GUDID SUBMISSIONS AND BEYOND

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In collaboration with Joe Hage and the LinkedIn Medical Devices Group

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Joe Hage: Hi this is Joe Hage. I have the privilege of leading your Medical Devices Group which, as of this recording, has 311,000 members worldwide and perhaps more than any other group members, John and Gary and the folks over at ReedTech, I think are responsible for our growth because they have consistently given us great value on this topic which is in such high demand that this is our seventh collaboration. John Lorenc is going to talk to us today about GUD submissions and beyond and then he's going to get on a plane and go to Thailand. So pay careful attention before his jetlag. John you're up.

John Lorenc: Alright. Thank you Joe. And again, thanks for having us with this webinar and thanks to everybody who's joining. Good morning, good afternoon and good evening. As Joe mentioned, my name is John Lorenc and I'm a UDI Product Manager here at Reed Technology. So for over the last three years of so been working in the UDI space. So today's presentation, discussion we'd like to have is about the GUDID submissions themselves and what happens beyond the submission. It's not the final step getting into the FDA GUDID, there's other areas in which you could leverage your UDI data.

The objective will be to have an overview of the FDA UDI Compliance mandate and to also discuss how to gather your data, ensure success when submitting to the GUDID as well as avoiding problems others have encountered. And mentioned earlier, how to understand how the data can be leveraged downstream.

So first, I'll have a brief overview of the FDA UDI regulation. Then I'll move into a UDI and GUDID implementation plan. Lastly, cover leveraging the GUDID data downstream and then we'll go into some Q&A.

What you see on your screen is probably famous to everybody. When the FDA released the final rule on September 21st, 2013, I know I was actually at a UDI Conference in Germany when that rule hit and basically everything we talked about while we're over in Germany while folks here in the US were preparing to get started. Essentially, the rule states that medical devices distributed in the United States must carry a Unique Device Identifier or UDI. And as part of creating these UDI's, the FDA created a system to gather all the information and that's called the Global Unique Device Identification Database. You will hear me refer to that as "good-ID" later in this presentation. Other folks say "goodid" but I tend to say "good-ID" so this is what I will be referring to. And this GUDID includes a standard set of data elements which identify the device for each unique device.

This slide shows some of the purposes of UDI implementation. Note that UDI itself is a data or at least the GUDID submission itself is a submission of data associated with the device. That submission alone does not provide all of these things that you see on the screen. However, it can start the conversation. We now have a standardized set of medical device data which now can make things like this much more efficient or achieve things we've not done in the past. True we have done adverse effect reporting in the past but now when the UDI start being added in the adverse events, you'll be able to experience some more efficiencies among that process.

So what is the UDI? The UDI is a unique numeric or alphanumeric code that consists of two parts. There's the Device Identifier and the Production Identifier. The Device Identifier is a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of the device. This is actually the information, the Device Identifier is what is submitted to the FDA into the GUDID.

Production Identifier is more conditional and it has information included on the label such as lot or batch number, serial number, manufacturing date, et cetera. This information itself does not get submitted to the FDA as part of your UDI submission and get loaded into the GUDID. Again, only the Device Identifier information will go to the GUDID.

Overview of the regulation, obviously there's labeling impact for your label to have, to mark and burry you with UDI both the Device Identifier and Production Identifier and have the UDI in human-readable plain-text and automatic ID and data capture technology. Barcoding. There's also data format changes that had to be applied to the labels.

With the UDI came Direct Marking requirements. There's tons of documentation available in the FDA's website and I believe I have some reference material at the end of this presentation which you could use at your own leisure to read up on some of the Direct Marking requirements.

And as mentioned, the FDA GUDID also being a key component of this regulation. Submitting that data and device attributes to the FDA which they process, validates and then ultimately pass over to the National Library of Medicine to host on a public website called AccessGUDID.

Lastly here is reporting. What you will begin to see or have already started seeing is some of the other responsibilities you may have will start including the UDI. Again, for more tracking and traceability. And it gets back to my point saying that the UDI itself does not alone provide track and trace but it helps make it easier to get there. Tie these other things together.

With the Label Data versus the GUDID Submission Data, some of the data as mentioned is going to be part of the Production Identifier which is more geared to what's happening in your labeling systems, on your product package label and the end-user would be able to see this information. Whereas the GUDID data are these large group of device attributes you may or may not be aware of depending on what's your product, how it is compiled to have up to around 62 fields and all that data has to be submitted to the FDA as mentioned ultimately hosted on the National Library of Medicine site.

However what we see is there's various sources of this data which becomes quite problematic. And having to go out and source or first identify and source where the data is coming from is quite a challenge in the front. So I want to kind of plant that seed right now as until later we start thinking about leveraging UDI as a way to start achieving master data management through device inventory in the future.

Another slide here under regulation, the classic timeline to Class 3 devices, we went through that wave in 2014. But then we was followed by the implantable life-sustaining, life-supporting devices submitted in 2015. As I mentioned to Joe, that's also when I had my first son. So I missed that. My son was born on the 23rd. But now we have the Class 2 devices. So creeping up on my son's first birthday, we have a huge wave expected of Class 2 to be submitted this year.

The FDA did hear industry, the contact lens industry had some pushback on submitting according to their original deadline they were given stated the nature in which their products was making it quite challenging to adhere to other timelines. Towards the end of the year last year, the FDA did publicly state that they will extend the deadline for soft contact lens manufacturers into 2017. They also mentioned that there will be a updated technical implementation guide released. I believe they said March of 2017 which will describe some of the differences in which you need to capture and submit the soft contact lens information.

Being a UDI System Product Manager, I love to have those specs a lot sooner than that. So hopefully some of the … as time goes on, the FDA could start releasing some details sooner rather than later. But lastly, we had the Class 1 deadline in September of 2018.

So note here, only 6 months left until the Class 2 submissions are due. So it's really time to get cracking on this solution if you have devices in that class.

I'm showing as simple as I can, 4-step approach of GUDID implementation. Starting up with your GUDID system prep, GUDID data prep, submitting the data and once your submissions are completed, moving into maintenance mode and also achieving some downstream use.

Step 1 with GUDID system prep, it's important to evaluate, select and implement your GUDID solution so in future slides we'll show some of the options there. Creating your FDA GUDID accounts. This is something that all labelers have to do no matter what type of solution that you choose, you will need a GUDID account from the FDA. And also creating FDA ESG accounts. If you're utilizing HL7 SPL to submit to the GUDID, you will require to have an operating ESG account. And that's for those who may not know, the ESG is the FDA Electronic Submissions Gateway which is utilized to make electronic submissions to the agency.

So starting first with identifying your requirements, this slide has plenty of links and again, I know Joe will be distributing these slides. So please feel free to use this as a resource and tool. Hopefully it's organized well and can help you find what you're looking for. So a couple links here of learning the basics of UDI. CDRH does a great job of e-learning system as well and they also post some recorded live webinars to kind of get their perspective of everything. And there's as you could imagine quite a bit of guidance to go through. With the final rule, guidance for industry and getting more specific into the data elements that are required to be submitted.

So as you have an understanding of, at least high level understanding of what's going to be required, you can start identifying what you have. What are your device classes, product codes? Be sure you're aware of what your compliance date is. The FDA does have some sort of exceptions. I don't know how frequently they grant extensions and things of that nature but all that information is available in the link at the end of the … in the reference material as to how to check that out. But for the most part, I don't see it being that active and then also check any industry associations and providers.

As you're looking more into your situation, one of the tough things that I see with our clients is where do I get the data? So that's a huge analysis effort that has to happen upfront to understand where the data is in your organization. Do you have any gaps? Are there owners of that data? What formats that data being stored and et cetera?

Also looking at any internal standards you may already use with the UDI. There are different issuing agencies you could utilize and maybe you're already using GS1 GTIN's or maybe there's nothing in place yet. So evaluate those standards.

Knowing how UDI is going to impact different groups in your organization, start thinking about how workflow, any compliance documentation training that may have to be changed to meet this new process that will now be a requirement. Or there may not be anything in place at all yet and you have to completely create all this from scratch.

Evaluating your internal systems, again, if you have an existing MDM, so if you have a master data management system already and you are foresightful and collecting all this data or at least something similar to the data since the FDA began talking about this, then you're well ahead of the pack and that's fantastic. But for the most part, what I see is there's perhaps multiple master data management systems that have different data for different reasons in different groups. So an evaluation has to occur there. For what's the FDA's going to be expecting the source of truth, what should be the source of value of each element, the true value. And then any other technology you may have with barcoding. How may that be impacted?

To evaluate and select a GUDID solution, you have a few options. At a high level, the FDA allows for manual entry directly into the GUDID database. So in that case, you would still have to gather all your data and you're entering it directly into the FDA system and saving it there. That is the FDA's data that's more for lower level volumes as you do have to manually enter each record one by one and it has limited functionality with what you could do with it afterwards. It's really designed just to get the data.

Another option is the HL7 SPL submission which is targeted for folks who have larger quantity devices want to make a more efficient submission and a way they could read data from existing systems or creating even MDM-type systems with medical device data that has a connection to the FDA to shoot changes when changes are made. So that is the solution but you also need the FDA Electronic Submissions Gateway and again, you would have to set up a FDA GUDID account as well. I've dived a little bit deeper now into these two options here.

So for the medical device manufacturers, as mentioned, you could perform the manual entry of those records in the FDA's interface and be there. You will be loaded in the FDA GUDID. From a HL7 perspective, you could purchase or subscribe to software applications in which could take in your data, perform various validation performed against the data to ensure it'll pass the FDA's check before submitted and then ultimately submit to the FDA again, into the GUDID. And we also see a good amount of folks outsourcing.

So they might gather the data and go through that effort or look for some help in gathering the data and then simply hand off that data template to a vendor and say, knock yourself out. And usually that happens also in a HL7 submission model. Few organizations we have seen have built their own. So if you have the staff and dedicated resources to stay on top of this, it's

essentially a fulltime job then we have seen that happen a few times where they make that investment to build in-house.

Some of the comparison to these few submission methods. There is first off for the FDA GUDID web interface, as I mentioned, you're manually entering the records. It's really suited for low volume. You have to QA within the system and you have the FDA's Helpdesk available for you but again, it's for slower … it's going to be slower in the event that you will enter everything manually but if you have one record maybe that's okay for you.

Hectically no software cost for utilizing the FDA's application. However, there's absolutely administration and data entry, QA labor cost. There's still … someone's got to do it. And that cost is still there.

From hosted software, you're using external software to collect data, build and electronically submit. This is more of these software as a service model where it's not installed in your four walls and this is also suited for low to high volumes. Technically, you have subject matter expertise that is available to you to support and training the system and it's a database-driven solution where you could do more work in bulk. You're essentially from a technology cost, you're renting the sheer database so you typically see subscription models but again, anything like servers and all that kind of stuff, you don't have to worry about it. That's the vendor that's managing that. And for the operational costs, it would be the admin labor. So even though you don't own the software, you're utilizing it. You're still going to have employees at your organization utilizing the software to submit to the FDA and maintain any records that may have changed.

As mentioned, the outsource service. There's that external partner that's really going to help you build the data, submit to the FDA and all that on your behalf. There will still be some resource needed because any contractor helping you is going to have to understand your organization and make up but there are people out there to help you do all that.

We do say it's the least internal effort. Again, other than the fact that you will need an owner in the organization to work with these consultants to ensure they know where to go to get the data they need.

Here also, you're renting a shared database or software whatever they have but you have now cost for the contractor and the service cost as well.

The last option was the on-premises installed software. So this is the build/buy, install, validate, train the whole suite internally. So we would only see this really recommended for high volume submissions. The only help you're going to get is going to be from the FDA Helpdesk because

you don't really have a vendor at this case. You are creating it yourself. And it's an internal effort unless you contract software development providers to help you.

In this case, you will own the software, you will also need to set up an ESG account because for the most part we see a hosted software that is connected to the ESG directly so you're kind of getting that in that subscription fee for usage of the system. Then operational cost obviously, administration of that system, maintenance of that system, operations and labor.

Now creating the FDA accounts, I mentioned this is required regardless of your submission type. You have to contact the FDA with a form and request to open up a pre-production GUDID account.

So this process starts with the labeler requesting via this web form and you identify which submission type you will be leveraging for UDI. Again, your option being web interface or SPL. If you do elect web interface, the FDA will go ahead process the request and open up a GUDID pre-production account for you.

So there you go. Pretty much end process there.

If however your submission type is SPL, you now will have to wait for the FDA to create a pre-production GUDID account and then they will contact you with logging information so then you can begin setting up testing.

Since you chose the HL7 SPL method, this is an XML transfer into the FDA system. So they do ask that you perform a few scenarios of submission testing. So that'll be required at any case even if you already had an account under another company. But then the labeler again as mentioned will submit those six SPL test scenarios and for the most part that's okay but if it seems kind of generic, the FDA might ask you to submit some more data.

Once complete, the FDA will email you and let you know that they've accepted that your test submissions were valid. They'll go ahead and create a production account for you. And now is the time where you will now redirect your ESG from your production ESG account to your production FDA GUDID account.

Once that's complete, you're essentially all set up for making live submissions. However you may not be ready yet but at least you have the connection.

Step 2 is collecting the source data and normalizing and validating that source GUDID data. And here, I also want to start again, painting this theme of master data management. As you see on this chart, there are various places in which data is coming from. Multiple storage locations and formats and we have this huge data collection effort now to obtain all of the GUDID data

elements. This is something that we're probably not going to want to have to replicate again in the future.

The slide shows again, more detailed examples with collecting data from production systems, PLM systems, URP systems, any regulatory relations that you have. And also the external organizations. This data set requires DUNS numbers from Dun and Bradstreet, GDMN codes, the information from your issuing agency. And now with the 55 or so GUDID values in the records, we highly recommend using a data template to organize and collect this content. What you're doing now is you're beginning to have your organization step into a master data management solution for your medical device portfolio.

If you think about it, you're working to make a regulatory submission, however, you're also doing a lot of work to organize data and centralize it when in the past, it was and as we could see was first out in all these different locations. UDI can actually help create a master record for your device. And with that thought, it might be advised to collect additional data fields. You're already going through all this. Say the FDA wants 55 but maybe there's some additional data you want to start collecting and associate with your device identifiers or maybe you're thinking about future submissions to international agencies and maybe this device is this class in the US but in Canada it's this class. Start thinking about things like that.

Here's an example of our data question template that we provide to our clients essentially again, laid out with all the FDA required fields but also expanded to see of you collect additional data. We also provide some reference tabs to help guide you in that data collection effort.

Screenshot here showing data which could be captured on the label. There are … we've worked with clients which stated, this is what I have. They didn't have this data available electronically anywhere. So we're literally looking at labels and looking at icons, determine expiration date and such. So you could see if that's something that you have to do. This would be an example. But data mapping, you would have to get into a standardized template.

Slide's showing some data collection issues that we've encountered and would like to share just to kind of fit the universe of data here. If you have 1,000 device records, so assuming a thousand device identifiers, and each record is 55 fields. We're talking about gathering 55,000 fields of data.

So some of that obviously may be similar and reusable but most are going to be unique. That's why they are unique devices. Again, data being in desperate locations. So identifying where that is, getting it and consolidating it. But still, start keeping in mind that how could we now end this and start centralizing this data later?

If there's data owners at the company, getting them engaged. Maybe there is no data owner anymore. Some of them left the company. There's going to be varying formats in which your data exists. This is the first time it is being submitted electronically and being put against rigorous electronic validation rules. So until you have that standardized data set, you could expect almost all variety.

And as illustrated with the previous slide, you may not even have digital format. You might have to use the label template as a graphic guide to identify what your data value should be.

Some of the fields that we've seen being more problematic are the labeler DUNS numbers. We saw this also when we're working with electronic product listing in SPL for CDER and CBER. When they introduced the DUNS number in SPL submissions, it was totally new to the industry. So there is some time that needs to be taken to do some research at your organization and find out which DUNS number is appropriate to use for your UDI submission. And that's all managed through a company called Dun and Bradstreet.

Now we have the GMDN or FDA preferred term values. We've see things where maybe the GMDN code's obsolete then there's a new term preferred. So just be mindful to ensure you're using what you have as the latest or if not, you may receive a message from the FDA when you submit that maybe obsolete.

There's also a whole slew of device identifiers that could be assigned. What we're mentioning earlier was the primary device identifier which is the DI part of the UDI. However, there's other areas in which in the data set you could have device identifiers and signs.

ReedTech actually recently released and e-book on device identifiers which will be available for download which goes into the descriptions of all the different actually it will be next week the different device identifiers and where they apply.

Also package and kit configurations. Being working with SPL for about 11 years now, kits always tend to be the challenge for everything whether we're working with drugs, combination products, medical devices. They just always seem to be special.

So now, looking to normalize and validate the source data, we're showing again the multiple storage locations or formats collecting that and now normalizing and validating. This is now we're getting close to the point where we're going to have a valid data set that we could submit to the FDA either web interface or SPL.

Normalizing steps, you're going to have to apply FDA business rules. So the GS1 GTIN have certain numeric business rules. There's certain date formatting. There's a ton of controlled

terminology. So you have to say CM and actually I believe my slide's a little misleading here. I believe it's "[cm]" is the technically correct field value.

So you have to insure you have it in that format. If you submitted centimeter to the FDA, that would not pass validation. There's also a group data that you have to if you're submitting one value, you have to submit all three and example of that is your clinically relevant size type value and units. There's also dependent data in there that as if you're answering yes to a particular True/False question, then a yes may mean and tell us what your sterilization method is.

So there's all types of different validation rules related to the way the data's being gathered. And I can tell you with experience, the validation, specifications probably just under 200 pages. So there's a lot of reading to do if you're looking to begin. However, there are some obviously some applications out there that could help guide you or also automate some of those translations for you such as ReedTech system.

Continuing with the GMDN code, I touched on this briefly earlier with the GMDN codes becoming inactive, checking that terminology to confirm the code is correct is key. If you do not do that and you submit anyway, that will be something you're going to carry back in what they call as an Act 3 Failure Message if you submit through SPL and the FDA would inform you that it's obsolete. So I would recommend doing that check upfront because the FDA is not going to tell you what the correct value is. So you're going to have to do that research anyway.

Again, looking at that list of values, with this being a HL7 electronic submission, it's very strict with the way in which you have your data formatted. It sounds really painful and I'd guess annoying but just to think that you're going through this rigorous exercise to get clean pristine data for all of your devices in your portfolio, what can you do with that downstream? If you're going through this exercise now for this submission requirement but at the end, you're going to have a very trusted source of medical device data in your organization.

Some of the lessons we've learned with the data are receiving incorrect data values. So with data not being electronic upfront, you may have some manual typing or whatever typing, your reading handwriting, so you got to perform some quality check depending on where that data is coming from. The incorrect date formats, not using controlled terminology. We've also seen the product identifier being included with the device identifier but that's not what is going to be submitted. Invalid check digits come across or direct marking DI or packaging DI's. Again, I will again state to lookout next week for that e-book on DI. They'll explain how they should be assigned properly.

We also seen valid labeler DUNS numbers. I mentioned that was a pain point in ensuring that the DUNS number that you register with the FDA and your GUDID account matches what's in your SPL files or your manual entry files when you send to the FDA. Invalid FDA listing number is

a little common as well and since it's a proprietary information, software service providers is something that and I'm not quite sure how it would be in your organization, it's a little gap there because there's no publicly available list to cross-validate that you have the right listing number.

So I've seen these come back sometimes where one organization thought actually listing number was something different than what the FDA thought. So it could realize some interesting feedback results.

Again, just with the information the FDA's looking to receive and the business rules that require proper entry, these are just a few of the things we're seeing. I didn't want to have 30 slides on potential data issues but I hope this top 16 will come useful and again, you could reference at the end of the presentation as you have the slides.

Step 3 is now we could finally talk about submitting. So submitting to the GUDID and verifying your submission is public. The high level flow of we've gone from gathering our data, normalizing it and now we're at a point to input in the web interface or submit via SPL and achieve success with published records. So now we're ready to go live. Manual entry, as mentioned, you're entering direct records into the database. You're going to have to send those for review. So you can perform an FDA validation check. You have to perform a QC of those records in there. Make sure they're accurate. Because once you hit that submit button, you're giving that to the FDA and setting the published state of the record.

For automated bulk entry, this is more of the HL7 SPL. This is when now you would be ingesting the data that you have gathered and validating that data. For most part, vendors validate it prior even getting to this point but you're essentially loading it into vendor system or your internally developed system and building the SPL system UDI files per the HL7 technical specification.

Once that's complete, you'll submit the UDI to the FDA via ESG. There's two different options. There's the WebTrader where you have to login to a portal site and then you have to submit one record at a time. That's not very tempting for a UDI solution. So what we elect at ReedTech, we have the AS2 ESG connection so we can send bulk submissions to the FDA. Essentially we know the FDA only really looks to have 500 active submissions occurring at one time per labeler. However, we're able to load in as many records are available and then throttle those submissions to adhere to the FDA's volume requirements.

So if you're looking for bulk high volume processing, the AS2 is definitely the way to go but you might have to do some customization to ensure you're adhering to the FDA's loading requirements.

Verifying your submission, you can verify in the web interface, you could log in, look at your data and do all this prior to your grace period ending. Right now it's 30 days. So 30 days after your UDI publish dates, the FDA will go ahead and publish your record in AccessGUDID. Your HL7 submitter, you're one to be monitoring looking for your acknowledgment. These are coming from the Electronic Submissions Gateway.

So Act 1 stating the FDA received something. It's like a handshake between your account and their account. On Act 2 states that CDRH received the submission package from you but still it could be a picture of Mickey Mouse. They haven't opened it up and looked at it yet. And now Act 3 is when they really drill in and analyze your SPL and perform the full validation. This will result in an Act 3 pass or fail message. If everything's fine, you'll get submission successful. However, if you have errors, the FDA will start returning you those errors in a spaced approach.

Unfortunately it's not all error messages throughout that entire file at once. They have about 4 steps of validation and as long as you get through the first step, they go to the next. But then if you have an error in the second step, they stop and send you a message and they never got the steps 3 and 4. So it's not very comprehensive with the validation result in one shot.

However, ideally if you have an SPL system, it's designed to do all that at once so you don't have to piecemeal this submissions.

Now you can indicate your GUDID record publish status. As mentioned, when you submit and UDI publish date has yet to hit, you'll be unpublished but once the UDI publish date occurs, you'll be in the grace period for 30 days. Once that's done, you're final published. You're in the public domain with your record. There are some things that can be done through the submissions interface to retire a product if it's being taken off market.

And I just like to remind everyone that if you have any questions with the content I'm covering, you can submit those questions throughout the session and we'll queue them up to the point where we get to Q&A. So you could just type them through one of the moderators.

The questions module. So some lessons learned on submissions, incorrect GUDID application information. This is a bit of a manual process I believe between labors and the FDA. This is when you're filling out that application to have your GUDID account created and we've known a few times where we were identified as a third party submitter with our correct DUNS number but then as we moved on to make submissions, our clients was getting failure saying that this third party submitter is not authorized to submit for this labeler.

So what was the problem there? The problem was, when we got notified by the FDA that we were set up, they didn't hectically set it up yet at the time. So we went with some test

submissions a few days later but their database truly didn't have the updated DUNS number for ReedTech in there and after a query to the FDA, it quickly and magically was resolved.

We also see people get submissions. There is submission record life cycle rules that you have to adhere to. A DI can only be submitted and published once. You cannot have multiple versions of it. However you can maintain a subset of the data elements after you've been published. Otherwise you're going to have to make a new submission for a new DI.

The missing FDA acknowledgment. So the volume of submissions for these GUDID submissions is quite substantial compared to anything else the FDA receives other than I'd say maybe adverse event reporting. Each primary device identifier is its own SPL submission. So there are times just to give you a sense of volume, to this point, I believe ReedTech has submitted over 130,000 UDI's and we've been doing this for since the submission mandate in 2014.

However, we've been making drug listing submissions since 2009 but since multiple products could be in SPL for that submission type, maybe we've submitted about 10,000 to 15,000. So just the volume just explodes doing the one at a time approach. And as a result, there's a lot of load for the FDA ESG to take so we do absolutely experience some performance issues where the system goes down. The FDA system goes down. They maybe lose acknowledgments. So you really got to have to have a solution in place to keep an eye on that. To ensure that you're getting back what you're really looking for. You're getting back what you're expecting.

Also, the FDA Helpdesk has been fantastic. They have a very well-set-up helpdesk system where you actually get a helpdesk ticket number and from all the queries I'd entered, I've always got a response in a reasonable time. However, if you're giving them more information in your query, I think it's better success to get a quicker response. One of the key things is the coreID is what you would receive in an SPL submission. If you're following up to see maybe where your third acknowledgement's been because it's been a few days.

So that's been very helpful. Submitting close to the compliance date is challenging because that's when we really see the peak of the FDA volume hitting their ESG account. So I would recommend if you're getting ready, just get it done as quickly as you can and not wait. In the past, the FDA has extended a compliance dates maybe like 30 days and a lot of that's because just the volume they're getting. So they could process all the data.

So try not to get caught up into the autumn rush of the UDI submissions. But then ultimately, we get there. This is where you'll be. This is the UDI repository that's hosted by the National Library of Medicine AccessGUDID. So once you have expired your grace period, it gets publicly visible. So I just want to stress that make sure your organization's aware of that grace period because that's the 30-day window in which you can make any corrections to previously submitted record that is yet to be published.

So they give you that time to double-check even though your submission went through successful. If you just go ahead and review it there and you have the opportunity to catch it before it gets published to this site.

So Step 4 is now we've actually kind of started production but maintaining the systems and start thinking about leveraging the GUDID data beyond your submission.

Start production with UDI. Confirming your device records, publishing GUDID as we're showing in the previous slide. Cutover process to include UDI on product and package labels and with direct marking where applicable.

You have to manage any existing inventory within a 3-year allowed window and flow your Device Identifier and Production Identifier from production systems to labels.

This is now a way you could use the data in other ways and how do you do that? This is where having a medical device master data management solution could help you achieve some of these efficiencies. You've gone through this rigor of collecting all this data. Consume it back into your information and maintain it from there and let it drive other process.

Data maintenance step is updating, retiring labels and GUDID records. So you have to keep an eye on that. If products are getting taken off the market, we're going to have to clean that up in the GUDID and add device labels and GUDID records for new products. They'll start experiencing this when you have a product change coming and you realize that a couple of values have to change and they go, oops, you can't change that. You're already published. The FDA's telling you this requires a new primary device identifier and you have to either retire the old one or let it ride until it's no longer on the market.

Under system maintenance, update, validate, train, we all know this. We say here for in-house software only but even if you're utilizing SAS, subscribed software, there's still going to be some procedures and SOP's that you're going to have to have in place with your organization and train on those and keep those current.

And knowledge maintenance, monitoring and implementing changes of the FDA regulations and guidance. There is a way to subscribe to email notifications. It's the same ones that everyone gets. We get them here at ReedTech and part of our day-to-day activities is always to ensure that we're on top of what is happening in UDI for USFDA and also what's coming in the future internationally.

For those of you who've seen one of our earlier webinars in which my colleague Gary Saner led, you might have seen a slide similar to this and the purpose of this slide at that time was to

show, I changed some of the labels but I kept the image. If Gary's on, he'll see. If not, I'll show him when he comes back.

It was previously showing well, look, you have data in all these places and you need it here to submit the GUDID. So but this is now later in the game. You did that. You collected all that data. What you should have now is you achieved the master data set, right? All of the data that you collected from all these individuals have now been consolidated.

So start thinking how could you leverage that? Bring that into a master data management system if you have one. If you do not have one, start thinking about creating one because now you could feed the data back to them as needed and always be relying on one single source of truth.

I think that's really an important discussion that organizations have to have so they can start receiving some value out of the investment that they made for UDI compliance.

So again, GUDID data as master data. It consolidates all the data that was previously dispersed in various systems. All that validation we were talking about earlier and also the pieces I chose not to bore you with. This data's gone through it. So what better source of trusted data could you have for your devices?

So again, I recommend taking that data to existing MDM systems or use it as baseline to develop one. Start adding more to the field. Leverage and synchronization of product data within labeling systems, ERP systems. This is all something that some folks are already doing. I mentioned including the additional non-GUDID data to strengthen that data set. It helps prepare you for what's coming next. If it's international submissions. If there's a new regulation coming up for customs called ACE where they have some similar data sets being required but then other data that is also not involved in the GUDID.

And how about some analytics? Now that you have this standardized data and also what's published on the FDA or AccessGUDID, what type of analytics could you lay around that to see if you could discover trends? You could even use it for competitive intelligence or analysis using the data that's on AccessGUDID. I mean there's certain values that do not get published to AccessGUDID such as like the FDA listing number. You're still going to keep that a mystery and I believe that you all are probably happy with that. But there's still a good deal of other data that I think will be interesting for the organization to consume and kind of start doing some data mining in.

And also keep an eye open on OpenFDA. If you are not familiar with that initiative, the FDA has been publishing data sets publicly. They put out some API's that you could utilize. There's adverse events. To this point, I don't think they have the UDI in the adverse events for

publishing yet but that'll be coming. Those adverse events are in HL7 ICSR coming from the same common product model from HL7 SPL. So all this data is meant to live together someday. So just keeping an eye out on that site and as data becomes available, you could see what types of things you could do with it.

There's the reporting. Reporting product data to consumers, distributors and such. You now have that ability if that's done from GDSN or what other means but now you have again, trusted source of data and speaking of ROI, this is a story that was brought up to me recently that I thought was pretty incredible. Where a company as I mentioned earlier, the FDA has these Act messages saying that your submissions have passed validation. So it'd be an Act 3 pass.

A company designed a tracking system or reporting system to read that positive Act 3 for that DI and kick off downstream processes automatically such as going into the order management system and shipping.

So whatever the process was before where they would you know, have complicated order management systems or a process in place to initiate a shipment, they automated all of that tying it back to the FDA response to your submission.

So I thought that was pretty remarkable and I just wanted to share that with everybody. Just kind of get the thoughts going on what can you do with this data?

And again, implementing a data governance program. If you don't have something like that in place yet, you do not have a master data management solution in place yet, use UDI as a way to start having those conversations in your organization.

So just in summary, we talked about the GUDID submission prep, the data prep, submitting your data, then maintaining and downstream use. This is just to try to get a little screen shock value that we're working on the Class 2's this year. You see in comparison to what our years prior were. We're expecting Class 2 to just be the largest we've seen yet. As we have some estimates as to how large it would be but with the experience we had in Class 2, I mean implantables and Class 3, we expect it to be quite a busy summer.

We do have the Class 2 UDI submissions guide available for download. So if you do not have this already, there'll be a link where you could access that as some useful information and being prepared for Class 2 submissions.

And that's all I have for slides at this point. And I'd be happy to take any questions.

Joe Hage: It's good that you'll be happy to take them because they are lining up. That was a great presentation John. Thank you and folks, you'll see in the chat box, I've already given you a

link to the page where you can download these slides. We are recording this. If you need to jump off, we understand completely but I will tell you that almost everyone is still on. That is a sign of a good presenter.

Rene asks, can we export data saved in a draft GUDID submission? If so, what export formats are available?

John Lorenc: So in a draft GUDID submission, I'm going to assume that she's referring to the FDA User Interface. I'll answer in both ways but I'll first start there. The FDA's User Interface does provide a ability to export into some other XML format. It's not even the SPL format. But I'm not quite sure if you can do that if you're only in draft. It may only be available that your record was published. But I can follow up with that and confirm if needed.

Now for HL7 SPL, depending on your solution, I can only really speak from the ReedTech product when records are loaded into our system, we have many different ways in which data gets exported back to our users. One of the main reasons is again, the master data management need even though you may have a friendly UDI submission partner such as ReedTech that will be kind to you and not be too rigorous on data import. We do all the dirty work inside the system then we export back to you exactly what's the FDA's controlled terminology is and values are so you could sync up with your master data management system.

Joe Hage: Thank you John. Next question, Jay asks, we are a paper document-driven company. Not Part 11 compliant. What exactly is the FDA expectations for the source of truth in this scenario? We utilized our MDM system for UDI. Just have a link to each product, part number and its associated D number?

John Lorenc: Okay. So we're talking fully paper-based at this point, there is information within the FDA guidance document with respect to Part 11 compliant expectations and they differ through the way in which you're submitting and so either if it's you have a third party submitter such as a ReedTech or you're using the web interface and the requirements differ a bit between those. So depending on what GUDID solution you have would really dictate what you still need to do from a compliance perspective because there's also requirements in maintaining the data set and we're expecting that that data set is being maintained.

So if you have this solution partner that offers you that storage and has the audit trail capabilities, your signature processes, then it looks like you'd be okay but again, depending on how you're submitting really dictate what the FDA's expectations are.

I haven't been aware of any audits yet on UDI but I'd imagine that's going to come and we'll start hearing about it shortly.

Joe Hage: Mark asks, what in your opinion is the best data storage/source formats?

John Lorenc: Data storage, source formats, well, you have a few options. What we've chose for our system is equal server for storage. Source formats, we like to be as flexible as possible but if you had to hold me down at one of them, I like XML because I think just XML to XML communications between systems is fantastic. However, if those capabilities aren't there, we're big on Microsoft Excel as well to serve as your template like data capturing collection. It all kind of depends on what fits your individual organization's needs and capabilities.

Joe Hage: Elizabeth asks, if I want to use the SPL route, is there a template for all attributes required and in the background, Dan answered. I thought it worthwhile to read out loud. You can send an email to RT-LSS@ReedTech.com and their staff will be happy to help you. I'll put that in the chat box for everyone.

Jay follows up with a question. We have DI records stored in the ReedTech GUDID template. So this gets populated from the data in the labeling, regulatory, et cetera. Can this final DI record template saved unto a protected drive folder be considered our source of truth?

John Lorenc: Within your organization, so if you're storing this on your end and loading it into our system, not making any changes, potentially it could be. But if there's any data transformations that have to be made such as centimeter to cm during the SPL conversion process, we'd recommend a … we have something at ReedTech that's called … it's a MDM feed that's called Successful Submission Feed in which once nightly when the FDA has responded to all your submissions each day, we'll take all the data exactly as it was approved by the FDA and transfer it back to you.

So we personally recommend that approach because the FDA blessed to me specifically you can't get any more truthful than that and depending on how that template is stored and who has access to it, I think it can be done but maybe it's not just the ideal solution.

Joe Hage: Casey asks, can we use the FDA PT code instead of GMDN to submit for the published record or are we required to update FDA PT to GMDN later?

John Lorenc: I believe you have options there. There's the … a lot of times we see when the GMDN code goes obsolete, they're asking you for the other code. I would absolutely always send these types of queries to the FDA Helpdesk because as I mentioned in the presentation, they are phenomenal at getting back to you and you know it because they track it. It's not just like sending someone an email and you're hoping they get to it. This gets logged into a tracking system. Your ticket gets assigned and they have metrics to meet to support those roles and with those types of questions, I always recommend just going to the FDA because you'll get the

latest thinking from them as opposed to maybe something we've experienced a few weeks back.

Joe Hage: She adds, can the version code be the same as the catalog code? Perhaps you just know that.

John Lorenc: Yeah we've absolutely seen that. Since the required, we've seen people putting the same thing because they don't have two different version and catalog numbers. I've seen that quite a bit.

Joe Hage: Elizabeth asks, are you experiencing delayed responses from FDA Helpdesk with Class 2? She's saying it's been several weeks.

John Lorenc: Well, we do experience some delays. I'm surprised it's been several weeks. The helpdesk itself I have not been quite active with the last week or so but on the ESG and the GUDID accounts, we were experiencing delays there. I believe they're trying to strengthen up their infrastructure and prepare for Class 2 and with the limited resources that are working this initiative that the FDA's in, there's the **[inaudible 01:04:29]** is in such that I think they're spread all over the place.

So maybe some of the other efforts that have been going on have been delaying Helpdesk response. But if there's … you can always, I mean you heard me say I recommend going there first but if there's other questions that perhaps you wanted to send over to one of the ReedTech subject matter experts, maybe it's something that we can easily answer. But ultimately, they do clear out their queue. They get to every message.

Joe Hage: Cristoff asks, for capital medical equipment using software and instruments, do you need to use GUDID? If there are ongoing improvements, do you need to submit those?

John Lorenc: There is specific … there's actually a … within the links of the presentation, there's links to GUDID guidance and frequently asked questions and within there, they start identifying or answering questions just like this about utilizing software and instruments. So I would recommend going to one of those links. It's going to be the FDA Guidance, Unique Device Identification Questions and Answers.

Joe Hage: Charles wonders what type of MDM system would you recommend.

John Lorenc: Well, we don't have any … I guess to be transparent, we don't have any partnerships or anything like that with MDM providers. So I'm kind of neutral to whatever types of solutions are out there. I'm sure some are quite expensive whereas others might be more reasonable for smaller organization. So I really don't have any to recommend. I will say that with the ReedTech system, one of our initiatives in expanding our solution is we're looking to

start expanding the data model so we can in essence start branching out to providing more of a master data management solution to our clients.

So I would say talk to ReedTech. But obviously there's the SAP's out there and Oracle and such. But they typically come with a pretty heavy price tag.

Joe Hage: Tammy wonders how to follow up on an unanswered FDA Helpdesk question. She has her … an acknowledgement that they received it and a case number but that's it.

John Lorenc: I have replied to those but I don't know if it was the original one. There's … I'm not sure if the region modifications you received is one of those you know, do not reply emails but I believe there's a way. I don't know if there's when you're in the UDI Helpdesk, a way to reference a previous case number when you're opening a new one. I think that can be done. But I'm not so sure they really go from the top bottom to probably just catching up on older requests. Usually …

Joe Hage: Marian asks, oh I'm sorry. I thought you were done.

John Lorenc: I'm done. Go ahead. Thanks Joe.

Joe Hage: Marian asks, as a startup, with a new device, when do you have to do UDI? Before submitting 510(k), with submitting 510(k)? Or when starting production? Good question.

John Lorenc: That was a good question. You absolutely have to have it before you're in the market. What I've seen with new devices is it is one of the last things that the submission is done as production may be getting started and you're getting close to a marketing start date. However, it's still … you need to be mindful of the labeling requirements of UDI and other things prior to starting production. If as if for some reason there is a misinterpretation of how that device either the direct part marking or what have you, you certainly don't want to have to go back and reprint labels or things of that nature when you're already at the GUDID submission stage.

So like ensure that you know, if you're using GS1 GTIN's you have all that labeled properly. But if you know that's all well and good, then you just go ahead and make sure it's done before you're actually marketing the product.

Joe Hage: Does Anne need to apply for UDI on the controls for specific compounds in plasma? She has IVD kits.

John Lorenc: So IVD kits, there is particular IFBT codes that is applied, yes. So not as common scenario but this is absolutely something we'd be able to work through with.

Joe Hage: Her addressing company are registered in DUNS using German words but her labels are in English. Is that a problem?

John Lorenc: That should not be a problem. We're only including the DUNS number itself in the submission so we don't even provide the name in the electronic record. Just the DUNS number. So that would be fine.

Joe Hage: Doug asks, are there other sources to obtain GMDN codes besides paying for membership to a GMDN agency?

John Lorenc: Not that I'm aware of. I mean digging in AccessGUDID perhaps for data that was submitted but not a definitive source.

Joe Hage: Thaddeus asks, when was the grace period raised from 7 working days to 30 days? Are these working days or normal days?

John Lorenc: Right. This is a funny story for me because here at ReedTech, we just launched the first version of our UDI software application probably in I don't know, March or April or so of 2014. And of course, we set up the grace period to be 7 business days just like it says in the FDA technical specification and we go live and everybody's having a party. We validated the system. Clients are loading data. And then we get an email from the FDA through that email group I was recommending to sign up for going, we're going to temporarily extend it to 30 days.

So we're like, no we just validated the system. So we had to go back and do a patch like right away but there's a lot of business rules related to that grace period ending. So we had under their control but so they did that back in 2014 even for the first Class 3 wave it was 30 days. We now are much smarter on our end and have considerable ways to change everything. So as soon as they say we're back at 7, we just got to switch the config file when we're back at 7.

Yeah that was one near and dear to me.

Joe Hage: John I know you have a hard stop in two minutes. I'm going to get one or two more quick questions in.

John Lorenc: Okay.

Joe Hage: Khalid asks, he has a DUNS number, he's waiting for the DNB to correct his information in the system. We're afraid we're losing precious time waiting on the DNB. Should we just submit a GUDID account request to FDA with the DUNS number we have already?

John Lorenc: I believe that would be the DUNS number that is good and you're just waiting for DNB to correct and if that's the case, I would say yes use what you know is correct. Send it to the FDA. You could even put some language in the body of the email in submitting that request

and advise them of the situation. But with time being of the essence right now, they want to proceed with getting the account set up.

Joe Hage: Okay. Last question. Casey asks, where do you locate the FDA listing number?

John Lorenc: It would … there's no online source. This is considered proprietary. So organizations would have to look into their 510(k)'s or such to find what their listing numbers are. It's all going to be within your internal files and records. So there is nothing really … I wish there was something because then we'd get out of that to our system development that you have the right FDA listing number. But that's like the one piece of information we can't get our hands on and it also does not go up on AccessGUDID.

Joe Hage: I would do you a great disservice if I didn't throw in Cristoff's question. Can ReedTech bring consultancy to any company?

John Lorenc: ReedTech's always willing to listen to what your needs are. So yes.

Joe Hage: I had a feeling that might be your answer. John that was an excellent presentation. I know you got to pack and get on the road to Thailand. Thanks for doing this for our members. For those of you who have another dozen or two questions in our queue, they will answer each and every one of you. We have your email information.

John, on behalf of the Medical Devices Group, thank you very much for sharing with us today.

John Lorenc: Thank you Joe. I enjoyed it.