Unique Device Identification UDI Requirements and Timelines

Joe Hage: Hi, this is Joe Hage, I have the pleasure of leading the Medical Devices Group, and one of the very best parts of doing that is I get to meet smart people from all over the world, and yes, in this case, Gary and Mark, I am talking about you. Gary Saner is the Senior Manager of Information Systems at Reed Technology and Mark Bayer is the Vice President of Business Development at Reed Technology, and they're going to teach you an awful lot in the next hour about unique device identification submissions and all sorts of stuff that I do not understand. And gentlemen, take it away.

Mark Bayer: Thanks Joe. Hello out there, I'm Mark Bayer speaking and we all want to thank Joe for working with us in collaborating on putting this webinar together and acting as moderator throughout the day. Okay, so you should all be able to see a title screen – FDA UDI Requirements and GUDID Subbn Solutions. We used to think that GUDID was pronounced "gudid," but the folks at the FDA clearly call it "good ID," so that's what we're going to be using as our term too.

Gary Saner: You're going to have to keep reminding me, Mark.

Mark Bayer: I will.

Gary Saner: Old habits are hard to break.

Mark Bayer: That'll be my job. Okay, quickly go to page 2, Gary. The second page just gives a quick overview of the agenda and I won't dwell on that. Page 3, if you have questions as Joe mentioned a few moments ago, you can look at your chat area down…we gave you a little graphic, and you can type your questions in and those questions will come to Joe and to us here. We are speaking to you from Horsham, Pennsylvania, which is just outside of Philadelphia. So if you have questions, use the capability that GoToWebinar offers right here.

Page 4 – we're just going to give you a brief overview of Reed Technology. Most likely very few of you know us, and so we'll give you a couple of pages on that. So now we're on page 5 and we'll give you a quick overview. We are a leading provider of content solutions and content life cycle management solutions. We have been in business over 50 years. We have over 900 employees, most of which are in the building that you see – the photograph to the right. We are part of LexisNexis, which I'm guessing many of you have heard of, and in turn LexisNexis is part of Reed Elsevier, which I also suspect many of you have heard of.

We are the contractor to the United States Patent Office and we process all the patent applications and grants for them, and so in turn, indirectly, many of you who have patents, we have already been processing your data for the work we do for the US Patent Office. Most relevant, we are service provider to over 700 life sciences companies. All of these at this point are pharmaceutical manufacturers. We ISO-certified, have been so for 15 years, and for the past five years certified to ISO 9001:2008, and we are a member of HL7.

If we go to page 6, Gary, the work that's most relevant that we do for the life sciences community is in the area of structure product labeling or SPL. We are, as I mentioned earlier, provider to over 700 pharma manufacturers already. Six of the 10 largest pharmas in the world use our services. Over 26,000 SPLs we have created since the FDA mandate in 2005 went into play for drug manufacturers. So the pharmaceutical community since 2005 has been working in SPL and we have been working along with them.

The Electronic Submissions Gateway, which is the FDA way of receiving data electronically – we provide service in that area and we are the highest volume submitter of SPLs to the FDA, and over the course of the years we have submitted over 13,000 for over 375 companies. So of our 700 companies that we do SPL work for, over 375 of them choose to use our Electronic Submissions Gateway capabilities also.

Page 7 – we have expertise in all the forms of drug SPL. I won't go through these—a lot of abbreviations—just to say we have the knowledge and the experience. We also with the recent medical device UDI activity have gotten very active in that and thus this webinar. We provide the services you see listed and we did participate, as you see in the last bullet, we did participate in October of 2012 in the FDA's SPL-UDI pilot submission. So we already have some real-world experience with the **[00:05:36] UDI and** SPL format. We also have worked with the **[00:05:41] information for use** SPL, which is available in a voluntary basis right now with the FDA.

Moving to page 8 – just a reminder, if you have questions, follow the little graphic and your questions will successfully get through to us. On to page 9, Gary. Great. The FDA's purpose for UDI – there are many purposes. The biggest one would be safety and being able to commonly identify devices. And I won't read all of these eight or nine bullets, but the FDA has clear purpose and public health benefits that will be forthcoming from UDI.

That's our background. I wanted now to shift it over to Gary to get more into the meat of the conversation. So we should be on page 10, and I'm going to turn it over to Gary.

Gary Saner: Okay, before we go to page 10, Mark, and thank you – just a quick comment on these 9, these actual UDI systems that the FDA's putting together. And that's an identification system, so this does provide a global central repository, certainly for national drugs marketed here in US, but the intent is to have this identification system in concert with other global regions across the world that are tracking medical devices and being able to identify them. So the issue about actually tracking over the course of the logistics food chain and being able to trace for a particular history, that is something that the UDI system is certainly going to support, but there's some additional work that needs to be put in place for those particular programs.

Let's go into the timing, on to slide 10. On the upper half of the screen, you see a timeline of the final rule taking place, that being released September 24th, and then there are various milestones for implementation of various classes. So for class III you see the red bar that would indicate that the UDI value needs to be placed on the label for that class III device, and in addition that UDI information needs to be submitted to the FDA as a GUDID database.

And then there are various milestones one year out, two years out, three years out, and five years out for the various classes. There's a separate class category there for the implantable, life-supporting and life-sustaining devices. There's a milestone at 2016 for class II devices and for class I out at 2018. So there's a **[00:85:53] five-phase** implementation applying UDI information to labels and also sending the device information/device identifier to the FDA.

The second part focuses in on those items that need to have direct part marking, and there's a two-year extension for each class. So if you see, class III devices need to have the label updated in 2014, and then there's a two-year additional time period, 2016, for those class III direct part marking items, and again for class III and class I, all being pushed out two years after the implementation of the UDI on the label.

Now, there's a couple of interesting key actions that have taken place. There's a couple **[00:09:54] now and in** the future. As I mentioned, on September 24th, a UDI final rule was released and we were all happy to see that eventually hit the federal register. In concert with that there was another document, a draft document, that defined the GUDID database itself, the values that go into it, and there's approximately 55 attributes for a particular device that need to be collected

along with device identifier sent to the FDA. So that document is a draft mode and the comment period—I'll jump down to the last item in that list—the comment period for that document is slated to end November 25th, and the FDA indicates that a final version of that GFI would eventually be put in place and released to the public.

There is a third document that certainly vendors and those that are going to be submitting bulk records to the FDA are looking for, and we'll talk a little bit more about this particular avenue of submissions, but the third document I'm referring to is this GUDID SPL Implementation Spec. That was originally slated to be released this month, but I actually had some conversation in email with Indira Konduri of the FDA and she indicated that because of the federal government shutdown there's actually a delay in releasing that document. It's now targeted for the end of November. So this is the document that actually indicates how to put the data values into an XML package and send it to the GUDID database itself for bulk submissions.

At the bottom of this screen, I put a reference in there to the FDA website. This is the link, basically the homepage that identifies any and all things about UDI. It's a nice launch page – it's well done and gathers all the information. It includes links to these draft guidances in the final rule and also a number of other good resource documents.

Mark Bayer: When you receive or when the presentation is done and Joe puts this up on the website, those links will be live and you'll be able to click right on them and get to those documents that Gary is referring to.

Gary Saner: Okay, so on slide 11, this page summarizes what was released in the final rule. So what is the regulations that you as a manufacturer need to be aware of? So there's a couple of main areas and I've grouped these into three major topics. First has to do with labeling, there's another section that has to do with direct part marking, and the third has to do with this submitting the data to the FDA and getting information into the GUDID.

So as far as labeling is concerned, there's a unique device identifier that is identified in the final rule and it's a composite of two separate identifiers. One is a device ID, and that is static, refers to the labeler itself and a particular model and version, and then there's a second portion – the production ID. The production ID will capture information that is much more dynamic. It's information about a particular serial number, it's the lot number, might be an expiration date, manufacture date, and so on. But that production ID along with the device ID needs to appear on the label and also on the package.

So on the right there's a lower shot of the typical label that the FDA had put together, and down in the bottom right you see a barcode that includes both the device ID and the production ID concatenated together in this particular case. It can be actually presented separately. But when they do appear on the label, they need to appear both in plain text so you would be able to simply walk up and read these particular identifiers, and it also needs to be in the AIDC technology, so an automatic ID data capture technology such as a barcode. So this is very much familiar with…we're very much in tune with what you're currently using to track your products. Certainly, other technologies 2D barcodes, data matrix, other types of technologies such as RFID and so on, are able to be used to provide the AIDC requirement. Now, in the event that the AIDC is not visible, so instead of using a barcode **[00:15:03] maybe use** an RFID chip inside this package. There needs to be a disclosure on the label indicating that this particular item is identified with AIDC.

There was also a lot of discussion about the date format. At this point in time, the final rule came out and made it very clear that a four-digit year, two-digit month, and a two-digit day all need to be in place. The date needs to be included, and in the places where you identify a manufacturing date or an expiration date, that particular date format must be presented on the label itself. The date, if it appears on the label as an expiration date for example, then it also must appear in that production ID component in the UDI that we had just talked about.

One last topic on labeling – UDI does need to be applied to software that is **[00:16:07]** software that is considered a device, so in the event the software is shipped out as a package, a physical package, then there are certain UDI markings on the package carton as well as discussion about identifying this particular piece of software in the about page of that particular software. If it's a downloaded piece of software, then obviously the package is not there, the AIDC requirement is removed and the presentation for this particular case would simply be the UDI in the about page on that piece of software. So that kind of summarizes the labeling, and the timing of all of these items are based on the compliance dates that we had looked at in the previous screen. So implementing your date change, getting the UDI onto the label, if you're marketing software – the timing in that software, is all based on whether it's class III, class II or class I device.

Now let's talk about direct part marking. This is an area where the intent is to permanently mark on the device itself the UDI—includes both the device ID and the production ID—in the event that this particular product had been separated from the package and also the label. So the example there of a scalpel just being a multiple-use and reprocess device, most likely the label for this particular device **[00:17:55]** disappear and through the course of the reprocessing, sterilization and

so on, all that is gone. So, in this case, the UDI must be permanently marked on the device itself.

The last major area that you need to be concerned with to be complying to the federal reg is in the submission of the identifier to the FDA. Now, I will make an emphasis here that what is being submitted to the FDA is simply the first portion of that UDI. Remember we talked about the UDI being a two-component device ID plus a production ID? In this case, just the device ID and a number of attributes totaling about 55 need to be submitted to the FDA. This data eventually would be made public, certainly individuals, patients, clinicians, doctors, public, whatever, could all go in and pull this information down and find a very specific identifier for a drug. So this is the advantage, Mark, that we had talked about earlier, being able to quickly track what device **[00:19:12].** If you have an adverse event, you find that device right away with **[00:19:15] recalls** and so on. FDA is very much interested in making this a global model and being able obviously to link this to other devices **[00:19:24] that cross…**

Mark Bayer: And Gary, to that point, for those of you who may be familiar with the SPL activity that had been going on on the drug side when a pharmaceutical manufacturer submits their labeling information in structured product labeling format, which is an XML-based format, to the FDA and the FDA approves that label, that data goes into the DailyMed, which is a database that is run by the National Library of Medicine, and the concept will happen here also in the sense that the DailyMed is a public database of all the drugs available in the US for sale. In time, GUDID database will be the same but for devices.

Gary Saner: Okay, so we talk about some of the high-level areas of the final rule. These are some additional…

Mark Bayer: Gary, let me interrupt just for a sec. For those of you who may not be familiar, there has been a proposed rule out for quite a bit of time that the FDA published, and Gary maybe you can tell me when that was actually published, but the proposed rule has been out for quite a bit of time. There was then a…the final rule was supposed to be published on May the 7th and that got delayed, and finally on September 24th, the final rule was published. So there are some differences that exist between the final rule and the proposed rule. What Gary is going to do here is going to highlight some of the few, the key points from the final rule that you should know about. So Gary, take it away.

Gary Saner: Okay, just a quick note on those dates. The proposed rule came out on July 10 of 2012, and there was an amendment to that rule that came out in December 19 of 2012. Both now are supplanted by the…

Mark Bayer: By the September 24th final rule.

Gary Saner: Yeah. Yeah. So we're into the final rule at this point, Mark.

Mark Bayer: Okay.

Gary Saner: Alright, so here are some additional highlights, the second tier of information that you need to know. We've covered the first three major categories. These are some additional items. The final rule is relatively long, good 45 pages in the federal register, and I picked out, oh, I don't know, I think there's eight or so items here. And then there's some items that didn't make the cut and I put down in the appendix. We don't have time to go over those, but when you receive the presentation you'll be able to look at those and spend a little bit more time identifying the things that would affect you. So I'm going to just hit a couple of these, explore some of the areas in how the FDA was approaching this regulation.

So we need to talk a little bit about a device package in the structure of a particular device product. So one example, let's take the scenario where five scalpels are sent together, they're all identical, same model number, and we'll call that the base product. And the term "unit of use" would actually be a single scalpel in that case, so we have five single unit of use products all assembled together in the base product. And then, as you move up into higher packaging, that particular box of scalpels then could be into a larger case and maybe 10 cases put into a cart, and so on. But at each level, the point that is noteworthy here is that a unique device identifier needs to be applied at each packaging level all the way up to the shipping container. So if there's some logistic identifiers that are used to move the product out to the distribution house and eventually the end user, those do not need to be identified, but all the marketed levels that are able to be sent out to the marketplace will need to be identified.

Now, there are some exceptions. In the particular example that I gave, let's say instead of five scalpels being in a box, let's say there was 25 adhesive bandages. Okay, well, **that [00:23:57] actually fall into place here**. Let's see. It'll be a single-use device, there's multiple in a single package, in that case class I, and it's not an implant. So yeah, sure enough, that would be exempt. So what that would mean is that a UDI would be required on the device package, in this case the box holding the 25 adhesive bandages, but each individual adhesive bandage would not need to have UDI on its particular package or its device by itself.

So there are a number of these types of exceptions. One that was very much discussed early going on in the proposal phase was convenience kits and combination products. So in a convenient kit, now we have multiple products that are assembled together. The bottom line in this particular case is that the UDI

would need to be applied at the kit level but not at the individual component, and it's similar scenario for a combination product – a UDI would be required on the product itself but the actual constituent components would not need to have a UDI. If that is your case with combination products, you might want to read a little bit more. There are some special cases where NDCs are used for the drug portion of that combo product.

Now, there is also some information about inventory. So at the time of a compliance date, so let's we're a class III device one year out and it's now 2014 – it's time to meet all the rules, and you have an inventory that is already marked, it's a finished product – you have up to three years to keep that product and be able to move it through the logistics chain and supply chain out to the public. So you have a three-year grace period of moving inventory out. All new products would need to meet the compliance rules, and that is included for each particular class. A class II inventory has this three-year exception as well. In the event you have class III devices that you manufacture, there is a provision to request their approval. The pressure was very high, so I would not think this is a slam dunk.

The last two here have to do with some things about that manufacturing determines updates for the actual device itself, and basically the bottom line is if there's a new version or a new model number that the manufacturer applies, then that would dictate that a UDI needs to be submitted. There's another little noteworthy thing here that is important where a UDI must now start to be included in the medical device reporting for adverse events and in your facility annual report, so as you fill these particular documents out you'll see inclusion of the UDI. And we don't have time, Mark, to go further on that. [Laughs]

Mark Bayer: Right, right. We did put in the appendix when the document is available through Joe's website, you will be able to see the appendix. Gary has put at least another dozen points regarding the final rule in the appendix. We could probably take this hour and a whole other hour just going through all the detail. We received many questions. We will not be able to answer all of them now in real time. We will answer a few of them that seem to have the broadest applicability to the audience as a whole, and we will answer the others individually personally back to you or to the group as a whole.

So Gary, what I'd like to do is take those last two in red. So let me raise the first question. If a class III device is currently in clinical study, does it need to have the UDI implemented now or when it is publicly marketed?

Gary Saner: So that's a real quick and easy one. It's only when it's publicly marketed.

Mark Bayer: Okay, great. And then the next one is, regarding direct part marking, is a label on the part not enough? And this person asking the question says, "My device is reusable but doesn't require sterilization."

Gary Saner: Alright, so this is a topic that was kicked around quite a bit. The direct part marking intent is to handle those scenarios where a product is reused and is reprocessed, and the assumption is that it's separated now from its package and also it's labeled. So yes, you do need to permanently mark the device itself. And I'll just put a side note in here – the proposal had talked about being multiple use and sterile between each use, and that was changed in the final rule to be multiple use and reprocessed. So the FDA actually broadened the scope of the direct part marking over and above what was simply just a sterilization process. Now it's a very broad term – reprocess. So it looks like in this case the answer to the question is yes, you will need to put direct part marking on that. It is reusable, but I assume that it's reprocessed in between each use. So if you have further questions, you can go ahead and send them in. I know there's a number coming in right now but we're going to force your hand, Mark, and pick up some of these in the end.

Mark Bayer: Yeah, or as I said, we'll do it after the fact just because we won't have the time.

Gary Saner: Very good.

Mark Bayer: Okay, on page 13, just to remind those folks who want to send questions, that's the way to do it and it's obviously worked successfully. Okay, on page 14, there are a number of pieces to the overall UDI puzzle within a device manufacturing company, and Gary has laid out these at a high level, and so it gives us a high-level view of some of the challenges that implementation of UDI calls for.

Gary Saner: Sure. The UDI regulation touched on many departments and different data disciplines and domains about your business. To implement a UDI compliance, I would recommend that you take a set of people and set them aside and give them some direction and goals to put a UDI team together, governance for what is actually going to happen, understanding the regulations, and at some point in time there will be a touch point into the upper left area – a financial. There is some funding and budgeting that would certainly need to be considered for this activity. At the top, product design. We talked about changes to the label in the event that you need to put a direct part marking on the product itself. Certainly now we're talking about some redesign of the product.

And moving further around the circle there, on the right – manufacturing. So now we need to incorporate a revision to the label, and in the event that you're doing

any additional manufacturing, to apply that permanent marking on the product. That has to be planned, put in place, tested, and verified.

Production control – your master data management systems, your ERP systems and so on. This new identifier certainly is now on the label and a number of companies are considering about how to leverage this change in their enterprise and also get some efficiencies in being able to track product by using the UDI. So this would impact on your supply chain and your inventory management and your logistics area.

Then at the bottom, actually we'll spend a little bit more time on this particular area – the regulatory. This is a particular activity where you'll need to collect, in this case, the device identifier, just that first component, and pull all those attributes for the data and make some submission to the FDA. We've also heard that some companies are taking this to the next step of moving that UDI into their sales catalogues, publishing updated lists for order entry and so on, and taking that full circle not only from **[00:33:03] down at manufacture of** product but out to customer-phasing information that now the UDI would be able to be **[00:33:09] apparent** out to order entry and procurement.

We have a side note over here on the right that most likely the data that needs to be sent to the FDA is probably sitting in silos. You have this data tucked away in various labeling programs, other type of ERP systems, regulatory programs, and who knows, may have been sitting in some spreadsheets on regulatory desk or whatever. Part of this task is certainly very broad, but when it comes down to regulatory, that particular activity is collecting that data and making sure that it's correct and normalized.

And in some cases the data may not be electronic format. Let me give an example of that. Let's say it's a single use product and the icon for single use is actually on the labeling piece of software and is sitting in the template for that particular product. So there may not be a data value anywhere in your department that has the fact that this is a single use item and could be quickly exported and put into the data set for submission. So there needs to be some investigation going on to find the various values about the device, and in some cases you may need to do a little bit of investigation into the template for the label itself.

Now, upon your signup, you have the opportunity to participate in a survey, and this survey was a quick touch to see **how [00:34:59]** industry has learned of the UDI regulations, how they're getting along with it, and some of the other activities. So what I would like to do is just quickly summarize this because you had involvement in putting this together and would like to report back to you.

Mark Bayer: Right. Absolutely. We appreciate that many of you took the time to answer the questions, and we wanted to share that information. So Q1 was to estimate the total number of product SKUs you need to submit to the FDA for all classes, and this obviously is the measure of volume – how many records of information will you have to send to the FDA? And as you can see, a large percentage said they were uncertain or not applicable, but the largest percentage, 41%, had a smaller number – less than 100. So that was a very interesting response.

Gary Saner: Quick note on that Mark.

Mark Bayer: Sure.

Gary Saner: **[00:36:00] We have seen some things in the specs that says the marketing fact** that by the FDA's definition of small company, about 96% of all the devices are handled by small. So this is in concert with other data that we have seen.

Mark Bayer: Absolutely. This was confirming of that. The second question, "What classes does your organization manufacture (select all that apply)?" and as you can see , class II devices, and I'm sure everyone on this phone call is aware there are more class II devices than there are I or III. On the third question, "How far along are you in identifying, collecting and organizing the UDI data that you will need to submit to the FDA? a large number were uncertain, and as you can see, with the 26% who are planning to start and 37% who have not started, we hope this webinar is well-timed to help you learn about this so that you can start the process of getting the data together get submitted to the FDA.

And the last question, "What method would you prefer to use to submit your UDI data to the FDA?" most of you are still uncertain. There is the FDA's GUDID web tool—we'll get into these in more detail—service provider, purchase software, or use internally developed tool. And we will expand on question 4 in a few more slides. So Gary, if you're ready, pick up on 16.

Gary Saner: Okay. I'm going to move over to 16. And this is a graphical view of what I had talked about earlier looking at your enterprise and gather data for submission to the FDA. there's a number of sites, locations and formats that need to be pulled together in data collection, and then normalized, validated because of the FDA specs. Then, you do have two options at that point in time. One is to take that data and go to the FDA GUDID webinar base and enter that data, or for bulk records you can put that together in a package that the FDA defines as actually an XML-based package referred to as the structure product labeling. So this SPL package then contains the same set of data, and then that is transmitted to the FDA through the Electronic Submissions Gateway. Successful data that has passed all validation is now sitting in the GUDID, and submitters of SPL then will get

acknowledgement back confirming that the data had made it to the FDA and had all arrived safe and sound.

This slide pretty much captures some of the things that I just talked about. I think for time we'll move on. The various steps here, 1 through 6, are things that we had covered. You need to look at your data situation to determine the best method, collect the data, and in the event that you are doing manual entry use the tool in automated entry for the SPL. And this is an ongoing activity. This is probably the one takeaway that you want to be aware of from this slide, is that you'll need to submit changes and revisions over the course of time so that it's a dynamic item that needs to be maintained.

Mark Bayer: Absolutely, and once again, just to be sure, the manual entry means using the…the way we were positioning this slide, manual entry refers to using the FDA's GUDID tool, automated entry obviously, particularly for larger volumes, will make more sense to be in some automated fashion, and we'll get to this in greater detail.

Gary Saner :So Joe, I just want to mention that we had talked about a **[00:40:12] live poll** but we're going to skip over that for time reasons, and I think what we'll do then is keep on moving through. Slide 18 talks about the particular data values that are part of this data record, and there's a number in this particular list. We'll take a rather detailed look at the list, put together descriptions and pulled together the validations out of the documents, and we're looking for some additional information how to package this obviously in the SPL implementation document. But this data came from the Draft GUDID Guidance for Industry, there's a link down here so when you get the presentation you could go there and take a look at it or go to the UDI website, but basically this identifies the fields. There's a number of ID fields, so there's a primary device identifier, a secondary device identifier, a unit of use identifier, we have direct part marking – we have a DPM identifier, certainly everyone's going to have this **[00:41:29]** identifier. And so there's a number of categories here, we'll go through all the full list, but they are totaling about 55 and it's something that you do not want to take too lightly because it takes some time to assemble these together.

Mark Bayer: A point I'd like to make please, Gary, is that if you notice, the third column in this spreadsheet, partially hidden of course by the box saying GUDID Data Record, it deals with validation. One of the things that's important throughout all of this is you collect all the information, you put this into some form of organization be it a spreadsheet, a database, a file system, whatever, but that data needs to be validated. You need to know that that data is correct, it fits the FDA's business rules, etc. You don't want to submit data to the FDA which they kick back and

say the data is wrong. So we have been spending quite a bit of time making sure that we have all of the data captured given the fact that the final ruling, the final information is not yet out, but we have built associated with this validation rules to make sure that when the data goes through and goes into the system it will be validated. This helps the accuracy greatly, and there is a great need for that. So I just want to point out that this is a lot of that nitty-gritty IT type of detail work which pays dividends when you make submissions to the FDA, and you want to keep that in mind.

Gary Saner: Okay, let's move on then. Next page, page 19, is where we're at. This identifies one, two, three four submissions methods that you would be able to consider in getting data to the FDA. First item is this FDA GUDID tool, second one is outsourced service, software as a service, or a piece of software. I won't go into the details of these, certainly you can review them when we send out the presentation, but basically the first one in quick summary is you go to the tool, you're able to enter your data, there's obviously some transcription entry here, and for low-volume number of submissions this would probably be adequate. As you look at higher volumes, then the lower three are probably ones that you want to take a look at, see if it would fit your particular model.

In an outsourced service, you simply supply data to the outsourced service vendor. Here you're not incurring the admin and operations cost but there is obviously a service cost to have this work done by the provider. In the third model, software as a service, basically in this scenario you're renting a tool from a provider and you simply log on to that tool, perfect your work, and make submissions, build SPLs and so on, and submit them to the FDA. in the last scenario, the fourth scenario, is where you would have an internal piece of software in your system and you may have an ERP or product life cycle management system, something that has an upgrade to handle UDI. This would be an avenue where you could upgrade or build or buy a tool to create the SPLs and then submit those SPLs to the FDA.

Mark Bayer: I will make mention that the Electronic Submissions Gateway has two formats of data entry. One is the Web Trader, very much a single submission package where you point to it and submit on an individual basis. It has two models, is able to handle bulk volume, and you certainly want to steer your connection in that direction, in my opinion, so you can do bulk. But in this last scenario, you own the tool, you do all the upgrades, **[00:45:57] install,** validate, and so on, and then actually incur the admin and operations. For your information, we'll get into this now in the next couple of pages when we are more specific about Reed Technology's solutions available to help you. The outsourced service and the SaaS – the software is a service, are the two that we provide. The FDA's GUDID

is obviously provided by the FDA, and there are many players who do have UDI software, and so we are in the second and third lines of this chart, and now we'll get to describing those in a little more detail.

Gary Saner: Okay, slide 20 is simply the transition. Again, you're able to submit the questions. We're going to discuss now the Reed Tech GUDID solution, and as Mark had introduced, the ability to use this particular solution in both a SaaS and an outsourced model. So I'll quickly go over the data flow in this particular model.

Over on the left-hand side, the medical device manufacturer has data again in various locations and needs to be collected and pulled together. That data then, if we're doing this in bulk mode, obviously comes in. The files need to be received. In some cases there's an optional data prep activity going on in this case, where if there needs to be some preliminary data preparation of the documents, for example, we do have the ability to do label capture, label data capture, meaning data that's pulled off the actual template and put into a data set, so this is used as necessary to do any preliminary data processing.

For those data files that come in based on a pool data set **[00:48:13]** structured data value with all 55 fields in a record, that comes in to the load in aggregation process. Load in aggregation then, as a result of that, data values are pulled out of the files and put into the database, and in the event that data came in in two different silos, for example, a portion of the record may have come from a regulatory area and the matching data may have come from an ERP system or a product system, then aggregating and assembling those data values together, merging them together is what takes place. Once that data is now in the database, we are able to validate per the FDA business rules and report back any changes that need to be made. Updates can be sent back to the manufacturer, so updates can be made at the source, or that there's also a way to make edits and updates in this particular online user interface and maintain values going forward.

Mark Bayer: So the point to be made in the rectangle here that Gary's pointing to is that information can come to us, if you have a SKU, and as Gary mentioned there are roughly 55 fields of data that will comprise the UDI record that will go to the FDA, if you have that SKU and you have all 55 of those fields collected and organized for argument's sake in an Excel spreadsheet, you can send us that record in its entirety. If you have—I'm making this up—25 done at one point and 30 more coming three days later, and you want to send the 25 and then send the 30—not saying you have to by any means, this is your choice—we can accept the 25, then we can accept the 30, and then we'll aggregate them into the full 55-field data record. And then as we had mentioned just a second ago, validation is critical, so you make sure that all of that information is correct. And since you

will most likely be sending us not just one or two records but tens, hundreds or thousands of records, you can see where that validation becomes very important to make sure that the integrity of each of those records is what it should be.

Gary Saner: So talking a little bit further about validation, there are a number of controlled vocabularies that go into making sure that the data is of a particular list of values or in a particular format that the FDA has identified. So, independent to the data coming from the medical device manufacturer, there's also a link that we put in place and pulled data on a daily basis from industry databases. So, controlled vocabulary at the FDA, for example, would be updated, and as data comes in for your particular SKU, we check it against the list of values. So things like the unit of measure for temperature or the list of values for a particular data value can be confirmed that, sure enough, this is actually from the official controlled vocabulary, and in the event we alert you for updates or a transformation.

So once the data has been placed we're going to move to the next step, which is the right-hand side of this blue object, the building, the validating, the approving of the SPL message. So now that the data's in place, there's a specification that indicates how the data is packaged into an XML file, the various concept codes and other types of things that surround that particular file, and we approve that against the business rules and the schema that the FDA supplies. This SPL then gets a review by the manufacturer, and upon approval certainly can do bulk approvals and make this happen in a bulk fashion, but one to many SPLs then are packaged and sent through the Electronic Submissions Gateway **[00:52:49] as to** particular connection that I had talked about, to the FDA.

We know that there's three ACK messages that come back: The first acknowledgement indicates that it made it to the **FDA's [00:53:00],** second indicates it made it to the CDRH center, and the third is a disposition of that particular data set – is there validation errors, if so, which fields are in error, or on the other hand is everything passing validation and we get a successful acknowledgement and a posting on to the GUDID database.

Mark, I also wanted to mention before we have some further discussion about this that the intent here is that this is a global scenario, so over and above just the FDA, we want to look at the EU and the PMDA that Japan and…

Mark Bayer: Absolutely.

Gary Saner: …Brazil and Argentina are making…

Mark Bayer: Right.

Gary Saner: **[00:53:47]**

Mark Bayer: Once you've collected this information, it'll be a resources to be used with all the regulatory authorities as Gary is mentioning, so getting it right and getting in there, so that's where that first validation is very important because at least you're validating that your data is correct. The second validation is the validation that the SPL, which is an XML message, has been built correctly. So by that then you'll be in much better shape when the rest of the world says, "Hey, we need this information from you also." Your database will be in good shape it'll be clean, it'll be well-formatted, and it'll be relatively simple to take that information, build whatever the appropriate message is to the other regulatory authorities, and send that forward.

Also, if you notice in the upper right corner, you'll notice there's "manufacturer (SaaS)" in orange and "Reed Tech (outsourced)" in blue. This solution as you can see on the title is both a software as a service solution or an outsourced solution. The difference is very simple. If you choose, you as the manufacturer, if some of your people choose to drive, if you will, to go the last mile—and we'll get to that in a second—if you choose to drive and control the action via the Internet, that's the data that's coming in, kicking each of these functions along the way, submitting the information to the FDA, that's our software as service solution. If you want and have us do the entire driving, if you will, taking care of all of the information and all of the steps along the way—we're happy to do that for you—that's the outsourced solution.

And as you notice in the middle of the title, we call this "the last mile." We were at a couple of trade shows earlier within the past 60 days. One was the UDI conference in Baltimore and the other was the RAPS Conference up in Boston, and most people had been paying attention to what was going on in the left-hand oval, but really, and that's borne out by the pull that we showed you earlier, but people had not yet had time because they were concentrating on the left was the right and logical and most important thing to do. Now it's time, when you have your data collected as shown on the left, to take that last mile, meaning, "How do I get that data, which is now nicely organized, into the FDA?" That's the last mile we're referring to.

Joe Hage: Gary and Mark, this is Joe. Just because we're getting close on time, I'm going to send a link now to everyone on the call in case they have to run out. If your question didn't get answered, and there are dozens of questions that I'm sitting on here, or if you might need Reed Technology's help, I have a name there, Haley Lentz at hlentz, L-E-N-T-Z, @reedtech.com. You can email her now or after this call. I see that you have it there. But I suspect that we may go a little long. Please,

everyone, know that we are recording this. We are sending out slides. I will have the entire presentation transcribed. And if you are able to stay a little longer, boy, guys, I must have 30 or 40 questions piled up for you, which we clearly won't get to. Thank you for a great presentation. I'll go on mute.

Mark Bayer: Thanks. Thanks, Joe. We have one more slide, that's the slide that Gary is showing now, and then we will take a few of the questions. And to Joe's point, there are tons of questions, so we'll try to pick a few which seem to have the broadest applicability. So Gary, if you would just finish up on page 22.

Gary Saner: Mark, I believe this was your slide. I'd be glad to do it but I think you were going to do that. [Laughs]

Mark Bayer: Oh, I was going to do this slide? Okay. You can see that we didn't choreograph the last slide very well. Anyway, the benefits that we see if you were to work with Reed Tech in taking that last mile, getting your content ready to go and get it submitted to the FDA, it's very straightforward. It's a simple approach. You don't have to change much, if anything, of your current processes. It's non-intrusive. You don't have to change systems, install software, anything along that line, either initially or for ongoing maintenance. It is cost-effective. You're not going to have to be buying any hardware or software, and going through the normal installation/validation/maintenance challenges and costs that that entail. As we mentioned earlier, we have a world of experience in SPL preparation and ESG submission, and we look forward to bringing that to bear to help you all in taking that last mile, and we have been in business a long time and we do know this whole business of content creation/life cycle management/submission to the FDA very well.

So with that, thank you for your time. We know it's 2 o'clock and there are a lot of people who probably are going to 2 o'clock meetings. We're going to hang in here a little longer and we are going to…give us just a quick second to pick a few of the questions, which as Joe said there are a lot, and we will answer those questions now.

Joe Hage: Mark, let me first start by saying, you know, as the guy behind the curtain I get to see all these comments coming in and you guys did a great job.

Mark Bayer: Well, thank you.

Gary Saner: Thank you very much!

Joe Hage: I'm getting lots of praise here. It's not me saying…well, actually it is me saying it, but there's a lot of people who are writing here who are really, really, pleased with the content you shared today.

Mark Bayer: Well, thank you, Joe, and most importantly thank you to all of you who attended. It's nice to have an audience and particularly a good audience. The questions indicate that you're a good audience. All the questions are really good. So thank you all for attending.

Joe Hage: The first question is mine. Is this stuff hard or is it just me?

Joe Hage: [Laughs] That's sort of a tough question. You know, there's a lot of detail associated with it, and one of the benefits that we bring to the party is that we pay attention and stay on top of all of the activities that are going on with the FDA. When they're making announcements, we know about it. We monitor their activities, we monitor industry activities, and in so doing, part of what makes this difficult is that there's just a lot of detail, and unless you're paying very close ongoing attention as a manufacturer, you might miss some of that detail.

One of the things we do as a routine, part of our service that we provide to our customers, is we do attend all of the appropriate meetings, webinars, telecons, etc., and from that we glean the information that we present to our customers. So if you recall back on slide 12, the final rule highlight, there is a ton of information that has come out recently, gleaning through that to find those things, the nuggets, if you will, is very important.

Joe Hage: Let me go ahead and ask Matthew's question. I'm sorry, I did cut you off, but I'm keeping in mind our time.

Mark Bayer: Okay. Sorry. Go ahead.

Joe Hage: Matthew **[01:01:53]** asks, "We manufacture devices that have multiple configurable options resulting in a large number of unique machine permutations sold under the same name. Each option does not affect the intended use, intended users, contraindications, etc. Is the current opinion that each of these will require their own UDI or a single UDI for the generic machine?"

Mark Bayer: Great question.

Gary Saner: I think in this particular case we need to evaluate what goes out to the marketplace and is it ordered, tracked, identified separately? And it looks like it is because of the multiple configuration options. So that's my clue, Joe, that this particular scenario would need a unique UDI for each of those configuration options.

Joe Hage: Man, **[01:02:49] Michael**, you've got a lot of work to do.

Mark Bayer: Yeah, yeah, right. Well, just to quickly add on to that point, Joe, there is the hierarchy. You can have a product, or a product line as this question implies, and you can have many SKUs underneath it for each of the options it can be delivered with, and how the market reads those, if there are separate products, in other words, they're ordered, "Give me the green, give me the red, give me the blue," each of those will be its own SKU."

Joe Hage: I suspect then I know the answer to Irene's question, which is, "If I have a primary, secondary and tertiary bit of packaging for a product and all of these packages have labels, do I have to place the UDI at the package and the label or can I just update the label and keep the package as it is?"

Gary Saner: So this is pretty clear in the final rule that the UDI must appear both on the device label and the package, and also applicable to each package level. So as you go up from the primary, secondary and onward, each of those package levels would need to have their independent UDI value.

Joe Hage: Okay. How and where will the expiration date for the product be covered and will these requirements apply to contract manufacturers?

Gary Saner: So for contract manufacturers looking at a particular expiration date, then I think what needs to be done here is that the expiration date of a particular lot and batch, that expiration date needs obviously to appear on the label itself, and therefore that needs to be applied in the date format that we talked about – year, year, year, month, month, day, day, and then there is a submission to the FDA that records this particular SKU, this particular device, during the time that it is on the market, and there is a value that is recorded as the end date, the termination of the marketing time. So that expiration date then is also packaged into the information that is sent to the public.

Now, let's review this just for a second. There's a date where the product starts to be presented on the market and is introduced to the market, and then there's another date when it is pulled off the market – basically it's retired or pulled, no longer marketed. So those marketing start dates and marketing end dates are the dates that are submitted to the FDA to keep the final rule up-to-date. The actual expiration of a particular device, let's say it's in a sterile package and it's only good for three months out, so that expiration date appears on the label but is not part of the database that are submitted to the FDA. Remember we talked about the two components – the device identifier which is really the device and the model being submitted to the FDA, then the production identifier which is just on the label would include the expiration of that particular batch or that lot or that

particular product. So I hope that answers it. I know we went around circles a little bit, but there's a difference between marketing start and end dates and expiration date of a particular lot.

Joe Hage: Thank you, Gary. **Deborah** asks, "Will extremely small implant devices such as brachytherapy seeds need a DPM?"

Gary Saner: Well, the good news for—I'm sorry, who was that that asked that?

Joe Hage: Deborah.

Gary Saner: Deborah? Very good. Well, the good news for Deborah is that implants fall into this broad exception for direct part marking, so she does not need to worry about it. There was a lot of concern, Joe, early on about very small products that would not be able to support a permanent marking. So, anyway, in the final rule, what the FDA elected to do was not include implants at all as to a direct part marking category.

Mark Bayer: And there was a lot of pushback, this guy was saying, by industry, and the FDA listened to that and made that decision not to demand direct part marking on implants.

Gary Saner: Mark, if I remember right, this was at one point in the UDI conversation the audience started clapping.

Mark Bayer: Absolutely.

Gary Saner: [Laughs] Jay Crowley said, "Okay, thank you very much." [Laughs]

Mark Bayer: Right. People **[01:08:09]** applauded when they heard that.

Gary Saner: It was great, and that's a big help to industry. So the intent here, by the way, is that electronic health records are now coming into play and the FDA is saying that a good electronic health record would be able to record the fact that you have a particular pacemaker installed and implanted in your body and you should be able to go back to that and identify the manufacturer and the other information. So it doesn't mean that the pacemaker is not devoid of the unique device identifier. It just means it doesn't have to be permanently marked with it. So hopefully it'll show up in your health record, Joe.

Joe Hage: Mark and Gary, just so you know how timely and relevant your content is, we are 10 minutes past the hour and a full two out of three people are still on the call.

Mark Bayer: We're happy to keep answering questions, Joe.

Joe Hage: Then I will ask it. Xavier asks, “Can you elaborate on the UDI requirements for downloadable software?”

Gary Saner: Yeah, so that was also a good topic of discussion. For downloadable software, obviously the AIDC marking—and there's no automatic way to track this. There is no barcode available to track this inventory or to identify this package. So the FDA has made provision for standalone software in this downloaded mode and indicated that you're able to satisfy the UDI requirements by putting the UDI either on a title page or on the about page, where you can find information and versions normally about a product. So that is the way it's handled. There are some other details in the final rule, but there is provision for that in the final rule and it looks it's going to be able to work by putting the content in the about page.

Joe Hage: William asks, “How does GUDID apply for integrated products? Are there any obligations on initial importers?”

Gary Saner: So there is regulations that…well, first of all, the FDA applies to the medical devices that are in interstate commerce inside the US. So if you as a foreign entity want to ship product to the US for sale, you'll need to make your product and apply UDI, an FDA identifier on your product and submit that information to the GUDID and have it in place and regulated by the FDA. So there's all kinds of regulations that would apply for foreign companies that perform business here in the US, and this now is another one that would be layered on top of that. So they would have to mark their product with the UDI on the label and in the package. If it's a direct part marking candidate, so they’ll need to put direct part marking on it. And in all cases, they will need to register and submit that device identifier to the GUDID.

Joe Hage: I suspect you will be hearing from **[01:11:52]** after this because they have a number of questions and we don’t have time for all of them, but a common theme between them is, “How much is this going to cost a small company?” I see that theme in a few questions.

Mark Bayer: We are just finishing up our pricing exercise, Joe, because the full complement of detail regarding what data fields need to be captured and waiting also for how the XML message is going to look when sent to the FDA, we're still waiting for some information to come from the FDA before we wrap things up. I guess this will sound salesy, so please forgive me. The whole concept of the outsourced service or the SaaS, the “software as a service” service that we will be providing is to make the pricing very reasonable so that you are not having to outlay any capital costs for software or hardware, anything along those lines, and on the other hand, you will get the benefit of our experience and our databasing and life cycle

content management that you would not necessarily get when you are working with the FDA's GUDID web tool. So the pricing will be reasonable and we will have that pricing finalized within the next couple of weeks, and we will make that available to everybody.

Joe Hage: I have to laugh. I'm looking in the comments. Cynthia wrote back, "It sounds hard to me too, Joe." And **[01:13:40] for** Matthew wrote back, "Ouch, put us in the 10,000 to 100,000 category based on your answer."

Mark Bayer: [Laughs] Well, one of the things I think people should understand is once the process, you know, collecting and organizing your content is important, but once you have that process down we're going to be able to take the volume and handle it very smoothly for you. So that's something that will be valuable so that that last mile, we will take—our intent is very simple – to take the pain out of that last mile. The collection of the data, we've spoken to a number of medical device manufacturers at the two trade shows that I mentioned earlier, and people are working very hard on collecting the data, and it was like, "Whoa, now what do I do with it?" And our whole business model is very simple – relieve that pain point.

Joe Hage: Mike asks, "What about devices that are multiple use but not reprocessed?"

Gary Saner: I'll have to think about that one. [Laughs] So if it's multiple use and not reprocessed – so I think he's asking about direct part marking, so the criteria there is multiple use and reprocessed. So multiple use without reprocessing technically is not a candidate for direct part marking. And there was some discussion, and I would like the FDA to become a little bit more comprehensive in their description of what reprocessing meant. I think industry what sterilization meant, and reprocessing is not nearly as clear and as concise. So does reprocessing simply mean wiping down with some kind of a cleansing cloth and now you're ready for the next patient? You know, it's that sort of thing that I wish the FDA would be a little bit more clear on. So Joe, I think on this particular one we better refer this question to the FDA and have them come out and start to put some examples or some implementation guidance in place about what does reprocessing really mean.

Joe Hage: We are now 20 minutes past the hour and we still have a full half of the people who joined us. Having said that, we should wind down. I'm going to ask maybe one or two more questions. Jill asks, "Does existing inventory have to be entered into GUDID?"

Gary Saner: Well, there is a three-year window. So at the time of compliance let's say these are class III finished good devices—so it does need to be a finished good with the

label in place and so on—they can be used for three years after the compliance date. So were talking about class III, so from September 2014, three years thereafter, you can still use your inventory. But three years and one day, if we take that discussion to the nth degree, you'll need to pull that product back and relabel it and put the UDI on it.

Joe Hage: **[01:17:11]** wants to know, "What are the requirements for devices already in the market and what is the responsibility for distributors and resellers?"

Gary Saner: So that's a good question. So now we have product already in the marketplace and the regulation as I understand it does not apply to those products, and so there is nothing that would dictate a recall of anything going to market or anything like that. So it's only on new manufactured goods and based on the various compliance dates, which is dictated by your class.

Mark Bayer: And then the inventory **[01:17:56] proviso.**

Gary Saner: Yeah, when you get the **[01:17:56]**

Mark Bayer: Right.

Gary Saner: Yeah. But any new manufacturing activities would need to **[01:18:03]** UDI.

Mark Bayer: Prospectively, yes. Has to go forward prospectively.

Gary Saner: Right.

Joe Hage: Cynthia asks, "What is **reprocessing [01:18:08]?** All we do is clear the **[01:18:11] logs**, wipe it down, and send it to a different user. It's a home use device. The FDA site doesn't say."

Gary Saner: Yeah, again, this is related to the question that we kind of touched on earlier, Joe. The FDA was not extremely clear on what reprocessing meant, and I think over the course of time there will be more information in a public forum about what reprocessing actually is. It can certainly be as rigorous as a sterilization activity or going through an MRI type of sterilization – or not MRI, but some other type of heat sense of sterilization process. Or it can be much less rigorous than that. And I don't have the answer to that at this point in time, and I think the FDA is really just kind of flushing this out as to what reprocessing meant. I know it's very critical for a particular manufacturer trying to determine if their cleaning activity is considered a reprocessing because it has huge impact on the direct part marking requirement, but at this point in time I think they would need to go directly to the FDA and pose the question until we hear something more in a public forum.

Joe Hage: Alberto wants to know if an entry error on UDI would be equivalent to misbranding.

Gary Saner: [Laughs] I believe it does fall into that category. There is a section in the FDA ruling about incorrect data, and we don't have time to go into those details but I would maybe go to that website and read. It's found near the end about incorrect data and manufacturer's response to that data. So, quickly, in a nutshell, if the FDA becomes aware of incorrect or data that they're concerned about, they have a provision to contact the manufacturer and the ruling indicates a 10-day response period that is set up for the manufacturer to explain the data or to correct the data, and then the FDA has the option to pull the data off the site if they still believe it's incorrect.

Mark Bayer: And that gets back, and I don't mean to be beating a dead horse, but that gets back to the whole validation issue we discussed a little earlier. Catching those errors beforehand, before they get to the FDA, is a critical activity. And so if you recall on the page—give me one quick moment. Bear with us please.

Gary Saner: This one?

Mark Bayer: Yes. [Laughs]

Gary Saner: Twenty-one.

Mark Bayer: Twenty-one, thank you. If you note on page 21, you have two validation steps that are going on, and they're built in there for one simple reason and it's just Alberto's question, and that is if you can in any way prevent bad data from going through the FDA's front door, you're doing yourself a great service. So the first validation is validating the content before we even put it into our database. And then, the second validation goes through again and validates that the SPL, that the XML, is correctly formed.

Building XML documents is not as straightforward to all of us as, say, developing a Word document would be, and so each of those two steps are there purposely to reduce any chance of error. There will clearly be some errors that are going to get through, and obviously if there is error in content, someone puts down a 7 when it should be an 8, that's going to be tough to be caught if it's a content error. But the whole idea is catch those errors before they get to the FDA.

Joe Hage: Don asks, "Where can a company obtain the requirements or 55 field data required to be submitted to GUDID?"

Gary Saner: So Joe, there is a link on the FDA UDI website and you want to look for the link that goes to the GUDID Guidance for Industry.

Joe Hage: Gary, if you have that link or someone on your team there has it, you can share it the audience in the chat box.

Gary Saner: Okay.

Mark Bayer: Hold on, Gary's getting it.

Joe Hage: Okay. I see you have it in the presentation. We're good.

Mark Bayer: Right. So that is not the actual link. I mean, it's a live link but it's not the actual URL characters. Can we get that quickly and throw it into the chat box?

Joe Hage: Either that or you can add it to the presentation before I upload it to slideshare.

Gary Saner: I think that'd be the better…

Mark Bayer: That'd be the easiest way, yeah.

Joe Hage: Sean asks, "Do we need to submit UDI when submitting product complaints, 3500A medical device reporting? If I use Reed Tech, how easy is it for me to get UDI information from Reed Tech?"

Gary Saner: So that is one of the provisions down in the lower sections of the final rule that adverse event reporting, your individual case safety reports and so on, the 3500A – we'll need to have a UDI entry. So in the event that you're using Reed Tech for this service, we would be able to report back out the UDIs for your products and being able to provide updates back to you. So I want to go down to…

Mark Bayer: Good old page 22 again. Twenty-one. Twenty-one.

Gary Saner: Twenty-one.

Mark Bayer: And point that out, Gary.

Gary Saner: So over on the left-hand side there's an update link where our databases are synchronizing data back at the medical device manufacturer, so as things are sent to us and make the roundtrip through the FDA and now approved, we would give a status back to the medical device manufacturer indicating that this UDI is now accepted and in place at the FDA and therefore it could be a candidate for these other initiatives. So if you have a facility annual report, for example, there'll be a prompt for UDI or a field for the UDI. In the same regard, your MDR, your medical device reporting, will be prompted for UDI value.

Mark Bayer: And let me just add to that, Joe, and that is the question I think it was Sean asked, you know, how easily you can get the UDI information from Reed Tech – very easily. The information that is here in this UDI database is obviously the

manufacturer's information, and the manufacturer right through the Internet will be able to tap into all of this information. This little icon sitting up here basically says you have access to all of this. So the information, you could just tap in, get that information, import it into the application that is being described or any application you need, or as Gary was saying, or and/or, you have the update that will be coming through.

We could also create some vehicle that automatically updates information for you in a customized way. Clearly, there will be some customize cost associated with it, but if there is certain information that a manufacturer needs on a regular basis for certain downstream use or other forms of processing, we could discuss that and figure out a way to make that simple and available to you. But the most important thing is this icon here can touch all of the data and get to the information themselves.

Joe Hage: We have a question from a gentleman whose name I cannot pronounce. I apologize, Mr. **[01:27:01] Okafor**. Or Ms., sorry. "What would be the mode of required direct part marking for something like a fiber optic light cable for a surgical retractor? Engraving? Laser etching?"

Gary Saner: I don't know **that we would [01:27:23]** that particular mechanical **[01:27:27]…**

Mark Bayer: We're not experts in that area, but we are data experts and content experts, but we're not manufacturing experts.

Gary Saner: So there are a couple of comments I'll throw out there. One is, as you start to look at the laser etching, there's items that you can actually machine into the product itself, there's possibility of **[01:27:54]**, there's a number of technologies that are available to permanently mark a product. And I don't know which would be best for that particular scenario. I have heard some discussion about obviously you want to look at the material and the durability, and in some cases, Joe, believe it or not, there's impact to your effectiveness test and the stability test and other types of test that you might have in place for that particular product. So if it's a very small, lightweight, thin-walled material and you start to do some mechanical modifications to that wall of the product, now you need to consider the strength – is there anything that would affect the durability of that product? And in worst cases that something happens and it's so drastic that you have to do some additional studies and clinical studies to make sure that the effectiveness has not been, or even that safety has not been detracted. So that's obviously **[01:29:06]** in the far end of the scale, but doing direct part marking with some of the small parts is very difficult and I think you need to take a serious look at the impact of making those changes.

Joe Hage: Can you include the UL, FCC and other agency approvals on the UDI label or does it need to be separate?

Gary Saner: I'm sorry, I missed the first half of that. Could you repeat that?

Joe Hage: Can you include the UL, FCC and other agency approvals on the label or do they need to be separate?

Gary Saner: No, they are able to be included. So if you **[01:29:44]** the UL and other…there's **[01:29:47]** and other type of…CE marks and so on, as long as the product meets those and meets the regulations for those certifications, there's no change in the UDI regulation that would affect those type of presentations.

Mark Bayer: Let me elaborate on that just a bit, Joe, or maybe extrapolate would be the better term. So let's say that 55 turns out to be the number of data fields that the FDA wants in every UDI record. If that's the case, different manufacturers might say, "Hey, if I'm going through all of this time and effort to pull all this information together, this may be the first time that such a comprehensive database is being developed by the manufacturer for all their products, particularly if they have multiple business units and divisions. You might, if you're a manufacturer, say, "You know, if I could collect an additional 10 fields on top of the base 55 that are going to go to the FDA because that would help me in subsequent management of my product lines," and any of the other many business reasons that you might want to augment those 55 fields, we can handle that for you. So what that would mean is that we would instead of be developing a 55-field record, we could develop—and remember, this is all I'm making up these numbers—we could develop a 65-field record which are customed to that particular manufacturer, which can help them manage other parts of their business that could be very valuable, and that information then can be put in the database and that database can be residents on our facilities, which is totally secure. We've been audited dozens of times by the pharma companies and we meet very stringent, secure practices, plus our ISO certification.

So if you want, we can put instead of just 55 fields here, we could put 65 fields. If you want us to host all of your content so that you do not have to even replicate it at your own facilities, we can do that for you. If you want us to be passing all the content back so that you can be refreshing your own master data management or other systems, we can do that for you also. The key is it's as flexible as you want it to be to meet the needs that you have in mind and have need for.

Joe Hage: Gary, I know that you're planning to be at the 10X event in May and I'd be glad to shake your hand at that time, I'd seriously consider having you do a workshop the day before based on the caliber and quantity of these questions. So give that some

thought. We are a half-hour past now. We still have a lot of people on the call. I think we should wrap it up. There will be a chance to take all these other questions and maybe you can answer them offline, and I can post them on the site as well because these are still great, great questions.

And I'll conclude with what Susan said a half-hour ago. She said, "I have to agree, this is the best and most informative webinar I have attended in some time!"

Mark Bayer: Well, thank you very much. It's been our pleasure, and speakers always enjoy an audience and hopefully the audience enjoys the speakers. We will provide this information to Joe. He will put it up. It has been a pleasure working with Joe. This is the first time we've done so. I'm sure we will do it again. And he will put stuff up on his website and we will put more information up on our website and try to make sure we answer all the questions we received.

Joe Hage: Folks, also I've invited Gary to join my Medical Devices Group Advisory Board. His information will be up there shortly, and that'll be another way that you can get in touch with him. You also have Haley's email address, which is hlentz, L-E-N-T-Z, @reedtech.com.

For Mark and Gary and me, I am very, very pleased that you joined us today. We will send out a link that will give you access to the replay, the slides, the transcript, and the additional questions. Thank you, gentlemen, very much, and thank you all for joining us from all over the world.