**UDI – GUDID- What Medical Device Manufacturers need to know**

**Joe Hage:** Hello everyone, this is Joe Hage. I have the privilege of leading your Medical Devices Group. We are now as of this recording 237,000 members strong, so thank you for that. And I think one of the reasons that we've grown so large is because of people like Gary and Mark who are, what would you say, this is the busiest you've been in I don't know how long, but they took my call when I said, "UDI is 55 days away and there are a lot of class III folks in the group who are either not started or they're needing some help, so can you get on the call and give some information out," and they agreed to do it for free for you. So Gary and Mark, thank you very much.

Before I mute myself, I'll just advise folks on the call that I talked with Gary and Mark just before we went live and their workload is getting very, very tight. So this is not a sales presentation. We're not pitching you. I will, however, say if you find value in this content and you feel you need help to make the deadline in 55 days, email them right after this presentation so you can get on their calendar. And we're going to use Haley's email address, so that's…here let me write that out for everyone. And in the meanwhile, I will mute myself—Gary and Mark, take it away—and I'll put in Haley's email address here to everyone.

**Mark Bayer:** Okay, thank you, Joe.

**Joe Hage:** You bet.

**Mark Bayer:** Hi, this is Mark Bayer with Reed Technology. Hopefully you all are seeing a screen with a slide, "FDA UDI/GUDID: What Should I be Doing Now?" If not, please let Joe know. With me are two of my colleagues, Gary Saner, who is our Senior Manager of Information Solutions in the Life Sciences here, Reed Technology, and Haley Lentz, who is our Account Executive in Life Sciences. And Joe is putting Haley's contact information, plus later on in the slides Haley's information including her phone number and all will be presented too.

So we have found that…Joe mentioned that we always have a jam-packed hour, which always goes over, for Q&A. Please, if you have questions along the way,

please insert the questions or use the chat feature on GoToWebinar and we'll get those questions here immediately, some of which we'll answer in real time, some of which we will hold till the end, and then some of which we may have to answer after the session is over. In the past we've gone past the hour and done as much as 30 minutes more of questions, and we are happy to stay on the line for that additional 30 minutes going forward.

Okay, Gary, if you could go to the agenda page, please. So you'll see an agenda page. We're going to give you a quick overview of who Reed Technology is. The registration information showed that many of you have not attended any of our webinars in the past and we want to just give you a quick sense of who we are. We're going to go over an update of the GUDID, and when we say homework meaning we're going to not really spend much time. It'll be something you can do, you can review, when the slides are posted both on Joe's website as well as our website.

The meat of the presentation is going to be that third major bullet. It's the GUDID to-do list. These are the things you really have to be paying attention to now if you're a class III provider because time is getting short, and if you're class II or class I, soon you will be wanting to pay attention also. We will give a brief overview of Reed Technology's GUDID submission solution, and Q&A throughout and then at the end.

So moving forward, this is just information as to how to send questions in, and let's go to page five and get started. On page five, Reed Technology has been in business now for 50 years, founded in 1961. We deal with content and life cycle management. We have over 900 employees, most of whom are in that building you see the photograph of. We're just outside of Philadelphia. And then if you may know LexisNexis, which we are a business unit of, and LexisNexis in turn is a business unit of Reed Elsevier, which is a large publicly traded company headquartered in the UK.

We are contracted with United States Patent Office and do all process all the patent applications and grants. Of greatest note to this audience is that we have over 775 life sciences customers both in the pharma space and in the medical device space. Structured product labeling has been in a mandate for the pharma side of FDA registrants since 2005, and thus we have been in the SPL space since the inception in 2005. We're ISO-certified, which is important, and an HL7 member, and recently a GS1 Solution partner.

On page six, and I'm purposely going quickly here because we want to get to the more interesting material, structure product labeling – we've been involved as I

mentioned since the outset. We have over 775 clients. Four of the five largest pharmas in the world are our customers. One of the top three medical device manufacturers is a customer already as UDI gets started. We have created over 30,000 SPLs. We have a lot of experience in this area. We have a wide number of global customers and we also have a number of our customers, a large number use the Electronic Submissions Gateway service that we offer.

I won't dwell on this slide. We have a lot of experience in SPL and that's what slide number seven shows. The one thing I do want to mention, the very last bullet at the bottom of the page, we are currently participating in the FDA CDRH GUDID load testing and that has been very beneficial. We have been helpful to the FDA we hope, and it has been helpful to us to see how things are working at the FDA. So we are involved and always have been involved in supporting the FDA.

Okay, this is the section that I was calling homework, meaning we're not going to stop on any of these slides. We're going to just page through them slowly but quickly because there's just not enough time to cover everything here. Most of this material is background material, and I'm suspecting now that the GUDID and UDI activities that have been out there for some time that most of you are aware of much of this information.

Okay? So with that in mind we're going to just quickly flash slide nine. I do want to point out on this slide, slide 10, that the key date is where the arrow is pointing, September 24th, 2014, for class III manufacturers. Next page talks about some key FDA documentation and you can look at this later. The next page, page 12, offers you an easy comparison and visual way of understanding the difference between with is label data and what is GUDID data and some of the overlaps of course. Page 13 is some recent regulatory news primarily from the FDA and brief new information from Health Canada saying that they're going to conform IMDRF's guideline. And that's our homework assignment that we breezed through.

Now we're on page 14 and we are…the class III providers, your deadline is soon, and so things are fairly time-sensitive for you with a September 24th deadline being 55 days away, and the class II and class I providers, particularly the class II providers, we're going to actually express a few reasons that Haley has found out in conversations with many customers and prospects as to why class II people might want to get started a little earlier.

With that, we'll go to page 15. And you may recall that when you registered for the webinar there was a brief survey on SurveyMonkey, and these are the results

of that. The first graph in the upper left just lays out the number of companies who are in each individual class, and obviously as I'm sure you all know being industry folks that class II and implantable life-sustaining and life-supporting group is the biggest group, about twice the size of class II and of class I, and we are not sure where the uncertains or not applicables came from.

The second box to the upper right, how far along are you in identifying, collecting, organizing information? If you're a class III provider and you're in the not started or planning area, then time sensitivity needs to be kept in mind. If you're a class II provider, then you have a little more breathing space. And then the last graph is, have you decided what method you will use? And we'll discuss methods later on to make more sense of that.

This page, page 16, is just to give…this is information that Haley has brought back from her contact with many prospects and many customers, and it's interesting that customers of device manufacturers, which is hospitals and healthcare providers, have started their own UDI implementation process and in turn are starting to ask of their medical device suppliers to provide UDI information. So that becomes something you'd want to factor in to your thinking if you're a class II manufacturer. And manufacturers who do adopt UDI early will go into the GUDID database early, and thus their products will be visible to many people that much sooner. You might want to look at the idea of starting early as a way of smoothing your workload because they're going to be…there's a significant amount of content that needs to be captured, collected, organized, etc., and starting early will give you a leg up on that.

The FDA, it could be like tax day in the sense on April the 15th a lot of taxes are coming in to the IRF. There are an awful lot of products in the class II category and if you get a head start you don't have to be concerned that as that date approaches in September of 2015 that there might be any bottlenecks.

An international compliance, the sooner you have your arms around the FDA's mandate, then you'll be in much better shape for international mandate as they come in play.

Okay, I'm now going to turn this presentation over to Gary. He will probably not talk as quickly as I did because he's going to cover the real substance of the presentation: What do you need to do, what are the steps that you need to be thinking about to become UDI- and GUDID-compliant? Gary?

**Gary Saner:** Well, a quick hello to everyone. This is Gary, and what I'll do is walk through some of the steps that we have identified. These are high-level steps. We tried to

include some very pertinent facts and individual steps that are things that you need to do to be preparing for in submitting the SPL records to the FDA.

The first step is kind of a background step. If you have not started this and you're a class III manufacturer, then you definitely want to sit up and pay attention and start working on this activity. We're only 55 days out and there's some homework that you really need to be engaged in.

The first sub-bullet under this topic is to become familiar with the guidance and the Final Rule that has been posted. I would imagine a good portion of you have already done that. There's links to the Final Rule, the guidance for industry; there's a data elements table that lists all of the fields; and there's a link there for those that are submitting their data electronically through the Electronic Submissions Gateway. There's a separate guidance document, an SPL implementation file zip package that is available for you to look at, become familiar with.

So that's basically going through becoming familiar what the requirements are and in some cases you'll find that there are some exceptions that you can make use of. We don't have time today to walk through all those details but we can talk one-on-one at a later point in time if you have questions. There's also issues that may affect your direct marking of the product itself and in this guidance is all the timing and…very similar to the chart that we cruised over a little bit earlier. So, basically what to become familiar with the background.

And then, secondly, evaluate your situation. So in many cases you might have some data already structured and recorded in sections of information. Maybe the regulatory information is pretty well prepared or you have a product life cycle management piece of software or master data management system and some of the data values are available, but you really do need to look and find where in your environment the data is located, who the owners are, are they able to provide the data, what format that data is in, and how is it going to be maintained. And I will stress that this is not a one-time submission – you do need to maintain this and keep it current in the event any of the data values change over the course of time.

The third sub-bullet there is something identified as issuing agency. So the FDA has identified three organizations. Three individual agencies have applied for and been granted approval from the FDA to be an issuing agent. So each one of these three have standards as to how to identify their product.

So most of you may be familiar with the GS1 GTIN. So that's the Global Trade Identification Number. So there that particular standard identifies in this case a

14-digit number for your product. Embedded in the front end of that particular number is an identifier for the labeler and the manufacturer itself. HIBC has a similar…and ICCBBA also have similar types of standards, and you will need to engage one of those three to be your particular standard. And again, the FDA does not issue numbers to you – you need to approach these agencies, learn their standards, in some cases…well, all these are purchased by them, so you need to make the purchase become a member of their particular group and understand how to apply product numbers for your particular inventory.

There is a link there to help you along the way that has some information about each of those standards. There's identification numbers that apply to the device itself, so there's a device identifier, and then also there's a production identifier, and those two concatenated together become the full UDI.

The other item that needs to be approached very early on is the AIDC. This is the Automatic Information Data Capture. So this is a technology, and most of the time this turns out to be a one-dimensional barcode or could be a 2D barcode, also accommodates [00:17:59] and near field type of technologies. The FDA was very neutral when as to what technology to use, but it does require the presentation of that full UDI, the DI plus the PI, to be presented in human readable form as well as a technology that is able to me machine-read. So these are some things that you need to be working on upfront.

I'm going to move to slide 18. There's impacts throughout your organization and it can be quite diverse, all the way from product design through the manufacturing areas, your logistics, sales and marketing, certainly the regulatory, and as you do your analysis and determine the scope of that you'll find that data that is [00:18:56] **hitting** in your project life cycle management, your ERP systems, will need to be updated.

And in particular the labeling system, you want to take a close look at that. The graphic shows the typical generic label that the FDA has been using over the course of time. There's various fields on there. Most important is the bottom right field that is the…in this case a one-dimensional example is showing the DI and the PI concatenated together, so there will be some application identifiers embedded in that.

If you're not using one of those three issuing agencies, then you'll need to look at the template and figure out if you have, first of all, space to include a UDI on that label, and you'll have to start updating the actual templates and the content to have this particular label updated out on the production floor.

**Mark Bayer:** Gary, we've received a question which is very relevant to the slides you're on, so why don't we answer that question in real time.

**Gary Saner:** Alright, the question reads, "What is the lowest level of PI info in the barcode format?" And let's see, test strip carton or the test strip bottle in the carton? Okay, so the Final Rule addresses this particular scenario where it applies a UDI to both the product and the packaging. So it's a twofold, two-tier-type presentation that needs to include the UDI. So the question there is…to answer the first portion, is it does apply to both levels, the product itself and packaging. Just a side comment: Unique UDIs need to be applied multiple level of packaging up to what is called the shipping level. So the shipping levels do not need to have UDIs, but if you put 10 items in a box or let's say 10 items in a bag and then five bags in a box, then both those levels need to have their own [00:21:19] **UDI**. But if that then gets put into a shipping [00:21:19], no need to go on there.

**Mark Bayer:** Gary, let me interject one thought here. Notice on the slide, you'll notice it says on the second bullet, "Labeling system…we have found that some customers are using…UDI is necessitating a lot of changes in their organization or it's offering an opportunity for a lot of changes, and so they're looking at updating labeling systems." So this is not yet officially announced. They just want to give a preview that Reed Technology is teaming up with Prism ID, who is the leading labeling system manufacturer, to offer an end-to-end type of solution to customers so that if you need to…if you're using UDI, if UDI prompts a review of a whole lot of parts of your labeling activity and you're looking for a solution that would have your labeling system…would bring you a strong labeling system associated with a GUDID solution, we, being Prism ID and Reed Tech, are going to offer a seamless solution for that. More about that will be announced shortly and so I don't want to take any more time here, but something to keep in mind.

**Gary Saner:** Alright, let's go back to the steps, and we talked about doing some background homework. Step two here in front of us is updating your systems, in particular the labeling system. I'm going to move to the next slide, and that is now going to step three where…this is a little bit more intense where now you're collecting the data that must be submitted to the FDA and into their GUDID system. There are…we'll have some slides a little bit later to talk about these individual fields, but quick overview, there's 55 fields that need to be submitted and the FDA derives seven more for a grand total of 62 attributes about your device product. So that includes the product…the device identifier itself, does not include any production identifier values—just want to make that clear—just the device identifier which is a static portion of the UDI, and a number of attributes, grand total that are coming out would be 62.

So there is some homework and some searching that has to be done, and as you pull those pieces together you might collect them in a structured format. Some people do that on SharePoint. Other people do it in a template, a spreadsheet template. We actually have a data template that we will make available upon request, lists all these fields—we'll take a look at it in a second—and it helps you organize and figure out what you need to collect if you have any omissions and it just helps organize that data collection process.

In some cases, you might find a couple of those attributes that need to be submitted are really not necessarily in a database itself. Let me give an example. You may have a template that includes the single use icon, and that is embedded into that template, goes with that product family, and that turns out to be one of the submitted values that has to be a true and false Boolean value that needs to be submitted – is this device single use? So it may not be sitting in a system as an individual field with a true and false connected to it. It may only exist as an icon on your template. So as you come across some of these fields, you may have to do a little bit of research to pull that information out of the templates, which could be a graphical storage at this point in time only.

As you collect data, you may want to be thinking ahead. There's some international activity, certainly EU, Health Canada, Brazil, China, Japan, so on, are all moving forward on UDI, and no particular dates but two years very well might have something in EC that would be required, and then quick adoption I think in other countries for a UDI. So as you're searching data, some of our clients have elected to collect a little bit more information about what they know in their global other agencies that they submit data to and start to collect that at the same time.

The fourth bullet has to do with the merge the partial records and this is a bullet that identifies that your data may actually be sitting in a couple of different systems, and since this set of data has never been really identified before by the FDA, so there's really no need to have collected this and have a nice, clean set of information prior to this particular activity. So this is the first time you really need to pull this together. I don't know that we have talked to anyone that had a nice, clean, 100% data set available. They needed to pull some data together. So merging the partial records from various locations is a task here. We'll talk about that a little bit later and actually we can help you in that particular process.

Normalizing the data is the next bullet. There's a number of business rules that the FDA has in place. There are business rules that apply to individual fields. There's a controlled vocabulary, so if you use a unit of use and you have centimeters in your system the FDA requires the abbreviation "cm" to be submitted. So there are

some issues in normalization, if you will, that need to be done. Sometimes we refer to it as just cleaning up the data per the specs.

We've listed a few—four in particular—fields that some of our clients have had problems getting to and identifying, sometimes take a little bit of extra effort. Labeler DUNS numbers may be new to this particular audience, the regulatory people collecting the data or the operations people. Finance people are probably your best bet, your resource to come up with your DUNS for particular addresses. Device identifiers, we already talked about this, getting a particular issuing agency in place and adhering to the standards of assigning numbers to products. GMDN, this is the Global Medical Device Nomenclature. You may have been using a term on your label itself but the code now needs to be pulled out and actually submitted. There is an option here where the FDA offers a preferred term alternative, so you can go to the FDA website, look up a [00:28:55] **check in term**, and find their particular identifier which would be four letters, and that can be used in place of the five numerics from the GMDN.

We get a lot of questions about packaging configuration, this last item, and as people start to implement and collect their data there are many questions about what applies at what level. There are exceptions for kits and other types of combination products that come into play and there are some unit of use exceptions, and this may take some time if you have a complex type of structure and figuring out what are the particular data values and how are you going to record this information to the FDA.

**Mark Bayer:** Gary, let me interrupt for a second. We do have some questions coming in and we will not, as I mentioned earlier, be able to answer all of them in real time but we will pick a few that we can answer in real time. There's a question there from [00:30:00] asking, "Can most hospitals read data matrix barcodes to capture a GTIN?" Do we know the answer to that?

**Gary Saner:** I personally don't know that, so…and that can vary and is really an item that you need to take up with your particular buyers. So some hospitals are high-tech and moving quite readily along and then would be able to use the data matrix, has no problem at all, but even as you move into different single-D and 2D barcodes there's probably symbologies inside those particular as well, so you obviously want to make sure that when you pick a technology that you can accommodate it internally in your system or you may need to update readers. And to your logistics chain as you move the product and distribute it out to the end user, they also need to be considered and they obviously have readers for tracking purposes. And then, to this question marker, the actual end user, they have technology obviously to keep track of inventory, and at the point of care many times there's tracking of the

device as it's applied to a patient. So all that needs to be in consideration as you look at making checks.

**Mark Bayer:** Right. Okay. Let's move on.

**Gary Saner:** Okay, let's go to the next slide. This was the list that we had talked about and that I referred to earlier. These are the 55 fields that need to be submitted, and seven of them have a little asterisk next to them and that indicates that they're derived by the FDA. Certainly won't go into all these, but the major categories have to do with identification, and the most important one is this second item in the top left, the primary DI number. That is a key field, and once you start to have that field identified you can start to build on that with some of these other characteristics. You have brand names, catalog information. You can have a secondary DI, and if there's direct marking that applies to this product there's some identification on that obviously.

The other groups have to do with labeler information, your regulatory information That's items around your listing number, the premarket submission authorization number, any supplements that have been applied, your FDA product code. And again, here's the list that we were talking about earlier, this GMDN code. Packaging, device counts [00:32:52] **in** the various levels, if it's a kit or not. And then there's a group of five fields that have to do with production control. Again, these are Boolean values, simply true or false, whether you control your product and have on the label a batch number, a serial number, a manufacturer date or a use by date, and then the expiration date or a donation ID number – simply true and false.

**Mark Bayer:** And Gary, if I may interrupt for a second, you'll note up in the heading of the chart there is a URL. When these charts are available on Joe's website as well as on the Reed Tech website, you'll be able to go and actually get this information—I'm sorry, this is going to be on our website, but the charts, all of the charts, are available on Joe's and ours. I'm sorry, I'm not saying this correctly. On our website this chart exists. You'll be able to go to it very simply, and when you hover over any of the individual fields of information it'll give you a better description of that field of information.

**Gary Saner:** Okay, I just want to touch on the last panel on the right having to do with characteristics. First few there are again Boolean true or false values, and then recording information about the magnetic resonance, the MRI, your size information, storage and handling, and some information about [00:34:21]. Now, some of these fields can have one to many values. So let's just say they…your premarket submission number or supplement number would be a great example.

You might have four or five supplement numbers related to a particular product, and in some cases you'll need to have groups of information set together. So off on the side over on the right, the type, the value, and the unit are a group of three that need to be submitted together. So as you are collecting information, you want to be able to accommodate the one to many scenarios and some of these complex relationships where if you answer a certain value such as must-have sterilization prior to use, then you obviously need to follow it up and in this case show the sterilization method that is to be used.

Alright, let's move on to the next slide. I'm on page 21, and I mentioned earlier that Reed Tech does have a template and this bottom left-hand panel shows you a little snippet of that data collection form where the information is identified in columns and you're able to start recording information. In addition to that, there is a tab that identifies the fields themselves, gives a description on how you need to identify that particular data value and some guidance about how the entry goes into the spreadsheet itself.

**Mark Bayer:** And this also is available from Reed Tech. If you'd like this, please be in contact with Haley whose contact information Joe gave earlier, or [00:36:18] **is it the latter part of this set**, we'd be happy to provide this to you.

**Gary Saner:** Yup. This has really become our bible, [laughs] basically. Looking at this like [00:36:27]…

**Mark Bayer:** Yeah. Well, I find…

**Gary Saner:** …where you have a lot of information…

**Mark Bayer:** Information.

**Gary Saner:** …[00:36:30] **you need to be comfortable** with the rules **on the road here**.

**Mark Bayer:** Right. Exactly. As a nontechnical person, what I find valuable about this is it makes it very clear what needs to be collected and what the definition of that information is, all of which base on the FDA guidance. So it's very informative and makes it very simple to see.

**Gary Saner:** Okay, we're going to move on down our list here, Mark. Slide…yeah, slide 22, step four. So we have done some homework, we have identified some products, we started to collect our data, and one of the decisions you need to make is now that you kind of have the internal systems taken care of you need to look at how your data is going to be submitted to the FDA. Many of you from our discussions have concentrated on the internal collection and application of that information to

the label itself. This is another step in the process that you need to consider and set up as necessary.

Over on the left-hand side you'll see the device manufacturer in that brown object and there is this device data that we just talked about selecting in center oval there. Getting that information to the FDA can be accomplished by four different methods, and I'll go through this starting at the…the first one I'll talk about is at the top. So one way is to create an account with the FDA using something called their GUDID web interface, and actually all of these methods need to have that particular GUDID account created, but in this first model the data is made available to a manual entry operator and that particular person keys the data in, and now you are able to make entries. Obviously, it's a methodical, pretty labor-intensive process. There are some entry quality issues that you might need to check on, so an entry person and a quality check person, and really intended for those manufacturers that have a relatively low volume in their inventory.

**Mark Bayer:** And just to make it clear, that manual data entry operator that Gary is showing there is someone on your staff. It's employee of your company. That's no one at the FDA who's doing that for you.

**Gary Saner:** Right. Okay, so let's move down to the second method. This method describes a hosted system where you make use of technology that's hosted and made available to you. You don't need to set up the infrastructure, the hardware. You're able to basically rent that particular platform, but you are responsible to process that data through the system. Many of these scenarios have, and I would think almost all of them, would have electronic data being imported into their system. They use databases to hold that data, version it, build SPL. And this is the first **that we** [00:39:59] as we talk about structure product labeling in this scenario, but the FDA does allow electronic submission of that data in an XML file that they have defined, and putting that data, capturing it into this particular format, and then that can be submitted automatically to the FDA through their Electronic Submissions Gateway. This is an option that allows electronic processing. It allows you to control that. You're not burned with some of the infrastructure costs but you are pushing the data through a monitoring video of the workflow and causing submissions to happen.

Another scenario would be the third one listed there, the outsource service model, and in this case you're making use of technology, again, outside of your firewall but the burden on you is really just to collect the data electronically and submit it to your third-party service staff. They then check that data, perform the validations, and process that data and submit it off. So the particular engine of the

process is similar except to the one I just described above, but here the actual staff and the labor effort is outsourced to a third party.

The last one that I'll describe is a scenario where inside your firewall your company elects to buy a piece of software, install it, do the validation, do the training, do the maintenance updates, and so on. So there's a scenario here where you can purchase software. You can actually build it yourself if you so elect or there may be an upgrade to a particular piece of software that you have now. So if you have a PLM or MDM system, you may have a UDM module available to you and you could layer that particular functionality on top of some existing software, and in this case your response would pull the data together, get the data into the system, and do all the platform validation and setup. Mark, did you have a comment on that?

**Mark Bayer:** I just wanted to point out the two in the middle, the hosted software or the staff service and the outsource service are offerings that Reed Technology makes, and we will get into our brief description of our services at the end of the presentation.

**Gary Saner:** Okay, very good. Mark, this next slide, 23, because of time I'm not going to dwell on this one.

**Mark Bayer:** Right, another homework slide.

**Gary Saner:** [Laughs] Right.

**Mark Bayer:** Look at this at your leisure, please, so we can keep moving along.

**Gary Saner:** Yup. It simply compares the different values and some of the [00:42:58] **costs** and descriptions that I alluded to earlier. As you, again, select a particular method, this particular slide, 24, that we're now looking at can…you should consider some of these things, how you're able to leverage your knowledge, whether your vendor is [00:43:20] **21-compliant** and what type of capabilities that you can use. I will make mention of the one down here at the bottom. If you're a class III manufacturer and looking either to buy or build at this point in time, 55 days, I think it's…

**Mark Bayer:** To buy or build a software solution that would be installed behind your firewall in your IT environment.

**Gary Saner:** Yeah. I think a reasonable time is too late for this particular scenario. It takes a significant amount of time to work through your procurement, your approvals, the implementation startup, validation, and so on and forth.

**Mark Bayer:** Right.

**Gary Saner:** This may be out of the question for those scenarios. I'm going to move on to step five. Now, at this point in time we've collected all of our data, we know what the submission process is going to be, now we need to start setting up something called the FDA GUDID pre-production account. And there's simply a link on the FDA website. Your name, the organization, the email, and phone is all you need to request this and you could simply submit it, and what you will receive back is this form, Step 5B, where…and this is just the top portion of the first page, there are three pages, but you put your information in about your organization. We actually went ahead and did this for a test process to do our testing with the FDA and so this is a copy of our particular form, but you'll need to put your DUNS number in there. You'll need to put your regulatory contact information. I would recommend that you select web interface and SPL for submission purposes. There's another portion of this particular document where you identify who the third party would be. If you engage us, we have our DUNS number and company name available for you. It can help you out with that.

**Mark Bayer:** Gary, there's a question that has come in which is very relevant at this point, and the question is, "What is a labeler DUNS number?"

**Gary Saner:** Okay, so this is a number that's created by Dun and Bradstreet, a separate private organization, not a government agency. Dun and Bradstreet is a private entity and they have unique identifiers, nine-digit numbers, assigned to each company location. So if you have a headquarters and five manufacturing sites, you actually have six independent DUNS numbers. And the FDA has elected to use this particular agency rather than start up another list of codes and identifications for establishment sites. They've elected to use this agency, Dun and Bradstreet, to identify those establishment sites. So we have some links at the bottom of this page in the appendix about how you can go to Dun and Bradstreet and actually find the code that may have already been assigned to your site, or if you don't have one you can engage Dun and Bradstreet to create a new one on your behalf.

**Mark Bayer:** Gary, another question just came in. Is there a cost for opening a GUDID account?

**Gary Saner:** There is no cost for the FDA GUDID account. There is no cost for the Dun and Bradstreet account either that I'm aware of. If you want to expedite the services, then there are some payments.

**Mark Bayer:** Okay.

**Gary Saner:** Alright, so let's move on. We now have submitted this form. The FDA will give you some credentials back and you can now open up a pre-production account with the FDA. Now, in the event that you are submitting electronically, so we

talked about the different methods, if you are submitting electronically using SPL, then you'll need to include Step 5c and the next one, 5d. If you don't already have an Electronic Submissions Gateway account, then there are some steps to contact the FDA. There are some detailed steps here. We'll go into them, but basically you need to get a nonrepudiation letter in place with them, set up a digital account. You need to send some connectivity tests, some compliance tests, and then apply for a production account. So basically this process, 5c, creates a submission service for you and it's [00:48:09] **roughly** independent of CDRH. So this is good for actually many of…or all the centers that accept electronic submissions. I will make note of the bottom where as part of our services we have this account already set up. It can be used for multiple clients and this particular step is part of our delivery to you.

The followup is a set of four test scenarios. So, again, if you're using the SPL submission [00:48:42] **check** you get your submission process in place, the Electronic Submissions Gateway, then the CDRH would actually like you to submit four test scenarios just to make sure that the [00:48:57] **whole** soup-to-nuts submission through Electronic Submissions Gateway and getting the data into the GUDID database is all able to be done in a pre-production mode. Again, we take care of this particular step for you, submitting the necessary SPLs to exercise those four test scenarios, and upon completion, successful completion of [00:49:17], then you can now go to step six where you apply for a GUDID production account. You use the same application form as before. The FDA would like a fresh copy of your intent and definition of the users and who has rights to do what, that sort of thing. Then you're ready to go live. You're able to submit data and you're able to do some either manual entry, manual viewing inside the FDA GUDID web interface, or you'll be able to submit your automated bulk entry through SPLs. And the final bullet there, now that that's in place, you have ongoing maintenance.

Mark, I think that's the quick steps one through six.

**Mark Bayer:** Okay.

**Gary Saner:** **Highlights** [00:50:07] underneath them but I think that's the necessary steps.

**Mark Bayer:** Okay, fine. Now, if we could, this next couple of slides deal with Reed Tech's GUDID solution. I'll make this quick. This is slightly salesy, I want to be honest about that, but we want you to understand our solution and it's really very straightforward and very cost-effective.

So the key slide is this slide right here, and you'll notice that the…what happens here? There we go. You'll notice that the medical device manufacturer is over on

the left again doing data collection and following some of the guidelines that Gary mentioned earlier. That can be imported, right? This is our solution represented by the blue. We accept data in XLS format, XML format, GDSN format or simple text format. We take that data, we transform it, and validate it as we load it into our database. That validation step is built on years of experience and is very important. It allows you to know if your data will pass FDA validation. Is your content correct? That information, and you can review the data once you're done with that, and if the data looks good you can then built your SPLs, validate them. You want to validate the SPLs, make sure their XML format is correct because the FDA has strict business rules on that. Then you can approve the SPL, submit it through the Electronic Submissions Gateway to the FDA. There are three acknowledgements that come back. One acknowledgement means it got through the front door of the FDA successfully, the second acknowledgement means it got through the front door of CDRH successfully, and the third acknowledgement, the most important one, did it pass? And if you have successfully gone through the validation here and the validation here, the odds of its passing are very important.

A question just came in, is, "What is meant by validating the data?" We are following a series of rules that the FDA has established plus additional rules that we have gained over years of experience where we look at the data to make sure it's correct. I'll give you a simple example. All DUNS numbers are nine numeric characters. If you by accident submit eight, we'll flag it. If you submit an alphabetic character amongst those nine, we'll flag it. So we have codified all of these business rules and our years of experience to make sure that the data is correct. Please understand, if you provide us a value of 27.2 and it should have been 2.72 because you moved the decimal place incorrectly or somehow that happened, we will never be able to get that because we don't know the content specifically, but we know the format of the content and any rules that we can apply we'd have applied.

**Gary Saner:** So I just wanted to clarify. Sometimes validations are used for compliance purposes…

**Mark Bayer:** Yup, it is.

**Gary Saner:** …so we actually independent system validation, computer system validation, with the [00:53:38] IQ, OQ and PQ activity. So I think, Mark, you made it clear that what we referred to there in the previous instance was data validation where we're checking against the specs.

**Mark Bayer:** Yeah. This box right here is very data-oriented. It's your data, your content – how does it stack up against the FDA's guidelines and business rules. This validation

is XML validation. Is the SPL built in the right XML format that meets the FDA's business rules? If they do, the information goes into the GUDID database, we process all the acknowledgements, generate reports, and that information flows back to you. We don't have enough time to go into this in greater detail but Haley of course will be able to do so.

And then the last couple of slides I won't spend much time, you can look at these, but our solution is very simple, it's nonintrusive, saves time, but my favorite is it's cost-effective because you are sharing costs, if you will, in an outsourced or staffed environment. And then it's flexible as we pointed out, a couple of quick things like…I do want to mention the system can absorb not just the data that the FDA demands but can absorb much other data, which is helpful to you if you want to put in proprietary information that won't be sent to the FDA but will help you organize your data, and also we have the ability to easily expand the content we capture so that information necessary for other global regulatory authorities can be captured, and then when they come online and their mandates go into play it'll be a simple button press to send things out to help Canada or send things out to the PMDA.

This system is compliant. I'll let you read that. And the point we made earlier and Joe made earlier, 55 days until class III submission. There are some resources that you can look at if you wish. There's Haley's full contact information, and now we're ready for Q&A, and there are also additional resources at back. Okay, so Joe, that takes care of the presentation piece…

**Joe Hage:** Thank you, Mark.

**Mark Bayer:** ..and I [00:56:09] a lot of questions [00:56:10]

**Joe Hage:** There are. I forwarded a few to Haley, you might have them already, and I have dozens more.

**Mark Bayer:** Okay.

**Joe Hage:** For our listeners, this is not unfamiliar scene. We're an hour into the presentation, almost every single person who signed on is still here very attentively and we have more questions than we'll be able to answer. So know that I will send an email to you later today with a link to this recording and to the slides. I will follow up with the transcript when I have that available. And if you need to go, no harm no foul, that's all good, but if you have time to stay on we have a lot of questions and they may be helpful for everyone.

**Mark Bayer:** And we're…I just wanted to…

**Joe Hage:** Go ahead.

**Mark Bayer:** No, I'm sorry, Joe, I didn't mean to talk over you. I just wanted to say that we'll be happy to stay and answer questions until the time runs out. So why don't we start taking these questions as we see them. There's a question right here that, "Did those last two steps…" this is in reference to the chart I was showing here, "Did those last two steps apply to a company entering data into the GUDID database themselves, reference—"

No. This is the…if you recall, let me go up, yup, there it is. Remember we discussed four different approaches that you can as a manufacturer use to submit content. You can go through the FDA's provided GUDID web interface. There is no charge for using the FDA's interface, but the way it's set up, even the FDA admits that it is best suited to low-volume submissions because you have to manually enter each record one by one by one and then there is no inherent database for subsequent updating, etc., and it would not have much value in providing your information to other regulatory authorities. This is very much FDA-specific. On the other hand, the other three methodologies will offer you greater flexibility because they're all built on a database and having a database is going to offer you a great deal of capability.

**Gary Saner:** So Mark, I see another question about the direct marking activity.

**Mark Bayer:** Yup.

**Gary Saner:** And this particular scenario has some components that are sold on their own, and the question is, how does direct marking apply to them? So the quick little scenario is there are three criteria for direct marking, first being is that the product itself is multi-use; and secondly is that it's reprocessed in between each use or patient, and that could be a sterilization or a cleaning activity; and thirdly, it is not implantable. So if you meet those particular set of criteria, then direct marking does apply, and in this particular scenario the question came in with individual products being sold separately on their own. So if you're able to have a buyer identify an individual item and it's ordered and delivered and tracked and identified also on its own, then each individual item would need its own UDI and direct marking.

Second question that I was looking at here had a question related to whether more than one barcode is allowed on the label. That's a great question. So you might have a barcode to satisfy the FDA UDI requirements, and then internally you might use a different technology for that particular tracking activity inside your system, and from what we're able to gather from the Final Rule, that is allowed

but you do need to have the UDI in place; your additional identifiers can be on the label as well.

There was another question that had to do with the device's legal owner versus the labeler, and this is pretty common. A lot of people have this question. And the FDA has taken a stance where they define a labeler, and then the question is, who is the labeler? So in some cases a labeler will be the actual manufacturer and they might actually have a contracted manufacturer doing the actual processing and labeling and kitting of the product and putting labels on devices. As we understand it, the FDA has come back—I've actually asked this question to their helpdesk—and they said that the manufacturer and any contracted manufacturer or other owners need to work it out on their own as to who will make submissions. So as I read it, the Final Rule that is, the device manufacturer, the legal owner, is the labeler, as you record that labeler DUNS number there is intent that the FDA has noted in their Final Rule that the labeler and the address…well, I should say the organization and the address on the label itself should match up to the submitted organization DUNS number. So that way, if an end user is looking at the GUDID database, which we know will become public and are starting to have question about whether a product has a recall or whatever, and we want to track it down so there's an address and name of the company on the label of the device itself, that should match up to the DUNS number that's in the FDA's database. So there is a little bit of question on that. I understand it's not super-clear, but the intent is that the DUNS number submitted pointing to an organization does align with the label and address or the organization company name address on the label itself.

There's a question about international organizations may not have a DUNS number, and that is true. In some cases, an organization may have not been assigned a DUNS number as of yet. We have found from previous experience in the pharmaceutical space that Dun and Bradstreet is rather progressive. They have a huge amount of not only US but non-US entries into their system, and organizations around the world from here to China literally have already been identified and have DUNS numbers. But in any case, if you find that you don't have one, Dun and Bradstreet will create one for you.

There was another question about the turnaround time for test submissions.

**Mark Bayer:** Right. Yup.

**Gary Saner:** That particular answer is a little bit dependent on the FDA. The four test scenarios I think is what was being asked here for creating the SPL submissions. Some of that is dependent on the FDA response and embedded in the test scenario is a day

delay, so you make a submission one day and then the following day you come back and make a change and see if everything works properly according to their unpublished and published rules and timing and the grace period and so on. I would allot three to four days as the minimum for that particular scenario to get all those test scenarios completed.

**Mark Bayer:** Gary, there's another question that just came in regarding steps five and six overall. Do they apply to a company entering data directly into the GUDID database themselves?

**Gary Saner:** Oh, yeah, I think this was a clarification of the question that came in a little bit earlier where steps…if you want to go back to steps, I believe it's 5c and 5d…

**Mark Bayer:** There you go.

**Gary Saner:** So steps 5c and d, the following one, again, only apply if you're submitting data electronically through the Electronic Submissions Gateway.

**Mark Bayer:** And that's as opposed, to be very explicit, using SPL, using HL7 SPL formatting for submission of data through the Electronic Submissions Gateway versus using the FDA's GUDID web interface.

**Gary Saner:** Yeah, and I think it's something that you could leverage if you already have an Electronic Submissions Gateway. If you use a third party that, again, already has that in place, for example we here at Reed Tech already have that in place and offer that as part of our package, then you don't need to directly get involved in steps 5c and d. And this can be quite rigorous, certainly for a small company. There are a number of technology challenges to set that connection up.

**Mark Bayer:** Right.

**Gary Saner:** Just a quick background, the Electronic Submissions Gateway has two types of connections that can be made. One is called the Web Trader where an individual file is browsed to and you have this application on your desktop, or on your system I should say, and once you browse through a file you can submit it off. And again, that's a one at a time type of scenario. You'd submit electronically but, boy, there's a lot of overhead point and click and so on, and then look for the acknowledgements.

The other type of connection protocol is something called AS2, the Application Standard 2, and that is what we engage for this particular business where you're able to put a volume of files into a folder and then have the AS2 utility process those automatically. So we basically push the button and let it roll. There is some load testing that Mark had mentioned earlier that we have done with the FDA

where we submitted a thousand records at a time, took a few hours to get acknowledgements back in this pre-production model. We hope that gets to be a much smaller response time, much faster as it moves into the production system, but again we're kind of dependent on the FDA's response time on that.

**Mark Bayer:** And the FDA is in the process of developing and debugging and working out its systems too. This is a very challenging brand-new-to-the-world-activity UDI and the GUDID database associated with it. I've gone back to a slide which was in the homework section where the FDA has publicly stated that the GUDID web interface designed for manufacturers with a small number of records, SPL is recommended for larger record volumes. And what this…the first one is relatively manual, it's very manual, and the second one is you're dealing in bulk batches, so that's the reason that it is much more efficient.

Okay, we have another question.

**Gary Saner:** No, that's one we already handled.

**Mark Bayer:** Oh, I'm sorry.

**Gary Saner:** I think we cleaned out the ones on our local list…

**Joe Hage:** Okay, yeah, I've got…

**Gary Saner:** [01:08:24] have some additional ones that you might want to chime in with.

**Joe Hage:** Yeah, actually dozens. So Gail asks, is it possible to include date of manufacture in an HIBC linear barcode? Specifically, can date of manufacture be displayed in the UDI within an HIBC linear barcode?

**Gary Saner:** Yes, that is possible. So there are two scenarios. If you're using GS1—I'll go there first—they have something called application identifiers, and you can track the various dates and enter that date. I will mention that when you embed dates in any of these issuing agency standards, whether it be GS1, HIBC or the ICCBBA, you need to put the date in according to their standard, and that is different than the date standard in the Final Rule. And Mark, I'm just going to…

**Mark Bayer:** Go ahead.

**Gary Saner:** …go up to the quick summary, the overview, and if you noticed in the top panel in the label area, there is a date format which is defined as YYY-MM-DD, and so you have year, month and day, and that has to be used for presenting any dates on the label itself.

**Joe Hage:** In that format?

**Gary Saner:** In that format. Now, if you are taking that date and embedding it in to your UDI in that barcode, then you have to observe the standard. So, GS1 with their GTIN standard has a particular format for that date. And for the question that you had, Joe, if this particular person or company's using HIBC, then they have a standard for the date and they actually have a couple of different ways in which they can present it, and you can then embed that date right into UDI on your label itself. Next one.

**Joe Hage:** Okay. Yes, we need to get Alberto to bed. He's calling in from Italy and he asks, what are direct part marking requirements for disassemblable products composed of components that are sold singularly in the market? Should each component be marked with a proper UDI?

**Gary Saner:** Yeah, in this case, this is similar to an earlier question that we had – if you have individual items that are sold and they meet the criteria of direct marking, again those are multi-use, reprocessed, and not implantable. So if you have a device that meets those criteria—and it's sold separately—then you need a separate UDI on each of those devices and a device needs to be marked with direct marking. Now, that actually can be one and the same. We'll just stop here just for a second to talk about direct marking.

**Joe Hage:** Actually, and let me interject a question from Jim, when is a device considered too small to be direct marked?

**Gary Saner:** [Laughs] Very good. So if you go to the Final Rule, the FDA actually had some comments come back in their proposed draft regarding devices that are way too small to identify or be able to mark. And they do have that exclusion in place where if it's physically way too small, and let's think about it, a stent for example, or something that's really small—now, a stent is implantable so it doesn't apply, so that was a bad example—but if there's a device that is extremely small, they have excluded direct marking for those. I would highly recommend, and FDA has mentioned this as well, that you so mark that in your design master file. So now you have some record that you looked at the scenario, the requirements, you looked at technology and you made the decision that it's just not feasible, and then record that particular decision date and time sort of thing.

Now, going back to the direct marking, various technologies are available – chemical etching, laser etching, ball peening. In some cases they'll be a mold chain, so if this is a process that has injection molding or similar, you might actually have a machining change to your mold process and now the injectable product has that device identifier embedded in it. The FDA has allowed a label to be applied to satisfy the direct marking as long as it's durable and is expected to

last the life the product. So some of those other technologies which are much more robust are certainly able to be engaged, but you are able to use a label to satisfy the direct marking activity.

The other thing I'll mention is in some cases the device does not have to be visibly marked itself but you can attach a tag or label by way of secure fastener to that particular device. So that gives you another little option where, and if there are space requirements or physical limitations you can attach a device—and for those that have been following this very closely at one point in time the FDA was talking about direct part marking and then in the Final Rule they took out the word "direct part" and just used "direct marking," and the intent there was to allow for this scenario where you might securely attach a label to the device and not actually physically embed the mark into the device itself. So I think with that little discussion we'll move to the next one.

**Joe Hage:** Yeah, I'm really interested in the answer to Sharon's question. She has class I devices that are reprocessed and distributed in a kit with class III devices. Does she have to have her class I ready by September 24th as well?

**Gary Saner:** So that's a great question, and as you come across this portion of your preparation and do some homework you'll find that kits are identified and they have some special scenarios. So Sharon will be happy to know that the components of a kit do not need to have their own UDI, and when that was announced at a conference that we were at [laughs] there was actually some celebrating [01:15:57] jumping up and down and clapping or whatever, [laughs] but…because this is really an intensive affair. But a kit does need to have a UDI at the kit level. So the kit needs to be marked, identified, but the components of the kit, in Sharon's case the class III and the class I, do not need to have their own identifiers attached to them. And think about it, when you're putting convenience kits together for the operating room or whatever, there's a lot of variability in that scenario and many times it's a fast turnaround response, so pulling the kits together at the last minute allows you to include components. But in any case, the kit needs to have a UDI, components do not.

There is a caveat. [Laughs] Yes, there's a catch. In the event you have one or more of those components that are sold on their own, so if you have a separate-line item and you market that product on its own, end user can buy and use that device on its own, then it will have to have its own UDI for that particular activity. But if it's always captured inside a kit, no, you're good to go.

**Joe Hage:** Gary Peters wants to know, when is point-of-care UDI required?

**Gary Saner:** So point-of-care UDI, this comes up…I'm not sure if he was thinking but I'll give a scenario that the FDA uses quite often. Let's say there's an adhesive bandage box and inside that box are 10 individual adhesive bandages, and in this point…or there's actually exclusion for this scenario. It's called the unit of use exclusion and the box itself would need to have a UDI connected to it and the label and registration to the FDA GUDID, but the 10 individual adhesive bandages in the box, as long as they are single-use and all the same version or model, then they do not need to have their own individual marking and don't need a UDI label on them. There's a little bit of a hitch where you actually submit a virtual device identifier when you make a submission to the FDA, so you create a number but you don't ever have to apply that number to the label of the 10 individual bandages. So I'm not sure that was where it was going, but if there are further questions then why don't we follow that up with a later question?

**Joe Hage:** Well, Samuel asks a similar question and he gets extra credit because he says, what about adhesive bandages you brought up in your first webinar? So he's been doing his own work. Along with single-use devices, how do liquid chemicals apply? Just used once and washed out – does that still fall under single-use?

**Gary Saner:** It might be falling under the combination product where many times you'll have in this case a drug product or a vaccine type of a product that is connected and delivered with a medical device, and let's say it's a syringe or one of these injectable pens, that sort of thing. There there are situations inside the Final Rule that are very explicit as to how to handle those. The combination product itself needs to have the UDI. There are a couple of scenarios where if the combination product has an NDC number then that can be used at that high level. But the device itself, if it has…if the kit—excuse me—if the combination product has an NDC number, then the medical device still needs to have a UDI. If the combo product has a device identifier, then the components do not—well, I think we'll really have to look that up on an individual basis. There are some special technical scenarios that would apply. I would recommend that he talk to us and we can point him to where that is on the Final Rule or look that up on his own. There are exclusions that are defined in the Final Rule. But in any case, probably walk away from this knowing that your medical device, if it's in a combo product scenario, then you'll need some type of identifier either at the kit or the individual product level.

**Joe Hage:** Gordon wants to know who issues the UDI barcode. Is it the issuing agency?

**Gary Saner:** Yeah, so that's a good question. The issuing agency as you sign up—and I think I mentioned that we here at Reed Tech even though we don't make any devices, we actually purchased a hundred GTIN numbers and I think we signed up for HIBC

as well just to go through the exercise of "see how this works," and what we discovered and I'm sure many in the audience are aware of this, but—as you sign up with an agency, let's say it's GS1, and I'm not favoring any one or the other, but the agency themselves will give you a first set of numbers, and let's just call it the prefix, where a set of numbers is applied to your organization and that might be four or five characters – the balance of those characters in the full device identifier needs to be administered by you, the manufacturer, and you meter out those, you assign those to individual products in your inventory. So you have a series of numbers all starting the same because they're all supplied by one manufacturer, and then you have individual numbers applied to your product in various configurations. So each of the more common standards, GS1 and HIBC, have a scenario where the agency applies the first couple of characters to the labeler, and then you as the manufacturer takes care of the second half.

**Joe Hage:** Nathaniel wants to know, what is in the production ID, guidance from FDA or internal format? Is it more than the lot number?

**Gary Saner:** Okay, so that's a good question. So there are a couple of things in the production identifier, they are coded by the standard, so again if you're using HIBC or other, you can read the rules in their standard about how to include production identifiers, and if a production identifier is on the label and they include the serial number or batch number or the manufacturing date or the expiration date, or if it's a human [01:23:59] type of product then there'll be a donation number, but if those particular numbers are on the label itself—and Mark you pulled that up, thank you. There are a couple of identifiers on this particular example. Over on the left-hand side there's a lot number and there's also a use-by date, so that's your expiration date. I think those are the only two dates on here. Yeah. So if one or more of those production identifiers, if they appear on the label, then you need to embed that value in the production identifier on the label itself. So the actual lot or batch number, if it's 123 on the label, then you should see 123 embedded into your production identifier. If you have a serial number that's 972, then you actually should see that data value embedded and you concatenate these together, so as many of those production identifiers – lot or batch, serial number, manufacturing date, expiration date or donation identification number, if you have used all of those, you have a very long production identifier. And actually on the other side if you don't have any at all, then your production identifier is [01:25:25]. So going from one side where there's nothing on the label all the way to the most complex side where you would make use of a lot, batch number, serial, manufacture date or expiration date, [01:25:39] **and a DIN** number for example, so yeah, if it's on the label you'll need to include it in a production identifier.

Just one quick reminder: When you're submitting the data to the FDA into the GUDID, you simply record a yes or no, not the value of your production identifier. So, "Do you control by serial number, yes or no?" The actual serial number is not submitted. Go ahead.

**Joe Hage:** [01:26:06] **Iwa** wants to know if the device is a system containing several components (attachments) all under the same serial number? Is it necessary to apply the label to each component?

**Gary Saner:** So this is a good question. We actually get this pretty often, Joe, where the question is, "I have pieces that are components to the system itself and they are all necessary for the system to operate, and if they're delivered together and it's one system then one UDI applies." In the event that they're separate accessories that can again be sold individually, marketed individually, delivered individually, then the intent of the FDA is to have individual UDIs on those. In the event that there are spare parts that are being delivered, now this is a spare part that's sold on its own but it's actually being delivered and then installed at the user site and put into the system. So now it's replacing one of the original delivered parts. Spare parts do not need to have a UDI on them.

So there are a couple of different scenarios when parts are being delivered. Just to summarize: Accessories need to be identified with UDI, spare parts do not, and a system that is comprised of multiple components all necessary for the system can have a single UDI.

**Joe Hage:** Kim and John want to know, how easy is it to change your update data elements submitted to GUDID? Once it's submitted, how often does it need to be updated? Variable information such as production control would continue to change over time.

**Gary Saner:** Yeah, so that's very easy to be done and some of that is dependent on what particular method you use. So if you use the manual entry, you'll be able to go into that web interface, identify a record, and now you will create a draft version of that as you make edits and then it goes into [01:28:27] **on publish state**, and then it follows through a couple of steps and becomes published. There's a grace period where you're able to make some edits, and then finally it's published.

So the other methods where you're using SPL as a submission, again as you have changes in your source data, then you would simply do a refresh and push that new record with the changes in it through the system and submit that new SPL, and that overrides…actually it doesn't override, it creates a new version in the FDA GUDID. So technically it's not hard to do. I think it's really just a matter of

taking that data and making the change and retracing the steps that you made on your original submission.

I will mention that the FDA has some rules about what fields can be changed when. So when you publish a record, there's a seven-calendar-day grace period where you can change many of the fields, all the fields except for the publish date itself. After those seven days, there are a number of fields that become locked and you're unable to change them. So if you see an error, you know, the FDA talks about some special scenarios in the case, but some fields are locked and then if you find that you need to change that or if you retire that particular product and maybe there's a model change and you no longer distribute that, well, you can submit value to the GUDID and have that device go into this state where it's no longer marketed. And then you can submit a brand new value that has the new model number or new version connected to it and it'll be a separate record; it won't be an edit to the original record.

So I know we don't have time to go through but of those fields that we looked at, there are 62 fields, there is a document available from the FDA that specifies what fields can be versioned and changed over the course of time once it's published and what fields are fixed and static, and if you need to change it you really need to retire that record and create a brand new record.

**Joe Hage:** We're at 90 minutes, but the good news is that I can see all the remaining questions on one page. The bad news is Anne Marie from Copenhagen just signed off because dinner was on the table.

**Gary Saner:** [01:31:08] **Maybe we're jealous,** Joe.

**Joe Hage:** So two questions about kits. If components in a kit—this is from Izzy—if components in a kit don't need a UDI, how will a user look up a component in the GUDID when there's no UDI on the component? If no PI on the label, will the UDI just be the DI? And what about the direct marking of kits, how should they be applied, for example, on trays?

**Gary Saner:** So the first portion is really a question for the FDA. [Laughs] I don't know how one, like an end user, is able to decipher a particular item that came as part of a kit, and when you think about it maybe the kit packaging has now been discarded and you're left with five items on the table and the bag that kept those together is now out in the trash. I don't think the FDA…well, I know they initially tried to have every component identified. There was a large pushback from industry indicating that it would be a burden. And so I don't have a good answer for that first one there, Joe. That's a difficult scenario where the packaging may be

discarded and now you have some items that don't have a device identifier on them.

The second part about direct marking, there is a question that came up related to this, I don't know, a few days ago, and we're waiting to hear back from the FDA. In the event a kit includes some devices that would normally on their own be candidates for direct marking but now they're delivered as part of a kit, does direct marking still apply?

So one side of that argument says because the item, the device, is part of a kit, UDI is not applicable, because components are exempt and only the kit itself needs to be identified. On the other hand, the argument says, well, that kit, once it's been used and it may actually be multiple-use and sterilized in between patients and so on, there's good business reasons, put it that way, that you might want to mark that with a direct mark.

We haven't heard back for that particular answer, so I'm going to plead pending on that one. We need a little bit of time to come for that.

**Joe Hage:** This third one now is our longest of our three webinars but I'd like to invite Abe, Donald, Joseph, Lauren, and Lynn to stay on the line. These will be our last couple of questions, okay?

**Gary Saner:** Okay.

**Joe Hage:** Lynn wants to know, how do you claim compliance with UDI if the date format with the barcode standards is different?

**Gary Saner:** Well, the Final Rule is pretty…well, it is clear that if the date, the standalone date in the label, and Mark, if you go back to that…

**Mark Bayer:** Yup.

**Gary Saner:** Thank you.

**Mark Bayer:** There you go.

**Gary Saner:** There's another detailed blowup I think of just the label itself. If the date appears by itself other than in the UDI, then the date requirement is the YYY–MM-DD. And it's very explicit, all dates on the label, standalone presentation, need to adhere to that date format. And yet, the FDA UDI was very clear as well that when you embed that date into your UDI, in the bottom right in this example, Mark, if you have a production identifier expiration date, let's say, then the date in there needs to conform to the standard. So when you think about it, the barcode reader that's reading that 1D or that 2D, maybe it's a data matrix format or

something, that reader is using the standards and the specifications to decipher that particular code according to the GS1 or the HIBC standard. And as you look through the standards, there are a couple of scenarios where it matches the FDA but there are many date formats that can be embedded in the UDI that do not match that YYY–MM-DD format. So if that particular format was used down in the UDI, the reader would fail to get a good read. So when you input the date in the UDI for the AIDC reason, then you have to conform to the issue in standard, whereas if the date is a standalone item [01:36:38] **the label**, then the FDA ruling takes place.

**Joe Hage:** Okay, I am going to send you Joseph's question to Haley's box because it's very long. I'll begin to read it for the audience though.

Regarding potential patient-specific custom device components, has this been address by FDA? Will the production ID become a means of manufacturing [01:37:15] **a lot of one** specific to a particular patient? That's interesting.

**Gary Saner:** Yeah, so I think the question is if you are in the business of [01:37:33] **"personalized medicine"** and now you build one item just for a particular patient, I think the FDA was pretty clear in the event that in this scenario, even if it's quantity of one, if it's marketed and distributed by the manufacturer out to the logistics chain to the end product, they make no accommodation for the small volumes or a single volume or single-item volume. So reading the Final Rule, a straight conservative interpretation would indicate that you'll need to put a UDI on that particular single item.

Now, this would be a good opportunity to talk about the UDI provision for requesting exception. So there is a clause in the Final Rule that says if you would like to apply for an exception, here's the way to do it, how to send a request in, what to submit, that sort of thing, and the FDA will evaluate that and let you know. So I would recommend the manufacturer in this case pursuing that to see if their single use would be exempt from the UDI. A straight read, I don't see any volume accommodation.

**Joe Hage:** I forwarded you a question from Abe. If you could read it aloud.

**Gary Saner:** Is this the one that says, "Is one barcode on the label only or allow two barcodes?"

**Joe Hage:** Yeah. Uh-huh. Yes.

**Gary Saner:** Yes, I think we addressed something similar to that where we mentioned that you definitely have to have the AIDC for the FDA, and let's say it's a single barcode

for that scenario. If you want to have an additional barcode that is acceptable for your internal processing, you know, there's some possible confusion because as you go through the logistics chain either the delivery organization or the end user now kind of has to figure out and figure out which barcode to use. One'll work and the reader may not understand the other nor have any reference to the other. So as I understand it, it's allowed to have multiple identifiers in barcodes, but you might want to try to help your users by identifying which is which.

Alright, there's another one from… "We are only making class I products, but I like to make decisions earlier and start preparation early." Good for you. [Laughs] Alright, "Can you suggest when is the best time to start step one to be safer meeting the 2020 deadline?" I think that's 2018, yeah, deadline that you need to look at, considering all the work that needs to be done. Right.

So we have been engaged in working with a number of class III manufacturers and in some cases it's been a pretty intense nine months easily for data to be gathered, cleansed, data validation. In this case, they were making use of templates and processing data and wanted to do some exercises, and we certainly are receptive to clients that want to do a user acceptance test for meeting all the compliance activities. So again, some of these things take time and we offer test scenarios and UAT environments to accommodate that, and it just doesn't happen overnight.

So to answer the question, I would allot at least a year, but as Mark had mentioned earlier you may find that your end users, your buyers, may start to ask for that information early. So let's just think about it. If you have a hospital that has started to change their system to accommodate UDI and they are starting to track information and they have a field in their system called UDI, and for purchasing, procurement, planning, and even tracking administration to the individual patient at the point of care, if they are starting to put that in place for the class III devices and have that in their system, it's very likely and we have seen this already where those end users start to push and request early adoption of UDI for those other classes, class II and class I in particular. So in that case, in this scenario, the industry actually pushes the adoption prior to the FDA's compliance [01:43:16] **date**. So just keep that in mind.

Any more there, Joe?

**Joe Hage:** Yeah, we're down to the last two, and I will tell you that no one else who's done a webinar with the Medical Devices Group retains an audience like you. We are an hour and 45 minutes in and you have half the audience still. That says something. This is a lot of value that you added today, so thank you.

**Gary Saner:** [01:43:43] they don't have too much to do [01:43:45]

**Joe Hage:** Yeah, that's right.

**Gary Saner:** [01:43:45] whatever. [Laughs] Never have anywhere to go.

**Mark Bayer:** [Laughs] Right, we just had lunch and happy hour's still many hours away.

**Gary Saner:** Yeah, there you go.

**Joe Hage:** Alright. Last two questions. Warren asks, do you know why FDA is asking for UDI to be assigned for the multiple devices within a base device package when not listed on a label? For example, a unique ID for an individual glove packaged in a box of 100, do they expect that the HCP will access the database to get this information?

**Gary Saner:** So I think we touched on this earlier where we talked about the bandages inside a bandage box and at time of submission into the GUDID the FDA would like obviously UDI on the box itself and that has to be registered and so on, and I think this question points back to a field that's called a unit of use device identifier. And the FDA has created this field for those devices, in this case the individual bandage, that are not marked and yet they want some kind of a virtual identifier on those individual bandages to be in the database. So to understand why, one might use this at the point of care. So if I was walking up and down the hospital floor and I had to apply an individual bandage to Patient A, I cannot administer the whole box of bandages. I wouldn't put 10 bandages on that wound. I would really only apply one. So the fact that there's a unit of use, a virtual number available to me to document that particular bandage going on that patient, and then if I go next door I would again make use of one of those bandages out of the box and use that same identifier, but again I wouldn't be applying a whole box of 10 to an individual patient.

So I think that's the crux of the answer, is that even though the individual use at point of care is not identified, for tracking purposes, possibly for planning and for management, procurement, usage, that sort of thing, the FDA asks for that individual device identifier. Alright, do we have one more?

**Joe Hage:** We actually have two but, Izzy, I'm going to have to have Haley follow up with you on that. Donald fittingly asks our last question, do you have knowledge of folks using the FDA database with success or is it a pain?

**Mark Bayer:** [Laughs]

**Gary Saner:** [Laughs] It is a pain. Alright, so we have engaged with clients and helped them to use the database. Submissions are by way of pre-production. Let's first of all couch all of this in the pre-production environment. So the FDA has established this pre-production environment. There have been some delays in the response times as the FDA learns and improves their system. So we had mentioned earlier that some load testing was done on our behalf, and always glad to help, I think there were four parties actually helping in that endeavor. And we're not here to fault the FDA. Any new initiative, any new database, any new technical intensive project which is going on here has things and improvements that need to be ironed out upfront. So I know the FDA is working hard to get that pre-production environment as best as they can and improve it, make it as efficient as possible, and then we understand now and we have seen a number of our clients starting to move into the production phase, so now the actual real data is being submitted and validated and published and so on. So I know the FDA's working real hard.

So as far as we know, submissions are easy. I think there's maybe some improvement on timing and response time, and I know the FDA's working on that. As to [01:48:44] **actual web interface** itself, we've obviously been on the web interface and looked at data to confirm that the values have come in and looked at content and so on, and it's a web-based environment, allows you to navigate, you are able to do some search and selections and so on, [01:49:07] **and all out of** individual device records. So one of the limitations is that, if you think about it, if you have a whole product family and there's a change to the product family catalog number for example or the brand name or something, one of the shortcomings that we have observed is you can't make bulk changes, whereas if you use, say a third-party system, many times if you're manipulating data inside a database you can make bulk changes and then apply, and obviously need version control and then submit the updated records and have that [01:49:58] **flag**.

So as you're looking at systems and think about maintenance over the course of time and also how that data, that core data, may be used in other international agencies and maintaining that…I think you'll see there is some value in maintaining the data in an external database. But really, that's really up to you to decide what's best for your scenario. And again, a few records may not necessitate a separate standalone third-party database. But I think that's the scenario. I know the FDA's working really hard to improve it, and for the most part it's functional and I think they're working hard to get things up and running by the September 24th, Joe.

**Joe Hage:** Gary, I'll conclude this call the way I began it. I think the Medical Devices Group is stronger because of members like you, and the fact that you gave all these folks

from all over the world this free information on what I consider to be among the hardest things going on in the space is a gift. So on behalf of the group…

[01:51:17]