**UDI GUDID Webinar from Reed Tech and the Medical Devices Group**

Joe Hage: Hi, this is Joe Hage and I have the privilege of leading your Medical Devices Group. We this week will surpass our 215,000th member worldwide. And I just love the community that we have built together, I see questions from folks all over the world and people jumping in to help, and frankly I attribute a lot of our success to people like Gary and Mark who are not only presenting content about unique device identification but doing it for the second time. Their first presentation a few months back was so well received, so many questions, and questions continue to come in, that I realized with their help that we have a really hot topic, it's very confusing, as I understand it the rules are kicking in in a few months, and quite simply these guys are my go-to for UDI questions. So I will mute myself, I'll be looking for your comments and your questions, I'll be reading them alongside, and I will hand the microphone over to our capable friends Mark Bayer and Gary Saner. Gentlemen, take it away.

Mark Bayer: Thank—excuse me. Thank you, Joe. Hi, my name is Mark Bayer and I'm here with my colleague, Gary Saner. We thank all of you for taking time out of your busy schedules to attend the webinar. We hope it is informative and helpful, and we're going to be covering FDA UDI requirements and GUDID submission solutions. Thank you also to Joe. We're doing this in collaboration with Joe and the Medical Devices Group, and we thank him for all of his help. And just to point out, the 10X conference that Joe is running is going to be held in Minneapolis, May 12th through 14th, something you might want to consider attending. It has grown dramatically over last year and covers a tremendous amount of good information for medical device manufacturers. And Gary is going to be conducting a workshop on Monday the 12th of May and it's going to be a three-hour workshop on UDI, so a lot of the things we can't get to today due to limited time Gary will definitely be able to get to at the 10X conference. So you might want to consider attending. We'll be there.

Okay, a brief look at the agenda. We're going to just quickly talk about Reed Tech for context. We're going to go over the UDI requirements, the GUDID challenges that you're facing, a solution to that that we have, Q&A, and then there is some stuff in an appendix. On the next page is how to send your questions in to us through the chat feature of GoToWebinar. Just follow the instructions that are shown there. And to Joe's earlier point, we would suggest that as your questions arrive, please send them in. Not saying we're going to answer them in real time, but this will help us get all the questions in and organize them so in the Q&A we can be as efficient as possible.

Okay, so preview, overview of Reed Tech. Some of you, many of you are on this attending our webinar now for the second time. Thank you for those who did attend back in April…excuse me, in October. We've been in business for over 50 years. We provide solutions for content and life cycle management. We're part of LexisNexis, which is a business unit of Reed Elsevier. I suspect many of you heard of those two companies. We handle all the contracts, all the patent applications and granted patents for the United States Patent Trademark Office, and we have over 725 life sciences customers who are using our structured product labeling services already, members of the three organizations as shown below, and ISO-certified since 1998.

Next page—I want to go through these very quickly—as I mentioned, we have over 725 companies that are life sciences companies that are our customers and over 28,000 SPLs. We have created over 28,000 SPLs since the structured product labeling mandate was put in place in 2005. The point, the important point about that is not the size of the number but the experience that we've gained. This is an area that we have great expertise. Your submissions will be made to the GUDID database through the Electronic Submissions Gateway, and we have made a large number of those. Over 400 of our 725 customers use our Electronic Submissions Gateway service.

On the next page, we have experience in all of the drug SPL types, and now as we get into the medical device UDI SPL area we already have some experience there, having participated in an FDA pilot submission program back in October of 2012, and this area here, services for medical devices UDI SPL is the focus of today's session.

I'm now going to turn it over as we get to page nine to Gary. He's going to review the UDI implementation timeline. We're guessing that most of you are aware of this, and in turn the fast-approaching September 24th, 2014 deadline for class III manufacturers. So Gary, take it away on page nine, please.

Gary Saner: Well, first of all, hi, this is Gary, and happy to be able to participate in the webinar today. Looking forward to another time where we can share some of the solutions that we have and talk about the requirements that the FDA has put forth and help you out. If you're at all familiar with UDI, you've seen this or a similar type of timeline before. I will concentrate in the top left-hand corner where it says Class III. That is the most critical, closest timeline milestone that we need to be concerned with later this year. It's actually less than seven months away now. Like I remember last year, we used to say, "Oh, it's next year, don't worry about it."

Mark Bayer: Yeah.

Gary Saner: Well, [laughs] it's now less than seven months.

Mark Bayer: It is, right.

Gary Saner: So on the 24th of September, that deadline for class III submissions needs to be in place, and then there is a schedule a timeline for those other classes in the implantable, life-supporting, and life-sustaining devices.

The other note that I will make on this screen is down here at the bottom there are now three documents that the FDA has released that are the key documents, certainly the UDI Final Rule back late last summer and the GUDID Guidance for Industry, and then at November there was a release of the Implementation Spec for the SPL record – that's the message that gets sent to the FDA. Noteworthy is middle of February there was a revision to that. Most of the content stayed the same and there were just some minor changes that we have been involved with and keep abreast of.

To summarize what the Final Rule was about, there are four major sections, actually three primary that are identified on this screen, page 10. The labeling section identifies the unique device identifier comprised of a device ID as the first component, and then concatenated with a production identifier or more to create the full UDI. And that particular identifier needs to be on the device label itself and also on higher-level packaging. It's presented in human-readable form. It's also presented in an automatic ID and data capture. So most implementations in the past have used the single ID or single barcode for that particular representation. 2D is okay, so if you're making use of data matrix or other type of 2d barcodes that's certainly allowable. And some have gone and used the RFID type of identification for the unique identifier as well.

There was some information about date format that went back and forth – YYYY-MM-DD. If the date appears on the label, it needs to follow that particular sequence. And some devices, some software pieces are classified as devices, and the UDI needs to be on the help or the about page for that particular piece of software.

Noteworthy is the direct marking requirement for those devices that are multiple use and reprocessed. So we have had discussions with Jay Crowley when he was at the FDA regarding reprocessed, and the implication there is that the device is cleaned, it's wiped down or it's sterilized or in some similar fashion reprocessed for the next patient. So keep that in mind – if your product falls into that category, you have some additional requirements to look at.

And then the third major area, which is what we'll spend most of our discussion today on, has to do with registering the device identifier with the FDA, and there are a number of slides that will explain this particular activity. The last one I'll just make a quick note – there are also reporting responsibilities. As adverse event reports come into play, your facility annual reports and so on, when unique device identifier is available in that product, then you'll need to include that in your report.

The next slide is slide 11, and I want to go over this because it can be confusing as to the content that gets placed on a label versus the content that is sent to the FDA and maintained in the global unique identification database, the GUDID. In the upper left there, you see that the UDI has these two components, the device identifier, and if there are production identifiers such as a serial number, a lot, a batch number, manufacturing date, expiration date, those type of things, if they are in fact used on the label, then they need to be included in a UDI and then typically put into that barcode.

GUDID data is quite different. Notice that it makes use of the device identifier but none of the production identifiers are included. So the things that control production are not included in the message that is sent the FDA. It's not in that database at all. So the device identifier, one field, plus a number of other fields, 54, that describe the product—the FDA refers to these as device attributes—for a total of 55 submitted fields. So you see in the diagram below that some of the data would be coming out of your source information, your MDM, as well your ERPs, other type of systems, and matched up with some labeling templates typically in the labeling system, and then that data is flowed typically to [00:12:26] **ink on** paper, and then that label is affixed to the product and also to various levels of packaging.

On the lower half, this avenue refers to the device identifier being pulled out of the source data and those attributes being collected into this cache area where the GUDID submission data is collected and then packaged into an SPL and sent off to the FDA, and that is checked and received and then validated, put into the GUDID database.

So the interesting thing is there are a number of fields, let's say 15 fields, that could be pulled out of the labeling system—that’s what the dotted line refers to—and matched up with the other 40 fields to complete the full set, or those 15 fields could be sourced directly from the original manufacturer source data systems. But in either case there are two sets of data, one that goes to the label. The other set of data, which is a different set, goes into the message that goes to [00:13:41] **the FDA**.

Mark Bayer: Gary? Gary, let me add one point here. If you notice in the brown oval to the left, source data can be in many different systems as Gary pointed out. Additionally, the source data might not even be in some systems. Sometimes the source data may only exist in hard copy or some other nonelectronic form. So that also could be, if that does exist or that situation exists, it's going to be challenging to get all that information in. We can help you with that if you need it, but the point is it could be anywhere as we have found in discussions with a number of customers.

Gary Saner: Now we'll dive into a little bit more of those fields in a second, Mark, but that's a real good point to remember, that you may have to create some fields or look around **your** [00:14:32] **but** most likely, since this is a brand new requirement, you have never associated these data fields together in the past and so it takes a little bit of work to collect that.

This page 12 identifies the actual label. This was actually copied from Indira's recent GUDID Account webinar back in January, but it's very well done and I did make a copy of it. So it identifies various fields, like the brand name in the upper left is able to be pulled from the label itself, and that star indicates that it can be used in regular text format and able to be flowed directly over to the label, to the GUDID data. But in contrast, the 22 field there, the GMDN description, which appears as text on the label, now appears to have a code associated with it, and the code is what is actually sent to the GUDID. So in this particular scenario, there is a transformation that needs to take place. So some of these fields you see stars next to, some are blue dots and indicating that there has to be some massaging of that data.

The other thing that I want to highlight is in some cases the labeling system will have a template. Let's say it has a template for this particular product family and maybe all those products are single-use devices, so this icon may be embedded into the template. So there's maybe not an actual data value indicating that this is a single-use product. Other examples might be sterilization required in that sort of thing. So Mark, those are examples where those data values may not exactly appear anywhere. They're embedded into the process, in the template…

Mark Bayer: Right.

Gary Saner: …but in that scenario there has to be some **work to them** [00:16:38].

Mark Bayer: Some capture, yes. It has to be captured in some way so that it can be submitted to the FDA.

Gary Saner: Yup.

Mark Bayer: Good point, Gary.

Gary Saner: I'll make one quick reference in the bottom left, the label name appearing on the label itself, this is probably going to be new to most of those people responsible for GUDID whether it be regulatory or an IT operations person. Again, in this case, a transformation has to be performed where the actual label or name and text is not sent to the FDA but a DUNS number—now DUNS number is put out by the Dun and Bradstreet organization, a private firm, and they have assigned numbers or you can get a newly assigned number to a particular company and a particular address. So that's another area where…I highlight that one because that's going to be brand new and a little bit different than some of the other features.

The last thing I'll talk on in this particular slide is in the bottom right. You see the unique device identifier on the bottom right represented in this case by a 1D barcode sample, but only the first half of that, only the device identifier, is collected and pulled out and put into the GUDID message. I'm moving to slide 13 now…

Joe Hage: Hey Gary?

Gary Saner: …where this is a full list of those…

Joe Hage: Gary, it's Joe. I'm going to bring you back to the slide you were on.

Gary Saner: Yeah.

Joe Hage: Let's keep this [00:18:09] because, wow, am I getting pilloried with questions here, and some of them are basic and around this label. So this might be a good time to address them. And yes, certainly we'll be making the slide presentation, the transcript and the replay all available. [00:18:28] asked, "Is the UDI created by the manufacturer or is it appointed by the authorities?"

Gary Saner: So that's a good question and we've come across that a number of times. So the unique device identifier leaves the first portion, [00:18:45] the DI [00:18:47] from three different organizations. The first one, most common, is GS1, the second one is HIBCC, and the third one, H-I-B-C-C, is the organization that [00:19:04]. Joe, could you mute your [00:19:10]? We're getting that feedback problem.

Mark Bayer: Okay, perfect. Thanks Joe. Go ahead, Gary.

Gary Saner: So thank you, Joe, it's a little bit better on our side now. So this device identifier needs to come from an issuing agency. The FDA has now approved three that I have mentioned—GS1, [00:19:30] **HIBCC**, and HIBCC—and those particular organizations at least the first two, identify a company as part of their UDI and

they will give you a code for that, and then the other portion of the DI is maintained by the company itself. So as a product is assigned a particular number, then that number's [00:19:56] in, and the organization, the GS1 or the HIBCC maintains a standard but the labeler actually completes that and assigns it to products.

Mark Bayer: Gary, I think you misspoke. You said GS1, then you said HIBCC, H-I-B-C-C, and you didn't say who the third one was. So H-I-B-C-C is obviously HIBCC. So it's GS1, HIBCC, and?

Gary Saner: [00:20:20] **IBCC**, sorry.

Mark Bayer: Okay, great. Okay. Okay, good. Joe, did you capture what you wanted there?

Joe Hage: Yeah, I put myself back on. And lesson learned, we both can't talk at the same time. I invite folks if you feel you missed the critical part of the answer there, you can type it in. [00:20:42] **Jody** asked, "Please repeat the issuing agencies, couldn't hear due to the feedback." Before you do, Jack asks, "Just to be clear, are unique serial numbers required in the DI? And please define what you mean when you say secondary DI."

Gary Saner: Okay, so there's the first topic, let's go to the first question there, "Are serial numbers embedded in the DI?" So…

Mark Bayer: No, no, first topic was to repeat the three organizations.

Gary Saner: Oh, okay…

Mark Bayer: Because we had the feedback going at that moment and it made it tough.

Gary Saner: Very good. So the first organization is GS1, the second one is HIBCC, H-I-B-C-C, and the third one is [00:21:35] **ICCBBA**, which is an organization that centers around blood and vaccine products. So the first two are the ones that are making up the most of the industry.

The second question was about the serial number. So the serial number, if it's used, it's not required, but if it's currently used on the label, then it must be part of the production identifier. So in the bottom right-hand corner, in this particular case a serial number is not used but a lot number is used underneath the catalogue number so that 12345678 lot number is used for production control. Therefore, that number would need to be embedded in the second half of this example in the bottom right, which is unique device identifier. That serial number, lot number, manufacturing date, expiration date and so on, are not sent to the FDA. They're only put onto the label itself. In this case, there are two production identifiers. We

talked about the lot number, and then there's also an expiration date that's "use by 2020-01-01." So that is used on the label, so that would be a second production control identifier built into this unique device identifier in the bottom right-hand corner. So I believe that covers those questions.

Mark Bayer: The secondary question.

Gary Saner: Yeah, the secondary, there's a provision inside the message that goes to the FDA where you would need to identify your primary device identifier and you have an option to fill in something called a secondary device identifier or an alternative device identifier as some people refer to it. That scenario is when a particular product maybe is in transition or for whatever reason a manufacturer has used both GS1 issuing agency for identification and also used HIBCC as a second issuing agency for identification. And you may have a product going out the door and it's a mix, there may be a transition, or internally you need to identify this, so in that particular case the message allows you to register both numbers, the primary DI and a secondary DI, and have that available in the FDA database.

So Mark, I think we covered the questions there and we'll move on.

Mark Bayer: Right. Joe, should we move on?

Joe Hage: Yes, go ahead move on, and I figured out it's because Joey left his earphones at home and I am not at home, and that's why we had the feedback. So I borrowed my friend's earbuds. Just one more thing and then please move on: I'm getting a couple of questions about timing, about grace periods – if you could just quickly address that.

Gary Saner: Okay. So there are some discussions about the timing. So when September rolls around, there are a number of exceptions, and we don't have time to go into all of them but I'm going to highlight a couple that are very crucial. When September rolls around this year and you have class III product already finished and sitting in inventory, then you have a three-year period of time where you can use those products and leave them in the distribution chain. But on the September 24th, any new product that is made and then labeled for distribution, it will need to have the UDI. So you have this ability to use up your inventory in a three-year period of time. There is also an exception that you can apply for up to June of this year for a class III product. If there's some reason that disallows you from making that date and would like a one-year extension, you can apply for that as well.

Now, there are other exceptions in things for various scenarios that are actually identified at the end of this presentation. We don't have time to go into all of those but when you download the presentation there are two—and I'm going to

quickly go all the way to the end—there are two slides at the end that summarize some of these Final Rule highlights. So the actual examples that I was giving about the inventory exception is down here and identified, and the class III extension of one year if you make request for that, and the second page has more of these type of examples for convenience kits, combination kits and so on. I'll leave that to you to look at after the webinar, and you can certainly contact us if you have further questions along those lines, and we'll be discussing how we can accommodate those questions with the internal account people here.

Joe Hage: So to clarify, Jack asks, "Does a product no longer sold that's still in the supply chain need to be in the GUDID?" And I think the answer is you have a three-year grace period depending on the class.

Gary Saner: Yeah, if it's an inventory, all classes have a three-year grace period, and if something is already out in the field and then is used by a patient, then the UDI is not retroactive. There's nothing that needs to be done to already delivered product.

Okay, so let's move on. Slide 13 identifies these 55 fields that we were referring to. They're broken into a couple of categories. We're not going to [laughs] identify each one here. But significant is that the 55 of these fields are submitted by the labeler and seven additional ones are populated by the FDA GUDID system, so by being able to read some values it's able to interpret and fill those items in.

There are two levels of complexity that I just want to highlight here. In some cases, you are able to make multiple entries for a single field. So let's just take the premarket submission number. It's possible you may have two submission numbers connected to this product, or you might have multiple supplements—that's even a better example—so in some cases multiple fields for a particular field. The other level of complexity that I'll mention is that some fields need to be submitted as a set. So the size type over in the right-hand size, if the size value and the unit need to be all filled in as a set, so if you fill in one you have to fill in the others. So there's that level of complexity.

And for packaging I'll just quickly mention that there's a sequence of packaging, multiple levels of packaging, and you do need to identify that. So there is a little bit of subtle complexity in this particular data set.

Mark Bayer: Okay.

Joe Hage: I have to laugh, you say there are two levels of…there are two complexities…

Mark Bayer: [00:29:39]… Joe, did you want to say…

Joe Hage: No, I was just saying that I can't help but laugh, Gary says there are two kinds of complexity and I'm thinking extreme complexity and moderate complexity. Those are the two categories.

Mark Bayer: [Laughs] Okay.

Gary Saner: [Laughs]

Mark Bayer: I just want to point out to everyone in the audience, this information, this slide 13 that you're looking at, is available on our website, and of course the whole presentation will be available through Joe on his website when it's done. Okay, let's go to 14 then, Gary.

Gary Saner: Fourteen, there are just two significant points I'd like to make about this. One is that here at Reed Tech we've evaluated the specifications and understood the description and built various documents around that to understand the validation and codify that particular set of validation rules. So that is one point to understand, that there are a number of specs related to each field. And then secondly, the list of fields and the order of fields to organize your data and list them in a particular fashion and help you to go about the company and find them. This particular view is from a data template that we have available and will be talking more about making that available to you. So basically these are two tabs from that template, one which describes the product, shows the description and validation rules; second one identifies the fields in a particular order and you're able to build a structured type of presentation.

Mark Bayer: The second one is actually an Excel spreadsheet template that's been…we've built and will make available. You'll be able to get that easily by contacting Haley Lentz, who is…we'll give her contact information later on so that you can get a copy of that template so that can be helpful to you.

Gary Saner: So Mark, that concludes our little review of what the Final Rule is, what the requirements are.

Mark Bayer: Right. Okay.

Gary Saner: I think this goes back to you for the next couple.

Mark Bayer: Right. First thing I just want to point out is that, once again, if you want to send questions, Joe is fielding all the questions and the way to do that is outlined right here on this slide. Okay, let's go to slide 16, Gary.

You may recall, many of you, over 400 of you filled out a short questionnaire that we posted on surveymonkey a couple of weeks ago, and we wanted to report to

you those results. So how far along are you in identifying, collecting, organizing your UDI data? As you can see, if you haven't gotten too far along the road yet, you are in good company because most people haven't. People are just beginning to pay attention to this. Manufacturers are just beginning to pay attention to getting this content organized and then thereafter submitted to the FDA.

Reading to the right, if you're submitting class III data, taking into consideration the deadline, when are you anticipating making your submissions? Most are uncertain at this point, so once again you're in good company if you're just starting out. Lower left, have you decided what methods you're going to use? And the answer is overwhelmingly not yet. And then lastly, if you were one of the folks who has decided a method, what method are you preferring? And you can see there are…we will get into these methods next in more detail, but most are still uncertain as to how they're going to do it.

So let's move on to page 17 and let's talk about the GUDID data submission methods. So most of the manufacturers we've been in touch with, existing customers, have been working very hard—in the left-hand side of this diagram in the round box—as they have been gathering their information and pulling it together. So how can they get that information into the FDA? And that's what this slide is all about in a very simple way. Gary will get into greater detail next because we think this is a lot of the meat of why you're attending this webinar today.

So the first way, which is known to many, many people of course, is to use the FDA's GUDID web interface. And this would require you're sitting there, individuals will sit at a terminal, will gain access, gain an account through the FDA, and then they will manually enter that data, [clears throat] excuse me, [coughs] pardon me, manually enter that data into the…using the web interface, and that'll get into the FDA and then ultimately into the GUDID database. The next two ways are provided as services using either a hosted software solution, software as a service, or a fully outsourced service. These are the two methods that we make available at Reed Technology, and we'll explain those later on. And then the last one is to either buy, build or upgrade software, and then use that software internally installed in your organization, and using that software make those submissions to the FDA.

So on the next slide Gary is going to go into more detail about each of these methods. There is no one method that will be good and suit everybody. That's why there are multiple methods, multiple ways of doing this. And though the hosted software and the outsourced are the services that we offer, we in no way

expect that everyone would use that. Clearly, different methods will make better sense for different people. So Gary will now describe these methods.

Gary Saner: Alright, so we'll go through the particular columns here, first of all, identification of the methods in the first one, the descriptive comments, and then two columns that have to do with cost, technology and operations, on the right-hand side. So for the first method, Mark, the GUDID web interface that you had mentioned…

Mark Bayer: Mm-hmm.

Gary Saner: …your third party is able to enter the data directly via keyboard into that interface. Obviously, this is suited for low volume. You get to appoint where it's not practical or cost-effective anymore, and there are actually some quality concerns – as you're transcribing data from one point to another, obviously there's a little bit of error. So there are text field entries that need to be typed in, and that is where there could be some checks that need to be applied to make sure the quality is high. Other fields are from a list of values, you know, you pick a selection, so the quality, the actual entry is no problem. You have to make sure you pick the right one. Obviously there's no technology software cost in that scenario but here you need to administrate everything, do the data entry, and perform any quality assurance checks.

Second one is this hosted software, and this is a model where it's very much like the first one where the technology is outside your control, it's not inside your firewall, it's in a third party, and in this particular case you're able to go to that site, they are able to upload data, and this facilitates electronic submissions, very high-volume file entry processing, and the system then builds the SPLs, you submit the SPLs to the FDA, to the Electronic Submissions Gateway. In this particular case, all the activity is done by the third-party platform and there's internal validation of the data, validation of the SPLs and so on, and we'll get into an example of that when we talk about our system.

But the last two fields, I just want to mention, you're basically renting the technology, renting the software, and there are some significant advantages obviously in that where you're able to avoid the purchase, the installation, the validation, the updates. So there's significant cost [00:38:49] in that. But in this case, you are supplying the labor to kind of push it through, not making data entry because that's done electronically, but basically being a production control and say, "Okay, I approve this, submit this," and so on, and looking at various reports.

The third model is the outsourced service model. In this particular case, you may have the knowledge to fill in some of these values and build the content, but because of time and other concerns you'd really rather just hand it off, and you'd

be able to prepare your data but you'd like to give it to this third party, and that third party then does all those things that we had talked about earlier—checks the data, validates it, puts it in SPL format and submits on your behalf—and basically you're able to meet the requirements of the FDA but with much less burden on your time and effort. So there's again no software cost in this particular case, but there is a service cost, so someone needs to go about checking it, validating it, so on.

Mark Bayer: And just to add perspective to that, it's basically pay as you go. You pay for what you need when you need it.

Gary Saner: Alright, the last one, we'll just highlight that, and this has been a typical scenario where when pressed for a new service a company will look to buy software, either build it internally or buy [00:40:26], or in some cases your product life cycle management tools or your ERP systems or your MDM may have a particular module, a UDI module available for you, and that might actually come out of your labeling system where there's now capability to do this collection of the data, validate the data, build the SPLs, and then you do incur the task of submitting those SPLs to the FDA. And I will make mention here that there are two flavors of that Electronic Submissions Gateway, and the one that's able to handle high volume is this AS2, this application statement 2 particular model, and that is what you want to really consider if you're doing high volume.

Mark Bayer: One point – these four methods, The Gray Sheet, which I'm guessing many of you are very familiar with, The Gray Sheet published an article back in January on just this topic, going through these four methods and talking about the pros and the cons of each of those. We'll tell you down the line how to get your hands on that article, and that might be helpful in your decision as to which of the methods would be best suited for you.

Gary Saner: Okay, [00:41:50]

Joe Hage: Hey guys…Gary let me interject this…

Gary Saner: Yeah.

Joe Hage: My switchboard is lighting up. Peter asked, "If you're submitting the…?" Pardon me. He asked, "If I'm doing a lot of them, do I have to do them manually or can I do them in batch?" And Haley and I are going back and forth and she said, "If you're submitting via the FDA web interface, yes, it's individual and private. If you're using HL7 SPL, you can do a batch submission, aka Reed Tech can help." And I said, "You mean that Reed Tech needs to do it for me? I can't batch submit on my own?" And she said, "Well, you can batch submit on your own in two

ways. First is to create a system that would convert files to SPL. This can be costly. Or you can engage a vendor like us and we could do a batch submission with a software tool or some type of solution that was made."

So I asked her about pricing and I'm going to send out a link to everyone in that chat window—send to entire audience—and that is Haley's email address so you can ask her about pricing about batch submissions, but just as an observer here I'm thinking, "Man, FDA, you couldn't have made this harder and it's expensive too, and no matter which way I go I'm going to end up spending money here, whether I hire your organization like Reed to take care of it or, heaven help me, if I try to figure this out on my own and build my own that could be even worse." So you know, they got me coming and going.

Mark Bayer: Okay, let me…Joe, this is Mark, let me just make a couple of comments. I mean, there are many ways to do this, and with this slide that's up now, points those ways out. If you do use the FDA's GUDID web interface, then you will have to enter each record, each GUDID record on a one-on-one basis. If you do want to use SPL, which is an HL7 schema, then yes, you can do it batch. And if you look at the chart that we just put up, yeah, the…if you are…see where the…yeah, I see where Gary is pointing, there is that little icon. This solution, and I'm trying not to be too salesy here, I want to make sure this is an informative webinar as opposed to a sale session, but these two solutions that we offer—it's the easiest way to make this description understood—the hosted solution or the outsourced, they use the same basic engine, the same basic software platform to do all of the organization, data organization, SPL creation, and SPL submission to the FDA.

The difference is that little icon. One of the people you just mentioned, Joe, who had written in, if that person wants to do and basically drive the car himself, be in charge of everything, just taking advantage of the technology platform that we built, that's what we call the hosted software, the software service solution. We don't touch a thing. The system is doing the work on behalf of that individual, and that individual is controlling everything about what's being done. If someone wants us to do that work for them because they don't have the bandwidth to do it themselves or for some other reason don't want to do it themselves, that's the outsourced service. So I just want to make sure that the person who asked that question understands there are many ways of going about this. If you use our solution, you can clearly drive the car yourself. If you are using the FDA solution, then you are, once again, driving that car yourself. And if you're using purchased or built software behind your own firewall, you are driving the car yourself. I'm hope I'm making myself clear by using that phrase, "driving the car yourself."

Joe Hage: I think it's more like…

Gary Saner: [00:46:22] it's clear enough. If not, clearly you want to get in touch with us.

Joe Hage: That was helpful, and I'd say instead of driving the car yourself, you're driving the tricycle yourself because you have to do it one at a time on your own most often, and for people who have hundreds of…

Mark Bayer: [00:46:37] **No, now** you do it…yes, and I think, you know, to the FDA's credit, they have built the GUDID web interface, it's a good system, but it is not as robust as a full software system that a software vendor or a services vendor like ourself has put together. But I think that's sort of the history of things in the sense that the FDA has provided a solid solution, but it's not the solution for everybody.

Okay, we can talk about this at a later time or have offline conversations with any of the attendees. So for the sake of time let's move on, and we're now on page 19, Gary, and I think this is a key page in the way of summarizing what we've just been discussing.

Gary Saner: Yeah, so we did mention that there are these four different methods as…and one is not the one and only, **we have to** [00:47:42] every scenario, we need to look at those, see how you put into that, what's your skill set, your mindset, where do you want to keep the data and how do you want to manage the data, do you want to hand it over, do you want to have the full do-it-yourself type of approach to this. I will mention for the non-FDA GUDID software tools that 21 CFR part 11 compliance comes into play here, and make sure you have that built into your plans or into your purchases.

The other type of evaluation that you want to be aware of is making sure that whatever solution is in place does SPL document validation, has access to control vocabularies from the FDA submissions, processing, and maintenance. So you can take a look at that in regard to your particular scenario and we can talk further as you make the selection.

Mark Bayer: Okay, so the next thing we're going to move to is to give you a brief overview of the Reed Tech GUDID solution, either the SAS or outsourced model. We're not going to belabor this because we want to open it up for more questions, but we do want you to do understand how we could be of service to you down the line. So Gary's going to quickly review page 21, and then I'll pick it up from there.

Gary Saner: Okay, we alluded to this scenario a little bit earlier where source data is collected on the left-hand side in the brown object where those fields need to be collected. We can assist you in doing that if necessary. But at some point in time you'll basically have those fields put together into a full set, and then through various ways, through a secure portal transfer or an upload, you're able to bring that data

in and we're able to do that in bulk fashion. In the event that there is some additional preparation and transformation that needs to be done, that is able to be accomplished and then the data is put into the database, and the next step is to have it validated. So there may be a couple of fields, and this is some scenarios that we talk about where all the fields are not in a particular data set and you are able to do edits and maintenance, able to edit a full data record or enter a full data record, or add just a couple of fields that may not be built into your electronic system.

On the right-hand side, once that data's been validated and approved, the SPL document is built and it is also validated against the schema, submitted to the FDA through Electronic Submissions Gateway, and there are a number of acknowledgements that come back, each of those acknowledgements showing the progress through the FDA, and eventually either a passed acknowledgement or a failed acknowledgement will come back with a particular error on a particular field or multiple fields. All that reporting is done and made available back to the user.

Bottom left is a connection now to the industry databases, in particular the controlled vocabularies. We do that on a daily basis to make sure that those are fresh.

The other point I'll make is the upper right-hand icon where the user can either be you as the manufacturer keeping an eye on this, doing uploads, pushing the data through and making approvals, doing submissions, monitoring the reports and so on, or it could be a Reed Tech user where in the outsourced model, after the data is handed off to this blue UDI system, then it's simply a matter of approvals on your behalf and all the other work is done in the outsourced model. Mark, did you have any quick [00:51:55]?

Mark Bayer: I just wanted to make it clear that this is a 24 x 7 system. If you're using…if that little icon that Gary is pointing to in the upper right is a person from the, you know, from you, your company, then we don't touch this. The whole thing runs lights out and we just are not involved. You control it 24/7. Everything is secure here. We have very strict security and we are 21-CFR-part-11-compliant. Or if we're doing the work, the only difference is that little icon in the upper right is a Reed Tech employee as opposed to a manufacturer employee. Everything else, the basic underlying engine and platform, is the same.

Gary Saner: So the other thing I'll mention on top of that is, thinking of the future, there are other regions beyond the FDA, the EU, Japan and so on, that will have regional requirements for UDI medical device. So our system is able to expand as those

definitions come into play, and then you're able to build that data set for a particular region. So FDA today, tomorrow it might be FDA and EU, China, Japan, Brazil, so on.

Mark Bayer: Okay. Okay, the last two slides are just a summary of the benefits of our solution. I don't want to dwell on them. It's simple. [Laughs] You just get in touch with Haley and you set up and you're done. It's very nonintrusive. It's least intrusive. You don't have to change what you're doing now. You just have to pull appropriate data out of your system, put it into our system, and you're ready to go. We can also help you in that collection of the data. It's very cost-effective in the sense that you have the advantages of efficient automated bulk submissions but you are not incurring traditional IT costs, which might include hardware, software, installation, validation, etc. You basically are paying for what you need and what you use when you need it and use it. It's very flexible. It accommodates, in addition to the 62 fields that the FDA is interested in having submitted for GUDID, you can submit other fields to us, which don't get published, but you can organize your data so that you can use this to help organize overall internal data if you want. And as Gary mentioned a moment ago, there's easy expansion to meet future UDI requirements that other global regulatory authorities are going to put in place.

Then the next thing is we mentioned this compliance, 21 CFR, and it leverages our significant experience in this area, and we are an experienced partner as I mentioned. I don't want to dwell on this anymore so that we can move on. That's [clears throat]—excuse me—that's the last slide of substance. We'll take questions in a second. There is the contact information. On the next page is contact information but there are a series of UDI resources that we've referred to here in this webinar which are available at no charge, just contact Haley, she can get them to you. We also have…we're working with a partner, Lernia Training Solutions. That's their website right there, and they have built a UDI training course which can help you better understand some of the details and nuances of UDI.

And then the next page, the FDA has published a ton of good information on their website. These are all of those links. The next page I won't even bother to go into for sake of time – it's a quick overview and then some other things. And then the last two pages are some of the nitty-gritty Final Rule highlights that Gary pointed to earlier in the webinar. And that's it for the deck. Joe, what do you want to do next?

Joe Hage: Okay. Well, first I want to thank you. Just like last time, as a percent of people who signed up—industry standard is you might get one in three, one in four to show up—half of the people who signed up are on this call right now and almost

all of them are still on the call an hour in. I just don't ever see this. So this is a really hot topic. Thank you, thank you, thank you.

As I expected, we have more questions than we'll possibly handle. We scheduled this for an hour, we will run precisely a half hour over, so those of you who can stay on you're certainly welcome to do so. Those of you who simply have to go, don't worry, we're recording it all including the questions. They'll be in the transcript and you'll have these slides as well. I also sent you the email address for Haley directly if you have direct questions for Reed.

You mentioned Lernia. They are coming to 10X, you're coming to 10X, and this first question comes from Steve Bixby my friend from Montana who is coming, so it'll be good to see all of you together. Steve asks, "Does the format matter for the UDI info that goes on the label? Is it like the food industry where the info has to be shown specifically in a specific font, in a specific place, or do we just need to show all the info somewhere on the label, or does it have to be precise?" So I'll leave that with you.

Gary Saner: So let me pick that one up. The UDI Final Rule does not address any of that additional information about the current label and how it's presented. So everything that was enforced before the UDI Final Rule came out is still in place as to location, what appears on the label, and the font size, and so on. There is—I don't mean to diminish this—there are some rules and guidance about relative size and so on. So those are rules are still enforced. The only thing that was added was to make sure that the bottom right, this unique device identifier, is now in place and it's in human-readable form, and secondly it has an automatic…like this AIDC, machine-readable, whether it be a barcode or RFD tag or whatever.

Mark Bayer: Next.

Joe Hage: Next question. Mark asks, "Can the description of the device be different from the GMDN description in the US and OUS?"

Gary Saner: Yes, it can. So the actual description on the label obviously needs to be in place, but when you're recording the GMDN to the FDA, actually just the code itself gets transmitted and you do have the opportunity to put a trade name as a separate field. So two fields go to the FDA and the GUDID. One is the GMDN code, and again that has a very specific definition associated with that, and then secondly, the trade name itself is able to be submitted in a pure text format.

Joe Hage: Let's see. [00:59:40] asks, "I'm using a data matrix to identify my products. Can I add supplementary data apart from the DI [00:59:51] **and EI**? For example, the company's name and contact.

Gary Saner: Yeah, so data matrix is very efficient and able to accommodate a lot of data. I have not heard any limitation on the content that is built into that data matrix. As a minimum, it needs to include the DI and the production identifiers that are used on the…or, you know, production control identifiers that are used on the label itself, but if there's additional information that is able to be embedded in that data matrix, I have not heard any reason why it cannot be. That might be something…if you want an answer back directly from the FDA, go to the bottom of our slides, look at that help desk link, and submit your question there.

Joe Hage: John asks, "Which company identifier goes into the barcode, the manufacturer or seller company, in an OEM situation?"

Gary Saner: So in this particular case, the identifier that's used by the end user for purchasing in commercial use, so you might have other identifiers on that label for production control and internal use, but the label that an end user would make use of to make purchase and move this through the supply chain is what the FDA is looking for. And when you think about it, the intent is to include the identifier that a patient is able to look at. In the event of adverse event or some safety concern, the patient is able to find this identifier on the label and if necessary get some additional attributes by looking this up in the GUDID database and maybe a recall centered around that particular identifier. If there is an additional secondary and internal use identifiers, those are still able to be used in the label itself, but the unique device identifier is intended to be that primary identifier.

Joe Hage: Thank you. So you know how I sent you guys an email from Wilbert in the Netherlands? Well, he is on the call. So hello Wilbert from Medtronic, and he asks, "If I show my expiration date on the label, that does not mean I control my **production** [01:02:43]. Should the answer still be yes in the UDI field about the expiration date?"

Gary Saner: So that's a good question. The fact that the expiration date is on the label, in my particular opinion on this one, is yes, the Boolean flag should be true, yes you do make use of the expiration date. So whether there are internal policies or whether there's a particular piece of software utility that checks the staleness or the life of a particular product, internally that's not what the FDA is most interested. It's most interested in whether that expiration date is available and therefore could be used by an end patient, and therefore the flag would be yes, go ahead and mark that as true in the GUDID data set.

Joe Hage: Thank you. Peter asks, "Who is responsible for submitting the GUDID when a contract manufacturer is involved? Is it the DI of the private labeler or the DI of the contract manufacturer?"

Gary Saner: So in this case you can go back right to the Final Rule and legally the labeler is responsible for the scenario where there's a contract manufacturer. So they're the one that actually bears the burden of making the submission. Now, they can work…

Mark Bayer: Just [01:04:33] there, when you say the contract…is that the contractor who is responsible or is it the manufacturer?

Gary Saner: No, no, the labeler itself.

Mark Bayer: The labeler meaning the manufacturer?

Gary Saner: No, the labeler may not be the manufacturer. [Laughs]

Mark Bayer: That's why I'm asking my question, so there's clarity in your answer.

Gary Saner: Okay, yeah. Yeah, yeah, exactly. So Mark, let's just say you're the labeler…

Mark Bayer: Okay.

Gary Saner: You contract me, the separate organization, to do some work for you, actually manufacture and…

Mark Bayer: Okay.

Gary Saner: …affix labels to this label…

Mark Bayer: Right.

Gary Saner: …and then make distribution.

Mark Bayer: Got it.

Gary Saner: So since I'm under contract to you, you bear the burden of making the submission.

Mark Bayer: Got it.

Gary Saner: Now, you may, with agreement with me, [laughs] ask me to do that or whatever, and in concert I might actually make that submission, but you are the one held responsible.

Mark Bayer: Got it.

Gary Saner: Now, it's a little bit different when you go to a scenario where a product is used by a third party, and let's say Mark you sell your product in 10-packs…

Mark Bayer: Mm-hmm.

Gary Saner: …and I'm a separate company, I buy those 10-packs from you and I put them together as a hundred-pack because I'm selling to hospitals and you're selling to little clinics, right?

Mark Bayer: Right. Yeah.

Gary Saner: And now I basically change the product configuration. So there is this concept of overlabeling or relabeling, and now I become a relabeler in that case and I incur the burden of…

Mark Bayer: The responsibility. Now it's yours.

Gary Saner: …responsibility…yup. And again, the DI will be inside my control and with my company identified rather than you.

Mark Bayer: Okay.

Gary Saner: So hopefully that explains that scenario there, Joe. Next one.

Joe Hage: I asked already a question about it, but more questions about timing, so I'm going to try to clear a couple of them together. Regina wants to know what bad things happen—that's my language not hers—to manufacturers who do not hit deadlines, and someone else asks, "How long do you have after you get the UDI number to submit it?" And I'll find the third question. Go ahead and get started.

Gary Saner: So if you miss a timeline, I've actually heard Jay Crowley wouldn't…he was at the FDA, imagine that – he basically misbranded. So if you enter your product into the marketplace without registering it, you incur whatever the enforcement is at the FDA for misbranding, and that can be severe. I think, from what I was able to gather, Jay, is that…

Mark Bayer: Not Jay. Oh, from Jay.

Gary Saner: Yeah, Jay Crowley at the FDA…

Mark Bayer: Right.

Gary Saner: …mentioned that you probably don't want to go down that road, just you want to be safe and make your submissions beforehand. If you're introducing a new product to the marketplace, this requirement is in place before you actually put your product out into the market. So it's one of those requirements, those checkmarks that you need to do beforehand, before you introduce out to the marketplace.

Joe Hage: So Ramon asks, “What is the timing once we submit the proper data to receive the UDI registration number?” And Randy asks, “Is there a time constraint to submit device data to the FDA from when the device is manufactured?”

Gary Saner: Okay, so the first one, I think the question has the wrong premise. You will not receive a UDI back from the FDA. There's not a registration number that you get back. So this is not like your product registration where you go to FURLS and you do your product registration or excuse me, your product listing or register your establishment and you get a listing number. So all that is still in place and in effect. UDI is in addition to that, and basically you submit your data to the FDA.

So the acknowledgement is by way of a…well, if you…first of all, there are two scenarios. One is, if you're using the FDA web interface, then you will get acknowledgement saying, “Okay, everything was valid and passed and your unique device identifier that you gave us has been accepted.” In the event you're submitting in bulk fashion electronically through the Electronic Submissions Gateway, there there's also acknowledgement that comes back as an XML file, and then the process that you're using, the system that you're using would need to go and receive that, retrieve that acknowledgement, and that is your confirmation that the data has been received at the FDA and you can go forward with your distribution.

Going back to the second question about “when do you do this in your manufacturing cycle and introduce it to a product,” so as your label is created you can submit the unique device identifier early and put a postdate of three months out, for example, when you actually are introducing the product to the market. But in any case, the registration has to be complete before you put the product in the marketplace. You can [01:10:09] things in your own warehouse and that sort of thing, but again when you make that product available to the public and any distribution channel, public distribution channel, then you have to have the UDI already registered. So next one.

Joe Hage: [01:10:28] looks as though is considering using you and they want to know, “What is the lead time from the moment the labeler submits information to Reed to the time it's submitted to ECG to the FDA GUDID, and will they be able to monitor your process of building, validating and approving SPLs once data is submitted?”

Gary Saner: So the first question about the time delay, as the data flows in to the left-hand side with no errors and, again, automated processing, literally hours that particular data record could be sent to the FDA.

Mark Bayer: Well, I'd interrupt and say it might not need to be hours if you are controlling, if you are, and we have used this before, and please excuse it if it doesn't make sense, but if you are the driver of the car, in other words you're using the service in a software service model and this is you, then you can pull the data and go through the [01:11:47] validation procedure. When you're done, you can build your SPL. You could get this out the door in a matter of minutes. There would be no delay on that because you're driving. If you ask us to do it in an outsourced model, we can, you know, if it's 2 a.m. in the morning, we can come and do it for you but the price you could imagine is going to be much higher. But during the course of the day, we would be able to do that for you. So when you are driving the car, you are in greater control, and that to move something can move through in literally a matter of minutes.

Gary Saner: So there are just a couple of milestones along the way just [01:12:35] **a few approvals**, and again, as Mark had mentioned, if you are monitoring those and as soon as validation takes place, then the actual processing time by the computer is…

Mark Bayer: It's infinitesimal.

Gary Saner: …is seconds, yeah. So the other thing that I think you had asked about was the SPL validation. So there are two levels, and you'll see validation at the data level. So this is those 55 fields that we [01:13:04] to earlier, matching them up against the specifications that the FDA has established and putting those business rules into place. For example, is the listing number meeting the format of the requirement? The DUNS number that you came up for your company is at nine numerical characters, and if it's 10, well then we know that there's an error. So there are a number of data validation requirements and they're at every field itself.

Mark Bayer: Yes, and I just want to point out, the system will catch those for you and flag you. So if by chance you erroneously put in 10 digits into the DUNS field when nine is the right number it'll instantly pop up and say, "This one's wrong," and that would be your flag to go back and say, "Oops, I made the mistake, I need to cancel one of those digits."

Gary Saner: Yup. And the same is true for all those…the FDA product code, you know, [01:14:04], whatever.

Mark Bayer: Right.

Gary Saner: So then the second level of validation has to do with putting this data into a message document. So if you're familiar with XML and tagging, there are a number of parent and child [01:14:19] **and structure-related** requirements in

building this document and a number of attributes that go with the elements and so on, and the FDA has quite a schema. Now, we're very familiar with that schema. We've been using the SPL schema since 2005 and CDRH has actually adopted the same schema that the drug industry has used. But in any case, that schema defines what structures and what parent-child relationships and what order and how the values are put into that document, and we check that message before it actually goes out the door, making sure that when that document is validated by the FDA – one, the data matches its business rules, secondly, that it's packaged in an XML message that is acceptable by the FDA.

Mark Bayer: I think one of the key things for folks in the audience to understand is that you don't need to know anything about XML or SPL or schemas or any of that stuff. The whole concept of the system is the solution knows that stuff, that's all been codified into the software, and it is not necessary for you to have to know any of it. You just have to know your data, get the fields of information together into the system, and then you'll walk through a very simple end user interface at which point it'll check, validate business rules, say, "Okay, the data's clean," then you'll say, "Build an SPL," it'll build the SPL, and then you'll hit the "submit to FDA" button, that's literally what you'll have to do, is it's purposely simple in its approach so that you do not have to know all of the nuances that are underneath what's going on that's visible to you.

And in turn the FDA will receive an accurate SPL, which will most likely pass right through and be accepted by the FDA as valid. I only say most likely because things can go wrong along the way, data might, you know, something may be amiss in the data. But those will be very rare. The whole idea is to make it quick and easy and not have to know all of that nuance.

Joe Hage: [01:16:46] has more than 600 parts to consider. What should she do, web interface, hosted outsourcing, what?

Mark Bayer: Well, we're probably biased on that, so we would probably say she should use the hosted or the SAS solution. But I would not want to…as I said earlier, there is not one size fits all. Six hundred is bulky enough that you might not want to key 600 records of [01:17:19] into the GUDID web interface, but it is more than capable of handling it. Software, if you purchase or build software to be used inside of your own environment, it clearly would be able to handle that too, but then of course you're dealing with the complexities and costs of that. I think it's a matter of time and knowledge available versus, you know, if…the most economical way of doing any of this from an out-of-pocket expense would be to use the FDA's GUDID web interface in the sense that is available free from the FDA. The cost there, quote "the cost," is you have to have the people power to put the

information in, and there may be some, depending on the quality of how good the keyboarding is, you know, the information may get in there accurately or not. I think that question would be best handled offline where we can ask, you know, more detailed questions can be asked and we can give you better answers.

Joe Hage: Okay, well, [01:18:31], you have Haley's email address, so you can follow up directly afterward. Emery asks, "If NDC members go away, who tells the pharmacies and managed care organizations? Some medical devices fall under OTC and Rx areas, but they are covered by insurance which require NDC numbers for payment submissions. How do these entities use UDI instead?"

Gary Saner: Yeah, I guess you see on the screen now [01:19:03] move to the last page of the presentation, which has a line or item about the NHRICs, the N-H-R-I-C's, the national health [01:19:18] **reference** IDs, codes, and the NDCs. So [01:19:22]'s position on this, by the way, let's go there first. [01:19:25]'s position is that by 2018 all devices will be moved away from NHRIC and NDC numbers to GUDID identification. So that said, going forward, I'm not sure how some of these reimbursement and other concerns…CMS again has some issues and requirements about using NDC numbers for reimbursement under various programs, but I think the actual details of that would probably be best addressed by going to the help desk in this particular case. I don't have those details on the top of mind right now to address that.

Joe Hage: Julia wants to know, if your company prints its own labels, what should be put for labeler name and labeler physical address?

Gary Saner: So labeler name would be the organization name and the address of that manufacturing site. So you do want to then—you can check with Dun and Bradstreet and it's one of those links that we can make available to you—to make sure that the address and company name that you put in place matches up with a particular DUNS number that Dun and Bradstreet has. So I'll just refer back to the pharmaceutical industry where there's been some level of interaction with Dun and Bradstreet to make sure that company names and addresses remain in place. And there are various levels of accuracy that is required here. In some cases, if you're only submitting the DUNS number itself, then the FDA will simply use that DUNS number and look up the labeler name. I don't believe there…and I have not heard of any requirements that are going to cross-check that against a particular physical label, but you know, the requirement is there that the company name and the address that is on the label does in fact match up with the DUNS number that is reported. So I think that addresses the question where you do need to put the labeler's name…the company name in the physical address for that particular site.

Joe Hage: I'm going to try to knock out three questions at once. Rick asks…basically it's about "what about really small things." So Rick asks, "What about the stent identifier where the serial number is clearly an identifier for the patient?" [01:22:40] asks, "We are an orthopedic medical device company. We manufacture class II bone void fillers, bone cements that get implanted to the body. In terms of the implementation, do we fall under [01:22:53] or implantable or class II?" And the third one has to do with "what about packaging that's not part of the device itself, does that get its own code?"

Gary Saner: So there are a couple of questions woven in there, let me have a stab at those. First of all, there is a reference in the Final Rule about a device being so small that it's unable to [01:23:29] **have** enough real estate for a label itself. So there is that scenario. Let's say if I was making, I don't know, a pin or something like that, right? And it was impossible to put the actual label on the product. In that case, [coughs] the FDA would be looking at the label on the packaging. So I might have either one pin in a bag or maybe 25 pins in a bag, but that bag then would need to accommodate some type of identification with a label.

The other question that came up, and I think it was alluded to when you started talking about implants, so implants do not need to have this direct marking on them. That is one of the exceptions that was provided in the Final Rule. There's a lot of discussion actually about requiring implants to have a UDI marked on them either by etching or ball-peening or some particular fashion, and again, the whole question about, you know, how do I do this, and it just became a very tedious activity. So the FDA backed away from that on implants, life-sustaining and life-supporting devices. And now those particular devices the FDA's relying on the electronic health record to keep the record intact so that if I had a heart valve installed or a pacemaker or something, then the identification for that product is now expected to be in my health record and does not have to be marked on the actual product that was implanted.

I think those were the two things that you mentioned, small and implants. Did I address the two questions there, Joe?

Joe Hage: I hope so. I'm not entirely sure. But if your question was asked and we didn't answer it to your satisfaction, go ahead and send an email to Haley at the address that I gave you earlier. I'm going to try to jam in another question or two and, once again, more than we can address here. A couple of questions around "what about Europe?" "Can Reed help with Europe? Is the FDA web interface suitable for other countries like in the EU? What can you tell us about outside the US?"

Gary Saner: Okay, well that's actually a really good question. Back in April of last year, the EU put out a directive…maybe I need to correct myself. I'm not sure it was a directive but it was a document – let's just say it was that. It was a document indicating the roadmap for unique product identification, or unique device identification. And that specification was putting forth a number of proposed data elements that were to be collected, and it mashed up very closely with the FDA's list. Now, there were, off the top of my head, I'm thinking roughly six additional fields that were identified by the EU that were to be added. So this is some regional fields only for EU that were identified. So in that particular case there's an expansion to the data that is originally collected for the FDA. So our system is able to easily pull those through. So when the EU does define officially what those fields are, then we will expand the database, and we already have provision for expansion in a number of fields, but now these additional required fields will be collected and then identified to be EU additional fields. And then when an EU record is created, it will pull any necessary fields from the FDA, almost 100% of those, and add on the EU additional fields and build a package and submit that to the EU system.

Mark Bayer: So let me correct, just throw in one point of clarification. You did say that they would pull those records from the FDA. They would not be pulling those records from the FDA meaning the GUDID database, they would instead be pulling those…[01:28:09] **that** information would be stored in the Reed system where the [01:28:19] already gone into the FDA, plus **these** [01:28:30] to the EU.

Gary Saner: Yeah, **the** [01:28:44]

END OF AUDIO

*Editor's Note: Sorry about the abrupt ending: We ran into connection problems.*

*Gary and Mark will present a three-hour workshop at the 10x Medical Device Conference on May 12 in Minneapolis. Click here for more information.*