How to Complete UDI Compliance by September 2016

Presenter: Gary Saner – Senior Manager, Information Solutions – Reed Tech

In collaboration with Joe Hage and the LinkedIn Medical Devices Group

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Joe Hage: Hi this is Joe Hage. I have the privilege of leading your Medical Devices Group which as of this recording has 317,000 members worldwide. And for those of you who have attended one of our UDI webinars, you will know the next part where I give credit to our growth partially to Mr. Gary Saner. This is our 8th webinar on this topic because of the number of questions and the demand for this topic.

Class 2 devices need to be UDI-compliant in 76 business days.

Then put your hands together, Mr. Gary Saner.

Gary Saner: Well thanks Joe. That's quite the introduction and we'll do our best to cover some topics this morning or this afternoon as you may be in different time zones and then we'll see about how we can take this period of time and learn how to go through the requirements and have everyone in compliance by the 24th of September.

So what we'll do is walk through some slides today. I will mention right up front that there'll be some homework slides meaning they're there for your reference and you can look at them a little bit more detail later on. Joe makes these presentations available through his website and that way we can concentrate on some of the high level critical things that need to be done and have suitable amount of time for question and answer at the end.

So I'm going to start to advance the slides. First slide here that you see is entitled "Help! How Can I Complete UDI by September?" and that's the topic that we want to try to address today.

So Joe are you able to confirm that we're on slide 2 now in the agenda?

Joe Hage: You are confirmed.

Gary Saner: Okay. So there's a couple of things that we need to cover in the beginning just to set the groundwork. We'll take a very quick recap of what the regulation says about various classes. Then we will spend the majority of the presentation on the various steps to walk through for you to complete your compliance by September. We'll reserve a little bit of time just to talk about our solution here at Reed Tech and how you may want to consider that to help meet the compliance deadline and then the balance of the time will be Q&A where Joe and I will interact and put those Q&A questions out for us to talk about.

So let's get rolling.

If you're in attendance, you're probably aware of the FDA UDI Regulation published in September 24, 2013 and just to recap, there's a couple major sections of that particular regulation. First one has to do with the actual label itself.

So this has to do with product identification and the FDA created an object called a UDI and we'll talk about that throughout this session. That's the Unique Device Identifier for the particular product composed of two components. A device identifier and a production identifier.

The device identifier actually identifies the labeler, the company and also the product down to the version level. And then as appropriate, the production identifier's added on. So that includes serial numbers, batch numbers, expiration dates and so on.

But the basic takeaway here is that UDI needs to appear on the device label and also in packaging in two different formats. A human-readable format and also what is typically flashing out to a barcode format referred to as Automatic ID and Data Capture (AIDC) type of format. And then the filer will also address the dates that appear on the label as shown on the screen there. YYYY-MM-DD.

There is a subsection of products that are used multiple times. So for single use, you obviously have to put that label in place that we just talked about but for those products that are used multiple times and reprocessed between patients, there are some additional levels of identification referred to as Direct Marking that the FDA wants to have you apply to your product.

The second major area, technically the third one here on the screen has to do with reporting this device identifier, this product identification to the FDA. They are keeping a database with this information as well as the number of attributes and we'll spend some time talking about that particular process and don't forget there is another tenet here of this particular regulation referred to as reporting and this particular section covers various places where UDI shows up.

In your annual reports, your design history records, complaints, your medical device reporting, any recalls that may be involved and tracking and so on.

So as a particular class of your inventory has UDI on it, then you'll need to include that in your reporting.

So what is the impact on industry?

So those particular rules and guidelines from the regulation will affect your labeling system, something brand new GUDID submission and the documentation.

The first and last labeling systems and documentation, you already have those in place and UDI will cause a modification to those where you'll need to make accommodations for UDI to be included in a label for example or reference in your quality management system or your stand operating procedures or so on. But the middle one is new and has not been required previously.

So pulling that data together and submitting it to the FDA, reporting it to the FDA is something that we want to talk about. The graphic that's up on the screen shows data on the left hand side inside your system and then the top leg with data flowing through a labeling system is what needs to be modified to include UDI and there's various utilities that you have in place and systems that you use for that. We'll talk more about the requirements for that labeling system as we go forward.

And then the second data flow, that leg that shows data flowing through a GUDID submission system to the FDA and then ultimately to the National Institute of Health, the National Library of Medicine puts up a website called AccessGUDID where your data records are made public.

So this is the critical slide concerning timing. Up to now, Class 3 device manufacturers have submitted their data and made label changes back in the September 2014 and those implants, life-supporting and life-sustaining labelers completed their work in 2015.

Right now, we're only four months out and actually 76 working days until those Class 2 manufacturers in the audience need to update their labels and also include a data submission to the FDA. And what that means because of that short timeframe, there's a sense of urgency that you'll have to act on. There will be some limits to the options that you have available at this point in time. Some of those solutions may be long-term in setting up and establishing, getting everything up and rolling and that would cause you to be late and pass the compliance deadline.

So there are some options and we'll highlight those ones that look like they're probably out of scope at this point in time as we go through the presentation today. It also may require that the

short timeframe may cause you to seek additional help, external help. Whereas if you had longer period of time, you might have been able to do this totally inside but now you may need to look to additional external help so that you can meet the compliance date and avoid any misbranding.

What we will do is walk through various steps for you to implement a UDI in a GUDID system. First one there is to get a plan together, do the preparation and then move into a preparation for the GUDID submission. Actually pull the data together for the GUDID and submit that data and then we'll talk about rolling into a maintenance, ongoing steady state process where you'd be submitting any changes and rolling products out the door with the new label design.

So as we walk through these steps, I've identified some subtopics that need to be covered in each step. In this particular one, the first one, UDI prep has four different sub-areas and we'll walk through those in the next few slides.

It's very critical that you include multiple departments and multiple team members. So it's very common that the regulatory would take lead in this team but you'll find that UDI permeates into many different areas of a company. Product design, manufacturing operations, around the circle there, regulatory quality, even sales and marketing and so on. And especially with the collapsed timeframe, you want to make sure that you do have representations from each of these departments so that you are not fazed with the "oh by the way, a few weeks to go before the deadline" and then realize that there's a major hiccup.

So include various representatives from these areas inside your company and it'll help spread the workload around as well.

Part of your investigation for that team will be to learn the basics, find out what is required for your particular product, you want to identify your classes and your product codes and so on. I highlighted a couple links here that you might want to go to. These are good introductory links and at the bottom, because of the timeframe, I strongly recommend that as you start to feel overwhelmed that you quickly refer to industry associations. There's a number of online information and education available. You may want to consider consultants in connecting with the vendors. Those people that have done this for the last two years are great resource for you to pose questions to and rather than figuring out all this on your own, which is going to extend your implementation time. I would highly suggest you talk to someone that has walked through this already.

So after you figure out these requirements for your inventory, next would be to evaluate where you are. So this is kind of we refer to as the gap analysis. Look at where your data is residing. Are you currently identifying it in one of the FDA approved agency? Like a GS1, HIBCC or ICCBBA standard?

If you are, that's great. If not, you need to contact one of those three and set-up an account and start understanding their protocol for numbering. Look at the various processes that you have in place and what systems that you have in place. Are they going to be compliant and able to handle UDI?

There are some external parties that do gap analysis to help you move along and there will be various comments like that as we work our way through the system today or through our presentation today where if you're overwhelmed, low on staff, need to accelerate, we'll try to give places where you can kind of collapse this and spread the work.

And then this final step in the preparation would be to give that particular standard in place so if you are currently not using GS1 or HIBCC for example, you'll need to map your identifiers over to that new standard and make those process changes. So keep your quality management system up-to-date.

And then secondly, as the final step in this preparation is to revise the actual label itself. So some companies I will mention here have taken this event to say, "Let's go across the board. Let's update our labeling system. And then we're thinking of doing this anyway. Now is the time."

Well, four months out from your compliance date, I would suggest that maybe this is not the time to make such a drastic major system change.

So one of your options here is to modify your current system in place and being able to talk to someone that is experienced in getting UDI onto your labels. It just complicates matters if you bring a brand new major system at this point in time. Not to say that it cannot be done, you want to realize that you have time barrier here and limited resources. And not only your labeling system but all your other production supporting systems.

So your ERP, your master data management system, the supply chain activities are all of these able to support the new UDI and just think about that new product identification on your product as it goes out the door. Who sees it? What systems do they have to read it? And think about able to have that identifier all the way down to the end-user.

So the next major step that we'll talk about is looking at the GUDID system and doing preparation for that particular system.

Joe Hage: Hey Gary?

Gary Saner: Sure.

Joe Hage: Since we scheduled this to be 90 minutes, I thought maybe I'd interrupt you here and ask some of the questions that have been asked already. Do you think that will work or do you think we should wait 'til the end?

Gary Saner: I think it'll be good to do some interaction. We'll just keep in mind the total time. **[Inaudible 00:16:42]** Let's go ahead.

Joe Hage: The company realizes it has not published one or several products by mistake, what's going to happen?

Gary Saner: Well, **[inaudible 00:17:02]** calls this scenario a misbranding. So they are extremely cautious. **[Inaudible 00:17:12]** as soon as possible. **[Inaudible 00:17:18]** that the FDA has **[Inaudible 00:17:29]** and getting started. I think **[inaudible 00:17:38]** some type of plan to get that in place in the event the FDA does come onsite and wants to know what's happening and why these products are not identified.

Joe Hage: There's multiple power cord adaptors and powered warming mattress that can be purchased separately or together, do each of the components need a separate UDI?

Gary Saner: So the FDA has addressed this particular scenario. **[Inaudible 00:18:24]** then the system needs to have a UDI and all the components fit into that category. From what you read it was marketed on their own. And that requires that those individual components had their own UDI separate from the system UDI.

Joe Hage: Okay. **[Inaudible 00:18:57]** of time with a similar question. She asked, if a kit contains three different **[Inaudible 00:19:06]** is exempt, it is submitted with the direct marking exempt selected?

Gary Saner: So I think what we have seen the FDA take the most cautious, the most extreme high risk component. So **[Inaudible 00:19:36]** yes. Another scenario where a kit might have let's say one product that needs sterilization. So the FDA again would use that rule of thumb and say take the worst case component and report the system level kit at the extreme level.

Joe Hage: Okay. So perhaps we should go back to our regularly scheduled program.

Gary Saner: This step that we're about to talk about here Joe has to do with preparing the GUDID submission system. We have established two major avenues to report data into this global unique device identifier. The first one has to do with manual entry so the FDA has website referred to as the GUDID web interface where you can go and like key in your data. Obviously **[inaudible 00:21:04].** The other option is submit the data electronically. And that particular protocol that is XML-based, and used by the FDA for other beta product information and submissions to the agency. So they have leveraged that particular standard **[inaudible**

00:21:36] and the very same data put it into this particular document and send it to the FDA electronically through the Electronic Submission Gateway.

This next slide details those two major areas into some **[inaudible 00:21:58]**. The first one across the top is the GUDID web interface manual entry. The SPL as well as the third and fourth avenue. Second one has to do with making use of a hosted piece of software that a labeler could transfer data to and have that piece of software manage and store electronically. Various rights for editing and so on and then into **[inaudible 00:22:45]** talked about. The third option available also uses SPL but in this particular model, you're able to submit your structured data that you have collected for all these scenarios and send that off to an outsource service and say, I don't have the time energy, effort at this point in time to take care of that. I would prefer that you handle that.

So this service model where that data is handed over to a third party and they would be able to build the SPL and submit for you.

The last one that would be viable except for this timeframe in my opinion would be to build your own solution and put it inside your environment or you may go out and purchase a piece of software, have it installed, do the installation, do the IQ, OQ, PQ validation on it and so on and do the training. **[Inaudible 00:23:55]** at this point in time. Use that obviously. It's going to be extremely difficult.

I would highly recommend that you pay submitting implants, life-sustaining, life-supporting and pick a solution that already has a proven track record rather than embarking on something brand new.

We will chart in detail but you can go back as homework and take a look at some of these characteristics for those various solutions. The four rows identify the FDA GUDID web interface. The hosted version on premises and again the note there the on-premise installed software. Software systems are able to be feared as far as pricing and capability goes. So I'll just give an example from our particular solution where we offer the hosted software and the outsource. And some of our clients only have a single record. So it's able to do small to large volume submissions.

Okay. So you can go back and take a look at those in more detail.

Joe Hage: Each of you try to click on them at the same time. I might have crashed my system so **[inaudible 00:26:17]** a little bit but I know this is a common request and perhaps it will answer some of the questions you'd otherwise ask.

Gary Saner: The slide that we have in front of us now goes through some of the characteristics that you want to evaluate as you pick a solution. Only in that timeframe the expertise **[inaudible 00:26:41]** our various modes of submission. If you're using electronic submission, are they able to **[inaudible 00:27:02].** There is an FDA requirement for **[inaudible 00:27:11]** connectivity to your internal systems to share data and make sure that data's synchronized between some legacy data that you have and new UDI systems. We're not going to talk too much today about the international roadmap but keep in mind that being able to scale up and also go **[inaudible 00:27:42].** And then again because **[inaudible 00:27:54]** timeframe to get information systems targeted and start to work on that. Then the next major step would be to create your FDA accounts.

So all labelers that are submitting data would need to create an FDA GUDID account and you need to submit information about your company and the FDA would respond with credentials. You're able to go in and start writing in a draft note and then also submit data. Those labelers that **[inaudible 00:28:52]** includes another step of putting a test together for the pre-production submission and then create again, with the **[inaudible 00:29:09]** some vendors will, you're going electronic or even the FDA account. Some vendors will be able to support you and guide you **[inaudible 00:29:22]**.

For example, we've done what I think as of today a hundred forty or so of these account setups. So we're well experienced and can help you answer and work your way through setting up accounts. And **[inaudible 00:29:48].** You want to look to **[inaudible 00:30:10].**

Joe we're at another break spot before **[inaudible 00:30:18].**

Joe Hage: As for questions have gotten away from us. We have dozens.

Gary Saner: Okay. Very good. So I'm going to move into the data set that needs to be submitted to the FDA. There is some common fields, off the top of my head, I believe it's 12 fields that are shared with the labeling system. So obviously the catalog number, the description, the device identifier and other bits of information are able to be shared on both the label and the submitted data set. But there's a whole host of other data and you'll find this data scattered about the enterprise. It could be in multiple file formats. It could be in various locations. It could even be in a spreadsheet of someone that has left the company.

So finding some of this is a little bit of a daunting task and good reason to start early and to start to carry out some of these areas, these particular data fields that are tough to come by or you don't have readily available. The other consideration is to make sure that you have access to some of the agencies that the FDA has pointed to for product identification. The Global Medical Device Nomenclature, the GMDN needs to be identified or using the FDA alternative is

something new called the Dunn and Bradstreet D-U-N-S number for company which you may **[inaudible 00:32:10].**

What I'll mention here on this slide is we talked about these task of finding data and you might find that some of the data does not actually appear in electronic form. So an example of such would be a single use icon on your label that appears and goes out with the product but it's not electronically held as a digital value that you can use a Boolean true or false and submit it to the FDA.

So there's some other considerations as you work your way through collecting this data. The last item on this slide talks about collecting some additional data fields. You might want to do that just for ownership but I probably would not recommend collecting your international regulatory data at this point in time. There's some time that you want to take in the future to do that but now is probably not the best time.

For your reference, this slide identifies those 55 fields and the 7 additional that the FDA derives from these fields for a grand total of 62 on the database and we here at Reed Tech offer a data template. So whether you use ours or another one, I would highly recommend starting to put this data together in a structured format. Many of these templates and guides allow you to have the FDA regulation guidance available. So it helps you identify what particular value and the format of that value needs to be recorded.

I'm going to leave this for a homework slide where we have found over the 2 ½ years of doing this that a number of collection issues occur. This is put together from things that we have seen. Those also include some items that the FDA has identified and shared with industry about their data collection and getting the data in place such that it meets all the validation issues that the FDA has.

We're going to move over to another step of this data processing where after you've collected the data, there's something called data normalization and validation and what do I mean by that?

Normalize the data means to make sure that it fits the FDA's business rules. So one thing to check for example is if you're using GS1 to make sure that you have 14 numerical characters. 14 digits. And you have proper dates. There's list of values that need to be observed.

For example, you might have centimeter spelled out in your database and used in various places and yet the FDA only accommodates the CM with that particular submission. And there's other examples here but the bottomline is trying to make sure your data is pristine is absolutely valuable because you don't waste time making multiple submissions to the FDA and getting feedback if your system that you have for GUDID submission is able to do a pre-check against

the FDA's business rules, you greatly collapsed the iterations that you need to do and some advanced systems are able to help you along this data transformation, normalization and validation.

Here's some more examples again, I'm going to leave this for homework and the next two slides go into very specific examples that we have seen that cause a particular record not to be accepted by the FDA.

So again, homework. Homework.

Now, next thing we'll do then is to submit the data. So we have put together a submission process for the FDA GUDID and we have collected the data and now we're ready to submit. So we're working our way across left to right on this workflow where at this point in time, we're ready to use the submission's particular method that we picked whether it's the FDA GUDID web interface or using the electronic SPL.

Here's some detailed steps on how that is actually done. There's a web interface user manual available so you could work your way through that and make data submissions through that. For the SPL which lends itself to an automated electronic more accurate type of submission, there's some steps there that you would walk through to build that SPL file and again, your solution should be doing that in the background and then sending that to the FDA which also accommodates bulk entry for multiple records that need to be submitted.

It is important as this verifies that the data actually did make it to the FDA. So you want to make sure that records are showing up as published and there's a grace period that we'll talk about. FDA's allotting 30 days grace period where you can make some edits except for the published date field and after that period, then there's a number of data fields that become fixed.

Verifying that data to the FDA on SPL submission is a little bit different. There's a XML file called acknowledgement file that's returned from the FDA. So make sure that your system properly addresses those acknowledgements 1, 2 and 3. There's three separate events that are acknowledged by the FDA.

Again I'm going to leave this for homework. These are some lessons learned from submitting well over 140,000 records at this point in time and you might want to keep this in mind so that you don't fall into that trap and again delay your publication.

After the grace period has been completed, those records that you had submitted to the FDA are available on this website. This is a public website, AccessGUDID. There's 4-5 fields that are redacted out but otherwise it's the data that you submitted and is made available publicly so you can do some searches and find that data and actually you can poke around and see what

other companies in your particular sector have submitted and that is one of the final confirmations that your data has been actually published.

Now we're ready to move into production and maintenance. So up to this point, we talked about changing the labeling system. We talked about the GUDID system, the data in the submission. All that is a criteria before you actually ship products out the door.

So once the product **[inaudible 00:40:14]** GUDID submission, that's the legal time. You are now able to ship product that is properly marked with UDI on the label.

And you want to obviously coordinate this event. You can actually ship product families early in incremental once the submissions are made to the FDA. So there's no reason to wait 'til your full inventory has been identified as a GUDID before you cut over all your products so this can be a phase. One thing to keep in mind is the timeline for that compliance date.

And then systems that are very young dynamically changing environment, the FDA changes specs periodically. There will be some data maintenance and if you have some values that change, the FDA talks about keeping those records up-to-date. There's system maintenance and there's knowledge maintenance.

So as the FDA rolls out new regulations and guidance, you'll need to keep abreast with those and make changes accordingly.

This slide details some of those timing events for label changes. If the value is actually appearing on the label of the product, you'll need to report that to the FDA GUDID before you actually ship that change.

If there's a value let's say you added a supplement number to the product. That does not appear on the label. So you have 10 days where you can start shipping products early but within those 10 days then you'll need to report that supplement change to the FDA GUDID.

I'm not going to go into this slide but again it's a homework slide. Most important to pick up off this slide is the bottom right panel that list the various fields that become fixed.

So once a particular record passes through this lifecycle from unpublished to published in a grace period to then fully published, those 11 fields would cause you to create a brand new device identifier and the new record.

So the impact of that is significant where now your whole identification system needs to be updated for that particular product.

So getting these fields correct is one of the prime activities to make sure when you verify or validate your data as it will not be able to be changed and will cause a new record to be submitted.

I would normally talk more about the global impact of UDI and activities that would taking place but in this 4-month timeframe, we're just going to have to put that on the shelf. There is not much consideration just to know that there is strong and active efforts being made around the globe in various countries, regulatory agencies are moving forward with UDI and there will be implementation timelines for those agencies as well. But it's not in the next 4 months so we're going to put it on back on the shelf.

This slide summarizes those steps that we walked through and I wanted to also show how they might relay in a timeline. In this particular page, we showed the UDI plan that is early and then immediately launch any UDI labeling system preparation. In parallel, you'll need to start the GUDID system preparation and again, highly value those systems that are already in place and running. Make use of those rather than try to invent something from scratch and then while you're finalizing that system, you can start collecting data.

So that actually will take you significant amount of time. You see a lot of data prep issues and then squeeze in that GUDID submission near the end. I would target a couple weeks if possible before the compliance deadline so that as you have any delays or problems with particular products, you have a little bit of leeway and then as soon as that registration or reporting has been done at the FDA GUDID and your labeling system is ready, I would cut over to your production system with UDI labels and start shipping products out the door. That can actually occur as soon as your submission has been made to the FDA and your labels are updated. You don't have to wait for the 24th of September.

In fact, you obviously want to back off a little bit of that so you have again a little bit of leeway. Ideally you would not interrupt the production flow. There are a couple of challenges that are quickly highlight. We expect well over two times the number of submissions from last year and last time I did a count earlier this week I think there's still about 400,000 submissions that are expected to be added.

So I think it's going to get rather busy at the FDA competing with other companies that are asking for help from the FDA Helpdesk. There's certainly a lot more Class 2 manufacturers than in the previous waves. So there's more companies. In many cases they're smaller staffed. They don't have the background knowledge so there might be more questions as a result and Helpdesk I think is going to see a significant overload. We also saw the actual data submissions being acknowledged in much delayed fashion. So what used to be returned in 12 minutes took 3 days as we got into that final week in the last few days.

So all that to say start early, start now and submit as early as you're able to.

Joe I'm going to switch gears a little bit and just for those people in the audience that would like to evaluate a particular solution, go into a quick description of what we offer and then we're going to move over to Q&A.

Let me quickly talk about the FDA GUDID solution. This is our core expertise where we sit between the medical device manufacturer and the FDA and offer a outsource model as well as a software as a service model where data flows into that blue block and electronically flowing data in. We validate all that data through the FDA business rules, keep version control. We have rules available and then allow a process of approvals to take place, build the SPL and then automatically submit that to the FDA.

So some of those things that we talked about earlier a vendor having a template for you to work off of, guidance, helping you through questions, helping you through account setup, sharing electronic submission gateway resource. No need to use your own. And just working your way through this whole process. All those things are part of the offering that we supply.

Since we do tier this particular solution to the volume of submissions, I think you'll find that it's very cost-effective. Most importantly for this discussion today is that is saves time.

So within a week, you can have a very quick startup and use a well-oiled proven and compliant system. It's very easy to work with. It's not intrusive into your existing system and it's flexible with a couple of different models of implementation and basically we help you walk through this scenario and supply support.

The last thing I'll mention is because of the years that we've had working with submissions, we have that expertise available for you and again, I think I had mentioned about over 145,000 submitted records.

So this is a well-oiled and experienced solution that you can consider and we compared the number of volumes or the volume of submissions that we've made to the total GUDID. It looks roughly about 25% of all the submissions that the FDA has, has flowed through our system. So it's a very significant major provider of that data.

We work with well over 140 customers. Again, very small to large and be glad to talk more. We do make available a Reed Tech UDI Guide and this is able to guide you along the way. This would be a free download so you can follow up that particular link.

Joe, I think I'm at the end of this presentation as far as the prepared material and what we would like then to do is have you take a look at some of the questions and put those forward and let's take the remaining time to help the audience through the questions they have.

Joe Hage: I have to say I'm surprised. I didn't realize you have done 1 in 4 submissions to FDA?

Gary Saner: Yeah.

Joe Hage: That's shocking.

Gary Saner: Yeah. 25% of all the records that are there.

Joe Hage: Wow.

Gary Saner: So I think what that means is a lot of small companies make their one or two submissions but we have some very large clients that submit high volumes and …

Joe Hage: Yeah it's just too much to manage on your own. Okay well I have a lot of questions here for you.

So Vincent asks, some of our devices are really tiny. They are two milliliter vials of reagents. The labels are 1 inch by 1 inch and don't have space for much of anything especially not a barcode. How do other companies handle this issue?

Gary Saner: Yes so there is a question about the product being way too small for the label itself. Some companies have been very creative in attaching a label so if this is a single-use product, they might put it in a bag and then put the label in the bag or attach the label with some type of a plastic fastener.

If the product needs to be direct marked, meaning it's used after the original packaging is probably dropped by the weigh side and discarded, then you have another issue and that falls into the direct marking and I don't know if we want to go there right now but I'll just quickly say there is an exception for the direct marking if the product is too small or if it would affect the effectiveness or the safety of that product, it would not need to be on there.

So there's not a general exclusion that the FDA has for the product being too small although what we have seen is some companies would write that up in their design history file and then have that discussion available in the event the FDA questions them for that particular very very small product.

Joe Hage: Gabriel asks, how does all this affect distributers who sell private-label products?

Gary Saner: So yeah the FDA has now only addressed the suppliers to the marketplace. So if you are a labeler or even a re-labeler or a re-packager, you might be a contract manufacturer, all those categories the FDA considers labelers if you will and they have responsibility to label their products.

Now once you get into the supply chain, the FDA has not enforced records of this as of yet. There is some direction from the FDA that this is going to be coming so that you'll be able to track a particular device all the way through its logistics down to the eventual end-user and patient so you might go to a hospital and then physician uses it on patient X.

So that I think is coming. Right now the regulation only applies to identifying the product as it's released and commercially available into the marketplace.

Joe Hage: Okay and Matt I think this answers your question too what he just said. If our company reprocesses other company's medical devices, are we responsible for labeling even though we're not the OEM?

Gary Saner: Yes. In that case, if you reprocess the product, you would need to put your own label on that reprocessed product.

Joe Hage: Sorry Matt. It won't work for you.

We had a couple of questions about dates. Is the day needed in the date or can we just say year-month?

Gary Saner: When there is a date that appears on the label and I'm going to try to back up to that slide, the day is required so if you have an expiration date that is showing on the label itself, you will need to include that date.

Now many companies had not really tracked that in the past so they are using the last date of the month as a default. There is a little bit of a discussion and I don't know if Matt is trying to ask about expressing the date in a particular format inside UDI.

Joe Hage: It was David and he actually said YYYY-MM.

Gary Saner: Yes. Right. So David may be referring to the year-year-month-month that is inside the GS1 protocol for expressing the date. Pressing a little bit of a contradiction where if the date appears as a standalone item what they call pretext out on the label, expiration of a certain date then that needs to include the day.

When you embed that expiration date in the value of the barcode and you make use of let's say the GS1 protocol does not include the date.

So **[inaudible 00:57:06]** if you still have a question. There is that what appears to be a contradiction between what the FDA's telling industry.

Joe Hage: And if you would go ahead and type and share it with the audience. Michelle asks, can you explain what the published date is in the GUDID database?

Gary Saner: Yeah that's a really good question and there's a lot of questions about **[inaudible 00:57:38].** It is a date that there's two … there's a couple of things. One is the day satisfies your responsibility for the device to the FDA. Secondly, it marks the transition from **[inaudible 00:57:57]** what is referred to. So the lifecycle of a data record. You could submit a data record today and have the published date two weeks in the future.

So between now and those published date, those two weeks are referred to as the on-publish time. So you get feedback from the FDA that it was accepted and so on but it's really held in limbo in this on-publish scenario and you **[inaudible 00:58:33].** When the publish date occurs, that marks the beginning of a grace period and only the owner of that record is able to see that data for that period of time. You can make changes to all the fields except the published date.

So you can't play with the published date. And then after that, the product automatically closes and then it's fully published and most importantly made available on the AccessGUDID to the public.

So there's **[inaudible 00:59:21]** during that grace period, the FDA, the holder of that data to make sure that especially those 11 fields that are all of a sudden going to be fixed at the end of that 30 days to go in and verify those values.

So hopefully that answers the question about the publish dates.

Joe Hage: Michelle also asks, is the AIDC another label versus the current label placed on the product? Can you explain this? It's not the UDI label, it's another label.

Gary Saner: Oh yeah that's a good question. It's not a new label. It's a form of presentation of the UDI data value itself. So let's say, the **[inaudible 01:00:17]** identifier happened to include **[inaudible 01:00:20]** for example. Device and production data would need to be appearing in human-readable form, meaning that it's printed out on the label as you know it today.

So it needs to be embedded into what the FDAC format in that presentation. But most of the industry has either used a one dimension or two dimension barcode. Technically you could use like an RFID type of a transmission for that. But the idea is that the FDA wants not only human-readable but also able to be handled accurately and efficiently through some electronic means.

So being able to scan it. So both of those items, both of those presentations need to appear on your current label.

Joe Hage: So **[inaudible 01:01:33].** There are another two or three questions in the queue here. We'll try to get to them. Just to manage everyone's expectations, it is the top of the hour. We are doing this for 90 minutes today. We are recording it and for those of you who were joining a Medical Devices Group webinar for the first time, I will have this conversation transcribed.

We have a question from Dora. Oh just by the way too, the question queue goes all the way back 45 minutes now. So if I haven't read your question yet, that doesn't mean I don't have it. Just stick around.

Dora asks, what if my product is an MDDS device? Medical Device Data Systems? Do I need to do this UDI stuff as well? I paraphrase there.

Gary Saner: MDDS.

Joe Hage: Data System.

Gary Saner: Oh right. So there is … it all comes down to whether or not your product is fulfilling the definition of a device and is regulated as a device.

So some data systems and I'm not sure if that's the scenario in this particular case, handle data **[inaudible 01:02:55].** Let's say for the discussion purposes, FitBit generates a bunch of data about your heart rate and records that data and it's stored in a data system. If that apparatus is regulated and controlled as a device, then it would need a **[inaudible 01:03:20]** UDI as long as again, as long as they're not considered a device.

Joe Hage: Just to make sure, if my company resells parts from GM regulation into **[inaudible 01:03:47]** at least for now?

Gary Saner: [Inaudible 01:03:56]

Joe Hage: Are you sure you're just not trying to drum up business **[inaudible 01:03:59]?**

Gary Saner: [Inaudible 01:04:07] Everything that … all devices that are marketed **[inaudible 01:04:14]** some exceptions, they have to do with the investigated device. The national stockpile and veterinary products and that sort of exceptions but a broad comment is that these medical devices, if they're commercially sold in the US **[inaudible 01:04:47].** So then the question becomes if the manufacturer's responsible. So the question is, who is actually the labeler and that party then becomes responsible to **[inaudible 01:05:09].** A German manufacturer is identified on the label. It's probably their identifiers, company's identifier and so on.

So in this case, I would say the German company is the labeler and distributing that product in the US they would be responsible to comply with UDI.

Joe Hage: Sorry Celine. Just **[inaudible 01:05:42].**

Gary Saner: That's a great question. So the **[inaudible 01:05:53]** an exclusion for existing inventory that is already **[inaudible 01:06:05]** and labeled and in stock as of the compliance

date, there's a 3-year window in which you can take that product, leave it as it is with no UDI and ship that product out to the marketplace.

So yes the exception does apply for existing inventory. Now if you come out with a newly manufactured and it was not fully assembled and **[inaudible 01:06:42]** then that … but existing inventory has this nice 3-year window.

Joe Hage: It's good to know. Thank you. Lisa asks, is there a timeframe for submitting new UDI into GUDID after the September compliance date for new products? So I have a new product, it's October **[inaudible 01:07:12]**?

Gary Saner: That's a check mark that needs to be part of your release standard operating procedure. So the FDA does want that device to be in before it's actually outside your control and released to the public. So there's a pre-requisite to have that device reported to have the UDI before it goes again, outside your control.

So what we have seen some companies do by **[inaudible 01:07:55]**, they'll start plans and realize okay, it's past September, it's a Class 2 product and **[inaudible 01:08:07].** So they have **[inaudible 01:08:16]** UDI with the product.

Joe Hage: [inaudible 01:08:31]

Gary Saner: I'm sorry. What was the question?

Joe Hage: The date of the UDI **[inaudible 01:08:44]** or the manufacturing date.

Gary Saner: The options there were manufacturing date and **[inaudible 01:08:56].**

Joe Hage: It's a different date.

Gary Saner: These dates that appear on products are many times could be a used by date. I don't believe the registration date is typically put on a label. Now when I was talking about a **[inaudible 01:09:33],** in the GUDID data has only **[inaudible 01:09:39]** date as part of that submission to the GUDID. **[Inaudible 01:09:47]** She was talking that registration date is what I refer to as the public … that's not on the label and that's again that we talked about earlier which is this date that the FDA uses to promote the product from initiates the grace period.

Joe Hage: So Brian follows up, so is this a format for dates? Pardon me. So this is a format for dates not a mandate for dates on the label beyond current FDA requirements?

Gary Saner: Great point and I neglected to mention that as we walked through. So all those production **[inaudible 01:10:33].** Even a serial number, a batch number and so on, the FDA rule says that if you don't have them now on your label, you do not have to add them. So it doesn't

require adding those particular elements to your label. But the final rule goes on to say if you are currently using those for production control and it's on your label, then you do have to flag that information and report that to the FDA.

Joe Hage: I got a double check for Maya. She thinks you answered her question. She has a multiple-use device, a therapeutic laser. It never expired so she's going to use the manufacturing date, okay?

Gary Saner: Got it.

Joe Hage: Good. Irina asks, **[inaudible 01:11:34]** two barcodes, device ID and production ID?

Gary Saner: Some companies do break it apart based on the issuing **[inaudible 01:11:46]**. The FDA has recognized three global product identifiers that will be able to create **[inaudible 01:12:01].** The one that is overwhelmingly used, well over 90% is **[inaudible 01:12:13].** And their protocol, that's something called GTIN, the Global Trade Identification Number. And there's a similar standard from HBICC which is also available. But in either case, the FDA asks you to go through that issuing agency. **[Inaudible 01:12:50]** basically run them together into about one very long string and have a long barcode or you can have two separate barcodes based on the particular standard that you pick.

Joe Hage: Okay. Next I'm going to ask some of Floyd's questions. To use the cat lock. It seems very urgent.

Gary Saner: Well I think that's the easiest one so far. Absolutely yes.

Joe Hage: Next, how often LOT **[inaudible 01:13:40]**?

Gary Saner: How often do we have to verify the …

Joe Hage: The labels on the containers. His follow-up question is, what is the required frequency for UDI verification?

Gary Saner: Oh okay got it. Now I understand this one a little bit better. Again the issuing agencies talk about **[inaudible 01:14:06]** label. And in particular the GS1 company has a reference to a code of B or better. And actually that barcode what is referred to as verifying that barcode to make sure it meets that quality is left up to the manufacturer.

So you might put in your design history file, a discussion about well, we have done some studies or we've some evaluation and it feels as though at the beginning of our run and at the end of the run is sufficient. You also **[inaudible 01:14:56]** another sample that says, oh **[inaudible 01:15:00].** We'll have a verification process. It's technically possible **[inaudible 01:15:21]** and an evaluation of the labeler has to conduct on their own as to the frequency of evaluating the

quality of the label and I will make mention at this point that the verifier is a totally different apparatus than a reader.

So you might have a barcode reader that interprets the **[inaudible 01:15:47]** in the light area and so on and comes up with a grade depending on the quality and it can change based on you know, your printing process especially the surfaces and the **[inaudible 01:16:10].**

Joe Hage: I don't know why I'm surprised but we still have a queue longer than the next 15 minutes will allow. So let's keep going and let's see if we can continue the game of **[inaudible 01:16:24].** Debra asks, for accessories to a medical device, does every accessory **[inaudible 01:16:32]** such as dust covers need to have a GUDID?

Gary Saner: In that case, the accessory question falls back under **[inaudible 01:16:44].** There is a definition from the FDA regarding accessories. A general comment is that accessories that are part of the device system would need to have a UDI. **[Inaudible 01:16:58]**

Joe Hage: Dust cover?

Gary Saner: Well, but then the flipside of the coin is let's say that that dust cover is not sold separately then that's a real easy one. You don't need to market separately. Attached to a particular box and it's covering some connectors or something or a connector and protection during the shipment.

So maybe the other device that is being shipped actually has a UDI on it and the dust cover is considered a component of that apparatus.

So in that case, it does not need a **[inaudible 01:17:51]** Joe and we'll need some more information to …

Joe Hage: This is exhausting. Seriously. I mean this is like **[inaudible 01:18:00].** Establish your GUDID account and input the data for the product. It's my understanding, pardon me. I'm sorry Michelle. I'm having a hard time on this question. Let me come back to it. **[Inaudible 01:18:28]** Manufacturing date also need to appear on the device label.

Gary Saner: No it does not. So that goes back to that original discussion that we had where the label does not originally have the data on it. Then there's no reason to add it. So it sounds like there's an internal **[inaudible 01:19:10].**

Joe Hage: Thank you for waiting. For new 510(k) submissions whose review period encompasses the compliance date, **[inaudible 01:19:30]** boxed area on the draft label showing where the UDID would go or client does not yet have established full manufacturing? They are just in design.

Gary Saner: Thinking ahead. I would **[inaudible 01:19:54]** time as part of your 510(k) application, one would need to identify something called the Device Identifier. So that, a part of the UDI but it identifies you as the labeler and also identifies the product down to the model number **[inaudible 01:20:18]**.

So you have no idea. And so on. So that's all production-based. So the FDA will not be asking that **[inaudible 01:20:34].** Suggested in the question, it's a great idea.

Joe Hage: Lauren, thanks for being patient. She emailed in a question. Do you recommend **[inaudible 01:20:47]** parts that are **[inaudible 01:20:50]** from the device's UDI?

Gary Saner: Well, **[inaudible 01:21:02]** I figured Joe sooner or later we'd talk about spare parts and replacement parts. Sure enough it came up right?

Joe Hage: [Inaudible 01:21:12] asked that question in eight webinars, is it?

Gary Saner: It's a very common question. **[Inaudible 01:21:19]** figure out the scope of the category of spare parts and spare parts, replacement parts, if they're going out and put into a finished device, they do not need their own UDI.

Once again, just like the tax collector has all these special scenarios. If you market that replacement part as available then it does need a UDI.

So if it's going out being shipped as a component if you will, **[inaudible 01:22:16]** replacement, no UDI required. And a significant **[inaudible 01:22:26]** is basically … if a spare part is an enhancement and for whatever reason significantly causes the safety or the effectiveness or maybe it's significant enough to be a different model or version, then the issuing of that item in assembling out the whole **[inaudible 01:23:07]** straightforward answer here is that spare parts and replacements do not **[inaudible 01:23:17].**

Joe Hage: And we have 80% of the people who signed on still are on. **[Inaudible 01:23:25]** medical device that is packaged in multiple container. Also from Lauren.

Gary Saner: Well, let's call this Device A **[inaudible 01:23:53]** and then the pouch goes into a box and then the box goes into a **[inaudible 01:24:07]** shipped out the door.

So what I was trying to illustrate is that in all those cases, in each of those packaging levels, there is only one Quantity 1 product in each of the levels.

In that case, the FDA allows you and actually, **[inaudible 01:24:30]** so you have one bag and one box. So one box and one carton. The final label that is shipped out the door, the FDA would like to have that UDI visible and apparent. If it's typically a normal procedure at the carton level, then you only need to have the UDI at the carton level. At the time of use, the carton is

discarded, the box is discarded and the pouch is discarded. You're now down to the product and the product has a UDI on it. Then that's all you need.

But if it looks like maybe the carton is discarded and the product sits on the shelf as a box, so the time **[inaudible 01:25:38]** container with the UDI on it. Again, it's always the same UDI when it's Quantity 1 in one additional **[inaudible 01:25:45]**. I will mention that some of these scenarios are covered in the guide that we have available. So starting up and learning about device identifiers and working your way through this process again, we're kind of talking very quickly through this scenario. But there is some good written material freely downloaded from website that helps you to understand these scenarios.

Joe Hage: Damien asks, with manual entry to the FDA, can you cut and paste records? Or does all data have to be reentered every single time?

Gary Saner: Well there is a limited feature, there is a function called copy inside that particular FDA web interface. So you can copy some fields. It requires you to change the ones that have to be changed so obviously you can't have two records with the same device identifier. And that does allow you to do some efficiencies. It does require you to obviously master value if you will and make **[inaudible 01:27:12]** to those fields that change over the course of time.

[Inaudible 01:27:16] Hugely there's a contact change to **[inaudible 01:27:28]** like an email change. As you make edits in the future, you do have to make edits one at a time.

So if you have a thousand **[inaudible 01:27:49]** and resubmit. As opposed to doing some **[inaudible 01:27:54]** you're able to make the styles and changes in a bulk fashion and spread it, distribute it across multiple records and then basically at a push of a button, you could submit updates to the FDA.

So there are some considerations in initial entry as well as editing in the future.

Joe Hage: Speed round, if you answer fast enough, we'll squeeze in one more. Is the FDA expecting GTIN for the device ID or the production ID? If a GTIN **[inaudible 01:28:30],** does the issuing body provide **[inaudible 01:28:34]** for sterili … pardon me.

Gary Saner: No. In this case, a GTIN number is referring to the device identifier. The values that relate to a serial number, a batch number and so on, they are applied by the labeler to the actual product label but the actual serial number itself is not sent to the FDA. Only the initial device identifier portion is. You will simply need to report the fact that there is a serial number on the product and that's a Boolean yes or no and that's a one-time entry.

So every individual serial number, batch number, those actual values are not reported to the FDA GUDID.

Joe Hage: Okay. Last question. Poor Lisa has twenty parts in a package and she sells hundreds of the kits in different combinations. What does she do?

Gary Saner: Well, if it's **[inaudible 01:29:43]** and I guess we don't have time to go into all that. If there is a **[inaudible 01:29:51]** individual sales, **[inaudible 01:29:54]** pieces all assembled together, one or more devices and the FDA has a special exclusion for that where just the kit needs to be identified with UDI and sent along the way.

In this particular **[inaudible 01:30:17]** individual components are ordered independently and just out of convenience shipped together, she could take identifying those twenty components with individual UDI **[inaudible 01:30:34]** all the thousands of permutations that would result from assembling those individual components. Either way, that should be reported in design history file in case …

Joe Hage: So **[inaudible 01:30:58].** The Reed Tech folks had graciously opened their headquarter doors to me and I'm going to host my next marketing and sales workshop there on August 8th and 9th. If you come, you get a twofer because I'm sure we'll get Gary to sit down in the side room and have some one-on-one time with you. You think you can handle that Gar?

Gary Saner: That sounds great.

Joe Hage: Okay. Once again, ladies and gentlemen, you know him, you love him, Gary Saner.

Gary Saner: Thanks Joe. This has been another … a very effective great time of interaction, Q&A and we were glad to help. So let's go out and work.

Joe Hage: [Inaudible 01:31:52]

Gary Saner: Right.

Joe Hage: Thank you Gary. Thanks everyone for attending and we will follow-up with the slides **[inaudible 01:32:05]** Thanks very much. Goodbye from Seattle.