27

You may request a GUDID test account through the GUDID account request process, and indicate that you need a test account. Submit your XML files using your ESG test account, and make sure you complete all of the required test scenarios. The files that you submit through your ESG test account will move through the ESG and load in the GUDID test area.

Submit your test scenario results for review to the UDI Help Desk. Follow the instructions in the GUDID Test Scenarios document to make sure you submit the right information. FDA staff will review your submission and, if successful, issue you the Production ESG & GUDID accounts. Then you may submit your HL7 SPL submission to GUDID by way of the ESG in the Production area.

Slide 28

Here are some important things to remember about the ESG and GUDID. As we said before, the ESG serves the entire FDA, with many Centers and many submission types. The ESG and the GUDID both have completely separate and isolated Test and Production areas.

Submissions sent through the ESG Test Account will load to the GUDID Test System, and submissions sent through the ESG Production Account will load to the GUDID Production System.

Slide 29

Many labelers prefer to use third parties for their HL7 SPL submissions. A Third Party is a company or individual authorized to submit device information to the GUDID on behalf of the labeler. The labeler must provide third party information during the GUDID account request process. If the third party is not associated to the labeler's GUDID account, the submission from the third party will be rejected.

Third parties provide different levels of service. They may:
- Provide just the software solution or tool to the labeler to generate HL7 SPL XML files, and then the labeler sends the submissions through the ESG. In this case, the labeler must obtain the ESG account and complete all the required ESG and GUDID testing.

- Or the third party may provide an end-to-end solution. The third party uses the labeler's data to generate the XML files and then sends the submissions to the ESG on behalf of the labeler. In this case, the third party obtains the ESG account.

Slide 30

Third parties who want to develop solutions and tools to generate GUDID HL7 SPL XML files to sell to their clients are given GUDID test accounts so they can use it to develop and test their solution.
Labelers who intend to use a third party submitter must still request a test GUDID account and must complete the GUDID testing process, either on their own or along with their third party submitter.
You may wonder why individual labelers must complete GUDID testing if they are using an experienced third party submitter. The answer is that the data drives the business rules in GUDID, and each labeler's data set is unique. Each labeler must perform GUDID testing with their data.

Whether or not labelers use a third party submitter, the Labeler is responsible for fulfilling the GUDID submission requirements. The labeler must ensure submissions are received and processed by the FDA. You should log in to the GUDID and view your records to make sure they are correct. The labeler is also responsible for reporting by the compliance date, and for all record keeping.

Slide 31

For those of you who are third party solution providers, you may test your GUDID HL7 SPL submission solution independently of the Labelers.

- Request a GUDID test Account, and indicate it is for HL7 SPL testing

- Dummy data for certain required attributes will be provided for testing purposes ONLY, upon request

- GUDID web interface access is NOT provided, and GUDID production accounts are NOT provided

As you work with labelers, third party submitters must complete GUDID HL7 SPL testing with each labeler, using the labeler's data. Also, make sure to use the labeler's GUDID test account.

Now that we have gone through the HL7 SPL Submission process, here are some key pointers to keep in mind.

It is important to read the "GUDID Guidance for Industry and FDA Staff" document because it describes the DI record life cycle, how to set up packages, and more. Don't limit your reading to just the HL7 SPL package of files.

Allow adequate time for testing both the ESG and GUDID. We estimate 12 weeks based on past experience, and it goes faster if the labeler has done the up-front work and testing to make sure the records are complete and correct.

The GUDID testing completion criteria is the bare minimum. The process is easier for everyone involved if there is thorough internal testing to ensure the scenarios appropriate for your products are accounted for.

Slide 33

Validate your submissions against the GUDID HL7 SPL schema. If you do not validate then you will likely encounter the unparseable error message that I mentioned on the Acknowledgements slide.
Do not submit the sample message that we provide in the HL7 SPL implementation package as a test submission, it is not validated.

When submitting via the ESG, please specify the Center as CDRH and the Submission Type as GUDID. If the submissions are not electronically delivered to the right place then you will experience the unidentified error message that I mentioned on the Acknowledgements slide.

Slide 34

Make sure to follow the Submission Folder Structure. The top level folder must be uniquely named. The lower level folder must always be named "spl" and there can only be one spl folder. The GUDID HL7 SPL XML submission file must be named "submission.xml" and this is the only file that can be in the spl folder. That means there is only one submission, or one DI record, in each folder structure.

If you do not follow the correct folder structure then you will receive the unidentified error because the DI record is not packaged correctly and the system cannot extract the submission from the folder structures and read the file.

Slide 35

Note that you cannot submit draft DI records via the HL7 SPL submission option. Records can be submitted as, Unpublished where the DI Record Publish Date is in the future, or Published where the DI Record Publish Date is today.

During testing, it is important that after your submission is submitted and loaded, you review it via the Web Interface. Login as a Labeler Data Entry (LDE) user and the Labeler DUNS number for that DI record should be assigned to you and show in your list. Verify that the information you sent in the XML file has loaded correctly.

For those labelers using a third party submitter, you are not finished when you send the data to your third party submitter. You are still responsible for your data and you need to make sure it is loaded correctly to GUDID.

In the GUDID Web Interface, if you click on the ViewHistory hyperlink on the DI record, you will see the username specified as SPL USER for all records submitted via the HL7 SPL submission option.

Slide 36

Let's briefly talk about Data Quality. As you know, GUDID is the master repository of Device Identification information and we want to make sure that information is complete and correct, so it is imperative that good quality data is submitted.

So how can you ensure good quality? I already described the process before you move to production. Complete internal testing for all of your different product areas, and verify your test records are loaded correctly by logging into the GUDID web interface and reviewing them.

After you move to production, you need to continuously monitor, review and correct records. There is a grace period in GUDID that is 30 days. During this time you can edit all data elements in the GUDID DI record except the publish date. Please use this time to review your information.

You can also use the export feature to export all your records in GUDID as XML files, and compare the data against your source system data and make corrections.

The records are displayed in our public portal, AccessGUDID, after the grace period ends, so reviewing your records for the first time once they are available in AccessGUDID does not help, at that point it is too late.

Slide 37

I know I have already said that the labeler is responsible for their data in GUDID, so I will say it a different way. Once the data is available in AccessGUDID, it is available to the public for use in searches, downloads and lookups. It is your data, and we all want the data to be of good quality, so please help us make sure it is complete and correct from the start.

Slide 38

You can edit your HL7 SPL Submissions. When you want to make a change to a DI record, submit the entire DI record, both the changed and unchanged portions of it. The DI record will be completely replaced in GUDID with the most recent information in the XML file. The document.setID attribute in the HL7 SPL submission file links all related submissions, so for each edit you need to retain and provide the same setID.

The document.versionNumber attribute in the HL7 SPL submission file tracks versions, so you need to increment this by 1 each time you edit and resubmit, even for failed submissions. For example, if you send a submission and assign document.versionNumber equal to one, and receive a failed Ack3, then increment the document.versionNumber to two before you resubmit. And a second example, if you review your data in GUDID via the Web Interface, either before the record is published or during the Grace Period after it is published, and notice an issue with the submission, fix the error, increment the document.versionNumber, and resubmit.

Slide 39

As you know there are two submission options for GUDID, the Web Interface and HL7 SPL. You may choose either option to submit, and we recommend you use the same submission option for the life of the DI record to maintain the data consistency, but we realize that is not always possible. There are some restrictions for editing DI records, depending upon where it is in the life cycle.

Records entered using the Web Interface must be edited using the Web Interface as long as it is in the Draft or Unpublished state, or in the Published state during the grace period. You cannot edit a Web Interface record using HL7 SPL until after it has published and passed the grace period.

Records submitted using HL7 SPL may be edited at any time using either HL7 SPL or the Web Interface.

Slide 40

After you make it all the way through the HL7 SPL testing process, here are some tips for submitting in production. Start sending your submissions in small batches to make sure everything is working, and then slowly ramp up. Limit the number of submissions sent at one time to no more than 500 DI records.

And if you do not receive Acknowledgements, please contact us before resending the submissions so we can check to see if there is an issue.

Slide 41

Scheduled downtimes for both the PreProd testing area and Production will be posted on our website under GUDID System Status. We will also post Unscheduled downtimes as we become aware of them. If the system is down and there is no notice, please report this to the UDI Helpdesk. You can subscribe to GUDID Email Alerts so that you are automatically notified of system outages, upgrades and updates. There is a link on our website to subscribe.

Slide 42

I hope you found the HL7 SPL submission information presented very informative. There is a wealth of information on our website regarding the HL7 SPL Submission process, the testing requirements for ESG and GUDID, and how to edit your records. And finally, please contact the appropriate helpdesk to obtain help if you need it. Thank you for your time today.

****