# How to Simplify Compliance with the New ISO 13485:2016

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In collaboration with Joe Hage and the LinkedIn Medical Devices Group

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**Joe Hage:** Hi, this is Joe Hage. I have the privilege of leading your Medical Devices Group which as of this recording has 333,000 members worldwide and one of the reasons we've grown as large as we have is we have members like Jon Speer who will give today's presentation about 'How to Simplify Compliance with the New ISO 13485:2016.'

Jon, the floor is yours.

**Jon Speer:** Alright. Thank you Joe. Let me make sure I get into the fullscreen mode and start sharing what exciting material I have going for today. We got a ton of information to cover. Obviously, ISO 13485 is a very important topic to the medical device industry. Many of you are probably already aware that this standard was revised just a few months ago. So the 2016 version is alive. There are changes. We're going to cover many of those changes today and help you prepare for this transition to a new 13485.

So for today, the agenda is quite simple. I'm going to give you an overview of 13485. I'm going to go over some things that have changed from the 2003 version to the 2016 version. I'm going to talk a little bit about the impact that could affect you if you're waiting to address these changes. If you wait and wait and wait, what could that do to you? Conversely, if you start to put some of these things in place sooner rather than later, what are the advantages to your company?

I'm going to talk quite a bit about eQMS software and how this can be a bridge to help you with that compliance and then we're also going to talk about five steps that you could take for that smooth transition and then Joe at the end, certainly we'll have time for questions as well.

So as we get into the session today, it's important for you to know a little bit about who I am, a little bit about my background, a little bit about greenlight.guru. I've been in the medical device industry for over 18 years now. I've had the opportunity to bring over 40 different devices to market. All kinds of things from wound pumps to central venous catheters to airway devices, a wide variety of devices. I've implemented quality management systems dozens of times. Going from scratch to full ISO certification. I've sat across from FDA inspectors and ISO auditors so I'd been there and done that. It's important for you to know that in this medical device industry, there are some of the top content in this space on things like quality management system, design controls, risk management and so on are things that I helped author. You can find those at a variety of places. Med Device Online, MedCity News, to name a few.

We also at greenlight.guru have the number one podcast in the medical device industry. It's on iTunes. It's on SoundCloud. So go check that out. It's the Global Medical Device Podcast.

**Joe Hage:** That is very cool. I did not know that.

**Jon Speer:** Yeah. It's grown like crazy Joe. We have some really exciting guests. It would be great to have you as a guest on that event as well.

**Joe Hage:** I'd be honored and go ahead and maybe Nick, go ahead and type in the URL for that podcast. Back to the program. Sorry.

**Jon Speer:** Alright. I'll tell you a little bit about greenlight.guru. Greenlight.guru is a company that was established to actually help make your life easier especially when it comes to implementing and managing your quality management system. It is designed specifically and only for the medical device industry. So the entire backbone of our platform is with FDA 820 quality system regulations as well as ISO 13485. Yes, even the 2016 version.

We also have integrated ISO 14971, FDA Part 11. For those of you that are dealing with quality management system, those are absolute minimum criteria that you need to have in place. Greenlight.guru also has support services from medical device professionals like myself, people who had been there, done that, who can assist you as you're bringing your products to market, manufacturing and so on and so forth.

So stick around to the end. You'll definitely want to do that. We have prepared for you, especially for you, Joe, your audience is going to get a special gift. We've created a QMS Audit Checklist. This QMS Audit Checklist combines both FDA quality system requirements, ISO 13485:2003 as well as ISO 13485:2016. So you can't find it anywhere else and we're going to give it to your listeners with this webinar free today, Joe. So special gift.

So I have four goals that I want to cover with you today. I want you to understand the major changes of 13485. I want you to understand why it matters to you. I want you to understand the benefits of taking action now rather than putting this off until later. I want you to understand how you can leverage technology to your advantage in the form of software solutions to manage and maintain your documentation, your records, your procedures. And I want you to take action. I want you to identify and understand steps that are going to be involved in taking action to addressing any sort of gaps or issues with respect to ISO 13485:2016.

So now we're going to get into this. We're going to lay a bit of a foundation for this material today. I want you to understand a little bit more about ISO 13485:2016 and I'm going to give you a brief overview of this. I'm not going to tell you a full history lesson. If you want that, Wikipedia does a fantastic job. Just go search for ISO 13485 in Wikipedia and you can read the whole history of how this came to be.

I do want you to minimize your distractions there. You should turn off Facebook. You should probably minimize Twitter. You should probably close your email. Grab a pen and paper or whatever note-taking device that you prefer. Takes notes because this is edge of your seat stuff. You all signed up for this. You're all taking valuable time out of your schedules today. So be sure you do that.

So what is ISO 13485? Basically it's a standard. It's voluntary but it is a standard that describes the industry best practice for quality management system requirements and criteria. This 13485 evolved over some period of time. It basically evolved from the ISO 9001 which is for general manufacturing. ISO 13485 is specific to the medical device industry.

Now there are several benefits to implementing a quality management system. Several benefits to doing so in a ISO 13485 context. The big deal here is regulatory compliance. That is the single biggest risk that medical device companies are faced with each and every day is ensuring that your processes, your systems, your documentation, your records meet regulatory scrutiny and regulatory compliance. ISO 13485 provides a framework for you to establish your quality management system in a way that ensures level of compliance from a regulatory perspective. That's the big deal. That's why this is so important. Your quality management system describes all of your processes, your procedures, the practices that you have in place at your medical device company and it should do so in a way that meets regulatory scrutiny.

An ISO 13485 has been put through the ringer so to speak from a regulatory perspective. FDA is involved, Health Canada is involved, the European Conformity. Regulatory bodies all over the world have set resources and included these resources in authoring this ISO 13485. So all of the

major medical device regulatory bodies in the world had been a part of the creation of ISO 13485.

I do want you to understand though that there are some things that ISO 13485 is not. It is not the law. Big difference between ISO 13485 and FDA 21 CFR Part 820 for example, FDA Part 820 is the law for medical device companies in the United States or for medical device companies who are selling products into the United States. That's the law. ISO 13485 again is a voluntary standard. It is not law. It is based on regulations in Europe, Canada, United States but adhering to ISO 13485 is not technically a regulatory requirement.

FDA for example if you have an FDA inspection and you point to that ISO 13485 certificate hanging on your wall that says, "You're ISO certified," that's not going to carry a lot of weight with an FDA inspector. FDA inspector is inspecting you to adhere to the FDA quality system regulations.

Maybe you're hearing this and you're thinking, that's a level of semantics. We can certainly dive into that in much more detail. I just want to make sure you understand what the difference between law and a standard is in this case.

**Joe Hage:** Jon, let me ask a quick question. So I have a client who has on his website that he is 13485:2003-certified.

**Jon Speer:** Okay.

**Joe Hage:** Is it a strategic imperative for him to get 2016-certified and boast that on his site? Or he's fine with 2003?

**Jon Speer:** That's a really great question and I'll probably hit on it here in a moment but I'll answer the question now because it is an important context to understand. The 2003 version has been obviously in place for quite some time. It's good that he has that ISO certification based on the 2003 standard. Over the next few years, he will be transitioning to the 2016 version of that standard. There are certain organizations known as registrars who will come in and basically certify a company compliance with the standard and each of these registrars will have a timeline over the next I think it's three years that they will require companies evolve and update their ISO certification to align with the 2016 version.

So if this client of yours continues their ISO registration, within the next three years it will be converted to 2016 which that's really the whole premise of why we're covering this material today Joe because there are differences between the 2003 version and the 2016 version and if your client is not ready for that and the registrar's ready to come in and do the 2016 certification and he hasn't done all of his homework, it's going to be painful. He's going to be

delayed. He's not going to be able to claim ISO certification. He's going to have to do a lot of work to get things up to speed.

So that's why it's important to start planning these things now.

**Joe Hage:** I'm really confused because of the way you used this slide and said, "Not required. Not a law. Not required." And then you said, "Required."

**Jon Speer:** Well, okay. So ISO certification is not … it's a voluntary thing. If you're ISO certified, it is telling the regulatory world that you have implemented a quality management system that has been objectively evaluated and audited by a recognized third party, a registrar. These registrars have to go through quite a bit of scrutiny from regulatory bodies but the registrars come in and objectively said, "Yes, medical device company ABC meets ISO 13485."

So by that declaration, it's basically stating to the world that this company has a quality system that adheres to expected best practices from regulatory perspective.

**Joe Hage:** Okay. Thank you. I'll let you continue and I'll note that one participant, JP notes, it's not required for the US. It is required for CE marking and distribution to the EU and other places that accept the CE mark.

**Jon Speer:** It's a generally accepted best practice. There are parts of the world where ISO 13485 is required. There are many parts of the world where we assume it's required but it's not technically. So again, we're getting into a lot of nuances. Just know this, ISO 13485:2016 is the current best practice with respect to quality management system. So whether you are ISO certified or not ISO certified, it is a fantastic guideline in helping you put in place the best processes from the quality management system perspective.

**Joe Hage:** Back on you. I'll be good.

**Jon Speer:** Okay. I mean it's your show Joe so anytime you have questions, just make sure you throw up some softballs in the air so I can just crush them out of the park, alright? Alright. So why did ISO 13485 need to change? Well, as Joe eluded, he has a client that is certified to the 2003 version. Well, that's been the latest version of ISO 13485 for quite some time. Generally speaking, standards of this nature are on a 5-year cycle. Suffice it to say, the ISO 13485 is long overdue for a revision.

So anyway, there has been a constant evolution. There's been a team, a group that's been working on this for years and years and years and over the course of time, it became clear that finally we absolutely had to have a new version of ISO 13485. The big thing is it's about driving towards regulatory best practices. For those of you that have been in this industry since 2003, think about how different the world is from a regulatory and quality system perspective in 2003

to present day 2016. A lot has changed in this industry. And keep in mind that the ISO 13485 standard has not changed really at all in that period of time. So this is a revision that's long overdue.

But there's a lot of input that went into this. A lot of input from regulatory agencies. A lot of input from manufacturers and making sure that this new version of this standard continue to meet expected best practices.

Again, more and more bodies have been involved in this. Like GHTF (Global Harmonization Task Force), countries from all over the world, regulatory bodies from FDA and Europe and Brazil and Japan and Australia all had an input into this standard. So some of this had to do with just basically making sure that the quality management system standard is really driving towards more of a single voice from a regulatory point of view.

Now Joe asked the question about the client of his who is currently certified to 2003 and if his client could continue the 2003 certification or if they need to make some sort of transition to 2016. So the 2016 version is published. It's been published for several months now. There is a guidance that's going to be developed but that's probably a year or so away. Expect that very soon but then the transition from ISO 13485:2003 to 2016 will be a fairly standard 3-year transition period and there's going to be some variability to this depending on who your registrar is.

I know if you're already certified, you definitely want to check with your registrar. Find out what their timeline is. I would expect that here within the next 12-24 months or so, there would be less and less new registrations for the 2003 version. That all new registrations will be only the 2016.

So if you have any questions, ask your registrar because each one will have a different implementation timeline. So what has changed in ISO 13485:2016? I want to go through a few things today. I want to talk a little bit about things that could impact you. Things that you need to consider as you make that transition. You should be making that transition to ISO 13485:2016. You should start that. Really, now. There's no reason not to.

But some of the big concepts are, we probably have all heard about risk management and how that's impactful to this. And that's one of the biggest changes to the ISO 13485 is this concept of a risk-based quality management system and the 13485 standard puts a lot of weight, a lot of emphasis on the risk management principles and processes that are described in ISO 14971. For those of you who are new to this industry, you need to find out more about ISO 14971. You need to find out more about ISO 13485. You can contact me. I'll have my contact information here in a few moments to share with you. But we've written some guides for those things to help walk you through that process and actually, Joe, we did a webinar with Joe Hage about a

year ago on this topic of risk management. I know it's available on the Medical Devices Group page for replay. So be sure to check that out. If you don't know how to get that, contact Joe Hage and he'll be sure to get you the link so you can review that webinar as well.

As I mentioned, the regulatory bodies have been very much involved in this new version of ISO 13485. The big goal here is this thing called MDSAP or Medical Device Single Audit Program and I know a few of you on the audience today have had the opportunity to go through one of these single audit program audits and I know some of you share some of your horror stories. I'm positive that this process will be smoothed out. There's a lot of bumps in this process right now. I know some of you are feeling some of those bumps. So hang in there. We'll get through it. But the whole idea behind the medical device single audit program is so that you can actually minimize the burden that each of our medical device businesses is faced with when it comes to audits and inspections especially on the quality management system. If you're ISO certified and you're also selling devices into the US market, you might be subjected to an FDA inspection. You might have an ISO audit and for every other market that you're in, you may be subjected to additional audits and inspections by regulatory bodies.

So there's a lot of promise behind this single audit program. And ISO 13485:2016 starts to build that framework for that particular concept and that particular process to grow some legs and actually be meaningful to our businesses.

The other thing is about making sure that all your documentation and records from a regulatory perspective are captured, addressed, managed and maintained. The other key changes on 13485 is basically making sure you put a lot of weight and emphasis on infrastructure. Making sure that you have resources in place. Making sure that your resources have the appropriate skillset training and backgrounds to do various roles and purposes within your company. There is also a much much greater alignment between ISO 13485:2016 and the FDA quality system regulations. The 2003 version of the standard had nothing. No clauses for example on complaint handling. Had no clauses with respect to reporting to regulatory authorities. The 2016 version has added two examples, complaint handling, has added regulatory authorities. There's a few other areas as well that we'll get into on a more detailed explanation here in a few moments.

So as far as … this framework is also identifying a clearer objective or path from an audit perspective. The idea is that you have your quality management system that of course meets these regulatory expectations but doing so in a way that's much more consistent from one market to the next.

Now I want to point out a couple of pieces of information in the ISO 13485:2016 standard. I want to draw your attention to Annex A and Annex B. First of all, you'll probably hear me say

this a time or two today. If you don't have a copy of the standard, go buy the standard. It's like $155 or something like that. It's well worth it to go buy the standard. No I don't get an endorsement from the ISO organization but yes if you're concerned about this or you want to put ISO 13485:2016 in place, you first have to have a copy of the standard so go buy that. Annex A compares the changes, the similarities between 2003 and the 2016 version of ISO 13485. So that Annex is a very very good guide.

Some of you might already be ISO 9001 certified as well. If you're not aware, ISO 9001 also had a similar overhaul about a year or so ago and Annex B actually compares the 9001:2015 to 13485:2016. So a common question is, can sometimes companies, especially contract manufacturers may have dual certification with 13485 and 9001? Will it still makes sense? The Annex B will be a good guide and the word that I heard is that yeah, it still might make good sense. So you need to evaluate your business and determine if that makes sense for you.

The bibliography is also very very good. It provides a lot of other reference documents that will be helpful in understanding. It would bring more context around 13485.

Alright. So I'm going to pause here for a moment. I know the font is super tiny. It's somewhat on purpose and there's several items that I put in bold, italics font and the reason, these are all the clauses that have are impacted from the 2016 version of 13485. And the reason I highlighted some of these in bold, these are the ones I'm going to go through in a little bit more depth and detail today and because they're more impactful as far as the changes are concerned but when you look at that Annex A table that I mentioned a moment ago, you'll see a lot more explanations. It goes into quite a bit of depth and detail.

So let me just dive in to some of these more impactful changes and talk a little bit about how these could impact you and your business and your quality system. The first area I want to dive into is the scope. The big thing about the scope is this idea of a lifecycle and I think that's been engrained in the product realization process that's defined in the ISO standard. It starts to really engrain that with us in some respects. But there is a lot more emphasis on this throughout the entire standard.

The other key thing is having control over outsource processes and understanding the impact of that from a quality management system standpoint. Also, it used to be an option to not apply certain requirements of the ISO standard and this is still an option. There is a little bit more freedom to do so. Of course you need to have an explanation and justification for being able to claim a non-application of a specific requirement.

I don't usually like to go into terms and definitions because there is so many standards of just definition after definition after definition. But I do want to highlight a couple of things that are important about terms and definitions in this standard. Mostly because there are quite a few

new definitions that have been added. Yeah a couple have been removed, a couple have been modified but pay attention to the things that have been added into this version of ISO 13485. Notice that now we have risk and risk management. Those are key words to pay attention to. Notice that there is a definition for clinical evaluation.

So there's been a lot of changes on the European medical device regulation and IVD regulation that are going to be hitting us here very very soon as well. So there's been a convergence from a definition standpoint so it's important that we have that context as we explore and dive into ISO 13485:2016.

I'm going to start getting into a lot more of the meat of the standard and some of the specific items that have changed as far as the clauses and the content of this is concerned. And I'm going to start with Clause 4: Quality Management System and 4.1: General Requirements. Basically, everything about this clause has been completely reorganized and the key things about focusing on what documents mean and how that impacts your organization and defining the role of an organization and really the key, this is where we start to get in that key concept of having a risk-based approach with respect to processes and this is a theme that it continues throughout the entire standard and we're going to touch on this and a couple of other cases today but risk-based approach. You're probably going to hear me say risk a dozen more times and I think that's the key thing that we just have to start to understand is ISO 14971 laid that foundation a few years back from a risk-based approach with respect to product design.

Well now, those concepts, those approaches are being carried on to how we design and develop our quality management systems and there is an expectation that as you make decisions throughout the entire genesis and management and maintenance of your quality system that you're using this risk-based methodology to make decisions.

Design and development planning. Now there are a number of these clauses that I'm going to go into specifically under design and development, the main design and development clause is 7.3 and then there are a lot of sub-clauses under that 7.3 umbrella that have all changed. If you're speaking FDA, FDA refers to design and development refers that as design controls. So for everything that I'm talking about today, design and development, design control, those are considered synonyms. And even before the 2016 version of ISO 13485, there was pretty good convergence and alignment between FDA and ISO 13485. And I'm here to tell you that the big changes from the design and development perspective of ISO 13485 increased the alignment with FDA.

So if you're a company that's outside the United States and you've thought about going to the FDA market but maybe are uncertain about the FDA criteria and requirements, pay attention to what's happening in ISO 13485 because these changes in ISO 13485 are going to be in greater

alignment. It's basically increasing the expectation. It's increasing the required behavior for design and development activities.

So this is a side note, you should know that design control deficiencies year after year after year are the number one reason why companies get FDA 43 observations. So get your design control processes right and I know a software solution that can help manage that workflow. I'll talk to you more about that as well here in a few moments. But in section 7.3.2, this deals with design and development planning. This was a bit weak as far as a clause was concerned before. Big thing I want you to focus on, traceability. Traceability is so important to everything that you do from a design control, from a design and development standpoint.

You have to be able to link your inputs and your outputs and confirm that your verification activities demonstrate your outputs, meet your inputs and that your validation activities address your user needs. So this need for traceability is now explicitly required as part of ISO 13485:2016.

Design and development inputs. Been a lot of input already. Increased criteria around this clause as well. This concept of usability has been growing in popularity. I know the purist out there might chastise what I'm about to say but usability, sometimes people refer to it as ergonomics. Sometimes people refer to it as human factors. I know they all are slightly different sciences and there are nuances to each but just know this, knowing and being able to demonstrate the usability of your device whether it's a software product, whether it's something that's handheld, it doesn't matter. There is a growing expectation that you address usability that you aligned with this standard IEC 62366.

Now FDA is also putting a much higher emphasis on human factors and usability and know that when you're putting together submissions to the FDA at that scenario that you're going to need to address as well. The other key things about design and development inputs, some of the changes, again, we're going to see this term risk management. It's happening again. There's an expectation in 13485:2016 that using your risk management process and your design and development process that they're integrated together. There's an expectation that your risk management activities are feeding into your design and development efforts and that you have specific design inputs and requirements that have been developed as a result of risk management. And this can be a really challenging thing to be able to demonstrate and to prove that that's becoming an expectation in ISO 13485:2016.

Design and development outputs is also an area that's changed. The verbiage or the wording that we're seeing in the 2016 version again is almost verbatim from what we have been used to in FDA design control regulations as found in 820.30. But you have to express design and development outputs that are in a way that could be confirmed through verification activities.

Think of design. I often use this as an example. Think of design and development outputs as your recipe for your medical device. The design and development outputs will list the materials, the parts, the pieces, all the things that go into your device and they need to be stated in a way that allow you to conduct some sort of verification activity to confirm that your outputs beat your inputs. And we'll talk about verification as well.

So design and development verification, you need to have … this needs to be planned. It needs to be documented. You need to have test methods and protocols. All these things need to be established. Yeah. These are practices that many of you probably have in place. They were not always explicitly defined in ISO 13485. So some of the areas as you get into what's changed about ISO 13485, in some respects, the practices that have been accepted and then placed at many companies were basically mimicking these changes. ISO 13485:2016 in some respects is a catchup.

As I mentioned, the previous version of the standard was rolled out in 2003 and here we are 13 years later. So a lot has changed in the medical device industry from then to now. So many of you may already have many of these things in place and so that's in some respects reassuring but then again, I want you to make sure. I'm just going through some of the more significant changes. There are a lot of items that have been addressed. A lot of items that have been added. A lot of new pieces in 13485. You need to do your homework to make sure that you determine how this is going to impact your organization.

Don't just say, "Oh well it's just that … they just changed the year on the cover page and it's good to go." Don't assume that. If you assume that, you're going to be in a world of hurt. You're going to have a lot of homework to do and catchup work to do when it comes time to transition officially to 2016.

Alright. So getting back to design and development verification. You need to plan this process. You need to have methods. You need to define your acceptance criteria. If you are doing some sort of test or analysis, you have to use valid statistical rationale and techniques. That's expected. You need to have results that are documented. You need to have conclusions. So these are all things that are expected as part of design and development verification.

Design and development validation is pretty much you're going to see a lot of similar languages. Again, verification is demonstrating that your design and development outputs meet your design and development inputs. Design and development validation is demonstrating that that product meets your user needs. So there's a lot of similarity between verification and validation.

This is an area where that clinical, I talked about one of those key definitions. It's one of those areas where that impacts. Clinical evaluation is very much a design and development validation

type of activity and so there's a much heavier emphasis on this and the need for conducting some clinical evaluation as it comes to demonstrating your product needs or user needs. And so this clause in 2016 version of the standard has become much much beefier as far as the expectations and the requirements are concerned.

Oh brand new section. Can you believe that ISO 13485:2003 didn't even talk about really design transfer at all and I think there was some implied nature behind that? Of course eventually you got to transition out of design and development and eventually into production but there was no explicit requirement for design transfer.

Now, keep in mind in A2030 that FDA design control regulations, there is a clause for design transfer. The good news is again, that these ISO 13485 and FDA are going to be pretty much not word for word but the concepts, the expectations are identical. So design transfer, brand new to ISO world, now you need to have processes in place that describe the transition from development into production or into manufacturing. You need to make sure those design outputs, I mentioned those design and development outputs being the recipe for your device. The other thing you should think about from design and development outputs is that's your preliminary device master record which the clause in ISO 13485 is medical device file and I'm not touching on that today but that's in section 4.2.3 of ISO 13485.

There is an expectation that your design outputs demonstrate that your product is ready to be manufactured. Once you transition and transfer that to production, you need to maintain a medical device file or an FDA terms of device master record that identifies all your drawings, parts, pieces, specifications, so on and so forth that are required to build. "Build". You're probably going to have … some of you have software products so build may be an operative term.

Anyway, very important that you have process in place to describe design transfer. Control of design and development changes. I mean this was in place already but there is an emphasis again here on this usability concept. There is an emphasis on safety and regulatory and making sure that those parts and pieces are captured anytime you make a design change. Design change could also mean something that you've changed after you released into production and now you have to change the material or a component or a part or a piece or what have you. Anytime you do that, you need to … you basically evaluate the impact of that change. How does it impact your form, fit, function? What does it do from a regulatory perspective? Do you have to go back and repeat some design and development activities? Does this trigger new design and development inputs?

All those things are factors as part of design and development changes. And then another new clause, design and development file. That's right. ISO 13485:2003 did not have a requirement or

an explicit expectation for having a design and development file. 13485:2016 has now made this an explicit requirement. Many of you are probably capturing these details already. The FDA correlates this as a design history file or DHF.

So yes, both FDA and ISO now require a design development file or DHF for your design and development activities. Other clauses that have significant impact. Big ones here are purchasing related clauses. 7.4.1, 7.4.2, 7.4.3, these all relate to purchasing, supplier controls. Again, we see that concept of risk-based. When you're identifying suppliers and where are you going to buy and purchase materials, components, services, whatever the case may be, you need to be using risk-based decision-making processes on those suppliers that you're using. And depending on the risk that that component or that material or that service poses in your finished medical device is directly commensurate with the level of control and scrutiny and monitoring that you need to put in place for your suppliers.

I've implemented approved supplier list. I've implemented supplier evaluation, monitoring, qualification, the whole gamut from a supplier management perspective and oftentimes we've implemented those approaches where you're doing some sort of evaluation on the criticality of that particular supplier. The expectations are being wrapped up. You need to have appropriate controls in place which may drive you to do more activities as far as supplier qualification and monitoring. You may need to do more work on supplier audits and things of that nature.

So again, what you do needs to be defined, needs to be personalized and it needs to be directly commensurate with your risk that that material, product, service that you're buying poses to your medical device.

So you can see how all this stuff is starting to feed together. It's a continuum. It's a total lifecycle process. So let's shift gears a little bit and start to talk about the importance of addressing the changes in ISO 13485 and doing so sooner rather than later. So again, risk-based QMS.

This is the world that we need to all start living in. The world in the regulatory environment certainly in the medical device industry has absolutely shifted to risk-based approach. If you recall, if you're ever part of that webinar that I did with the Medical Devices Group and Joe Hage about a year or so ago where we talked about risk management, I believe I predicted that risk management would be the single biggest area of focus for regulatory agencies in the medical device industry for the next several years and we're certainly in that era right now.

When you go to a conference or an event where FDA speaks and the FDA speaker uses a risk management and risk-based approach and risk-based QMS and that's part of what they're speaking about, we should sit on the edge of our seat, take note and pay attention because FDA

is saying this, other regulatory bodies are saying this. This is where we need to be making sure our companies are moving as well.

And really, it's all about making sure at the end of the day we're making medical devices and medical devices sometimes save lives and they certainly improve the quality of life. And it just makes good sense. I mean from a business perspective that the products that we design, we manufacture and that we sell and are used that they're safe. That they're effective. And we want to make sure that we've mitigated risk out of our products. It's just common sense. That's why I got into the industry. I suspect that's why many of you are in the industry.

So just take a moment and pause and think about what if your product that you're designing, you're developing was used on your Mom, your kid, your grandmother, your grandpa? This is why we do this folks and I don't know about you but eliminating or reducing risk as much as possible is pretty important to my family and I'm sure that it is for yours as well.

Really, it's all about better processes. If you have a well-defined approach, a well-defined methodology, it should be something that allows repeatability. It can reproduce consistent, somewhat predictable results. So this goes across the entire quality management system to make sure that you know that your team, your resources, your infrastructure, your personnel can file these processes and procedures that you implement in a way that's going to ensure that the products that are being designed, manufactured, developed, so on and so forth are as safe and effective as possible.

The other key thing about this exchange is making sure that you have better alignment with regulatory expectations. That's the key thing. Safe, effective alignment with requirements. So there are a lot of costs that are involved in certainly keeping, managing and maintaining a quality management system. I got a news flash for you. If you were not aware of cost of establishing, maintaining and implementing a quality management system or for some reason you still think that it's optional to you, get out of the medical device industry. I don't want you developing or designing any devices and have any chance of being used on me or my family.

A quality management system is a framework. It is an expected best practice. It is requirements and in some parts of the world, it is the law. So if you're not willing to do that, then you're not willing to do what it takes to be a medical device company. So you should stop listening to this webinar. You should go do something else for the next few minutes of this time that we had allotted for today. But there are cost that are involved.

If you already have a quality management system, then you already have ISO 13485 in place and you already aligned with the FDA, the cost to transition to 2016 may not be as significant as a company that has nothing in place. And please, please, please if you already have a device to market and you already have regulatory clearance and for some reason you don't have a quality

management system but now you're suddenly realizing how important it is, please contact me. We'll get you squared away as quickly as possible. It's better to do it now than never at all. Because I can assure you if you have an inspection or an audit from a regulatory body, that's not going to be a fun experience. That is going to be a very very expensive endeavor for you to get things corrected and you're going to have a black eye when it comes to regulatory perspectives. But it's very important that as you build this quality management system, you want to make sure that you do so in a way that is appropriate and the right size for the type of company that you are and you want to make sure that you have alignment with regulatory bodies because guess what, those are the resources that are going to come in, look at your compliance and asses your quality management system and make sure that what you have in place passes muster and generates a documentation and records that are standard.

Now, as you consider the state of your quality management system, there are ways that you can optimize some efficiency and yes it is possible for software to help simplify your compliance efforts. Especially when there's a software solution such as greenlight.guru that's been designed specifically for this challenge. We have built this product, this platform to align with FDA regulations, to align with ISO 13485, yes even the 2016 version.

To align with ISO 14971. To build risk-based quality management system and approaches that's embedded into the greenlight software platform. And part of the greenlight platform is about what we call the Smart 5-Phase QMS Methodology. And to go into just a little bit of that, there's an approach to this. First you're going to scope out the initiatives from a quality management system. You're going to start to go into the make phase of your quality management system efforts and bite off and build and bootstrap your quality management system as you go through this process. You're going to get to a point as you're developing your devices where you're going to send those off for regulatory clearance and approvals. You're going to get that authorization as part of that approved phase and then you're going to move towards the release of these devices into the marketplace and then all along the scope, make, approve, release phase, you're building your quality management system or finding a quality management system and once you release, you're going to track.

A big key part as defined in ISO 13485 is this idea of continuous process improvement. This idea of a continuum or a lifecycle. Not only from a product level but also from a company level. Also from a quality management system level. So there is an expectation that you're tracking and monitoring and maintaining your quality management system over time.

Key thing about your quality management system is you want it to be bulletproof. There's a few components of making sure that your quality management system is bulletproof. It's three prongs. People, processes, technology. People, that's really you. The people who are willing and

investing their time, effort and energy to participate in webinars and events like this. That's key. That starts the whole process.

Process, that's another key component of establishing a bulletproof quality system. Things like being aware that 13485's changing, understanding that you need to have a smart methodology in place in order to identify the impact and the gaps of those changes and how it's going to affect your company. And then technology, this is what I'm about to dive into. This is where greenlight helps you as part of that three-pronged approach.

But it's important to implement a bulletproof system because we've talked about how impactful this is from a legal perspective. If you're a medical device company, it's required. I know it's going to help you get to market faster. If you do this the right way, a quality management system actually aids you and helps you in getting to the market faster. It do so in a way that's just overall smarter and more risk adverse and do so in a way that allows you to streamline efficiency throughout the entire process.

It allows you to focus on what's important to that medical device rather than filling out ten extra forms because your inefficient process says that that's what you have to do. So you remember a moment ago when I talked about some of the changes in the design and development clauses of 13485. Now there's a requirement for traceability. Traceability is so important at every step along the way. And this idea of objective evidence means that you've got documented records, documented results and if you have that traceability component and the objective evidence, then you've got the keys to the kingdom. You have everything that you need when it comes to quality management system or quality records and compliance as such.

I had a manager tell me many many many years ago that if it wasn't documented, it didn't happen. And if you've ever been across from an ISO auditor or an FDA inspector and you're asked to answer or address a particular question or comment that comes up, they're always going to ask court documented objective evidence. They will never just take your word for it.

So that's a key concept. You have to have the documentation in place. And you have to have the assurance that that is a spot where you know where you're going to find it. It shouldn't be buried on somebody's desk. Sometimes you think about traceability and documentation and how long this can take.

Yeah. I understand that but it certainly feels that way. And if it feels like it's too complicated to address traceability and too complicated to address your documentation then you definitely need to get a hold of me. Contact us at greenlight.guru. Request to talk to somebody because if it's taking too long and it's too complicated, your system needs to be overhauled and we can help.

Because let's be real. I mean you're professionals. You are very smart people. You're more than just a person that can push paper out. And Joe, I meant to point out here. I think those guy's nostrils in this picture are bigger than the beard I had last year when I did that risk management webinar.

But anyway, you need to focus on what you do best. Whether that's designing products or addressing regulatory submissions or managing your quality system. Focus on those things not just being a paper pusher. Because this is why your companies need to improve. Paper is very very expensive and it's amazing to me that even in the year 2016 that more companies have paper-based quality management systems in place and documentation systems in place than any other type of solution. That's crazy. And I think there's this conventional wisdom and know this, conventional wisdom is always wrong.

Conventional wisdom says that a paper-based quality management system is the cheapest and the easiest and I'm telling you folks. It's just wrong. It's just dead wrong. It is not. We have case studies. We have documented evidence at greenlight.guru that will prove to you that paper is by far in a way the most expensive.

Don't just take our word for it. There have been organizations such as LNS Research who have been evaluating all of the best practices when it comes to quality management systems and health companies do this and what LNS Research found is that those who still have paper-based systems in place are the lowest level of sophistication. They're ad hoc. They're still trying to hack everything together.

The market leaders have realized paper is not the way to go. The market leaders have realized electronic quality management systems designed for the medical device industry are the way to solve this problem.

So with the paper-based system, you're going to have missing documents. You're going to have missing records. Your document revisions are going to be out of sync. You're going to have things that are lost can never be found. I can guarantee it. And nothing is more painful than sitting across from an auditor and being asked to produce a record and not being able to find it. It will happen to you.

With a greenlight.guru experience, it's impossible to have a procedure or document record be published and have missing signatures. We've designed the workflow to ensure audit success. Plain and simple. It's your best case. It's your best situation. So why not take advantage of that?

We make sure that all of your documentation and records, your procedures, your forms, everything that you need to control is stored under one roof on one location. A single source of truth. We've integrated workflows for design control and risk management. So all of the things

that go through design and development and risk management align with one another and oh yeah they meet 13485 and they meet ISO 14971 and they also integrate with your entire documentation and recordkeeping system.

So it's really pretty simple. If you're comparing greenlight to paper, there are ten ways that can save time by using a greenlight.guru approach. I'm not going to read every one of these. You're smart people. We already know you could do more than push paper around. You're designing some of the best technologies in the world today to save lives. But simply put, let's keep you back to doing that rather than trying to figure out where that red folder is on Tommy's desk or why Mary … what happened to her work when she's on vacation next week. Where is all that paper? Where is it going to go?

Let's get you focused on prioritizing work. Making sure that you're focused on traceability. Making sure that you're designing medical devices that are safe and effective. Just to give you some glimpse. You've designed a whole new fresh user interface. 2016 software designed for medical device professionals that allow you to easily and seamlessly manage workflows, be able to see where documents, records are in the system.

So …

**Joe Hage:** Jon, just to make a housekeeping note, we're almost at the top of the hour. I know that you're almost finished. We have a couple of questions in the queue. For folks who need to drop off at the top of the hour, know that I've already uploaded the slides on the website. I'll be sharing that link in a moment. If you all go for it at once, my site will crash. Apologies in advance. And we are going to record beyond the top of the hour so Jon, if you can stay on just a little bit to answer some questions, we'll continue and if you do have to drop off, I'll send you a link to them so that you can hear what everyone had to say.

**Jon Speer:** Alright. And do stick around for a couple of minutes if you're able to so that way we could be sure to get you that QMS audit checklist that we prepared for this audience. And I just have a few more slides, few more opportunities or challenges that you're going to run into using paper-based. You're going to have a hard time with traceability. For those of you that have built traceability using like a spreadsheet, try integrating that with risk management. You can't do it.

I mean okay, sure some of the contrary on the audience will try to prove me wrong and write some macros that would work only for you but it's just really limiting your ability to scale and grow your business. It's time consuming. It's spending time on low or no value add activities.

So on greenlight, we focused on a workflow that aligns with ISO 13485:2016, that aligns with FDA and allows you to manage and maintain and focus on that traceability component that's becoming more and more important and expect it from a regulatory perspective.

So there's a lot of problems with some of the other solutions that are out there. They're hard to use. I mean paper is hard to use. Trying to keep file cabinets manage and maintain server-based documentation, other legacy battleship solutions that are out there. They are not designed for the needs of a medical device professional. And so that's something that I want you to keep in mind. They also don't even know what ISO 13485:2016 is. They're not even aware of that yet and they certainly do not know how this is going to impact your business the way that we do.

So keeping track of design controls and risk management, it's about a continuum. It's about knowing where your product is at various stages and being able to identify the risk and reduce and mitigate that risk throughout that entire product lifecycle.

So when you combine the best practices that we have in place at greenlight.guru, aligning with all of these regulations that I've mentioned to you already. FDA 21 Part 11, ISO 13485 and ISO 14971 with the medical device professionals that we have on the greenlight.guru team, implementing 13485:2016 is going to be a breeze. All you have to do is go to greenlight.guru, click a button, request a demo and we're going to have a fantastic discussion. We're going to help make sure that your compliance with 13485:2016 is as simple as it can possibly be.

Remember when I talked about a bulletproof quality management system. People, processes, technology. As I said, you guys are the people. You've invested your valuable time to participate in today's webinar. Your processes, yeah we have the smart 5-phase QMS methodology that we'll work with you on. Yes you have processes that are fine and the third part of that piece that's vital to you is the technology piece. And yes, that's where greenlight.guru can come in and be an asset to help you gain some horsepower and efficiency in your efforts in your quality management system.

So there's five steps to get going. Number 1 as I mentioned, you got to get a copy of this ISO 13485 standard. It's $155. You got to buy it because without it, you have no idea what the expectations or requirements. Know that there are differences between 2003 and 2016. And this is pretty well defined in the Annex A of the 2016 standard. It's not as simple as waking up tomorrow and just flipping the switch and thinking that you can be good to go. You will have to make improvements to your quality management system.

That leads me to number 3. Conduct a gap analysis of your existing quality management system versus the ISO 13485:2016. And if you want that free QMS audit checklist and you want to schedule your free 30-minute strategy session, here's a link to do so. Greenlight.guru/qms-audit-checklist. Click that. Sign up. You'll get the checklist. You'll get a free 30-minute QMS

strategy session and we'll help get you on your way to ISO 13485:2016 compliance. The fourth key step, get a hold of your registrar. Find out what their timeline is. That's going to be a key. And then number 5, make sure you establish a quality plan based on the results of your gap analysis and your registrar timeline.

So again, you want that free checklist. It defines a roadmap for FDA 820 as well as ISO 13485:2003 and ISO 13485:2016. You have all three versions. They're all contained in one simple easy to follow checklist. All you have to do is go to greenlight.guru/qms-audit-checklist.

So key takeaways. The reason for the change of 13485 is really about increasing the expectations for medical device companies. Making sure that you have risk-based methodologies and approach in place. Aligned with regulatory expectations such as programs like the medical device single audit program which is expected to roll out in 2017.

So it's about better visibility and alignment with those expectations for the medical device industry. Again, take action. Find somebody. Put them in charge. Make them take action as far as getting you where you need to go from compliance with 13485:2016 and follow these five steps.

So, Joe.

**Joe Hage:** They are lined up with questions.

**Jon Speer:** Alright. I'm ready.

**Joe Hage:** On greenlight.guru, Sarah asks, there is a startup program. We're not a spin-out of a named incubator. Oh pardon me. Probably we are now a spin-out. Is it possible to apply as a startup?

**Jon Speer:** Sure. Absolutely and Sarah, the best way to do that is to take that link that you see on screen and click that link. At least get that free checklist at a minimum. We'll get that 30-minute conversation scheduled with you and we'll learn a lot more about your startup and how the greenlight platform can help you.

**Joe Hage:** Peter asks, is there a new approach with respect to QBD Six Sigma techniques and SPC continuous process verification?

**Jon Speer:** Well, I'm not sure that the specific details appears questions but you know, QBD and Six Sigma, these are all quality methodologies that are used to analyze processes. I mean there's a lot of parallels between like a six sigma approach. Six Sigma uses the DMAIC approach which is pretty much in alignment with the ISO 13485 methodology of plan, do, check, act as well as some alignment with the smart 5-phase QMS methodology that we've established at

greenlight.guru. I don't know that there's a new methodology or tools per se. We've evolved the smart 5-phase methodology to basically meet the needs of the medical device industry and align with FDA and ISO 13485.

**Joe Hage:** Robin asks, is there an anticipated date for harmonization in the EU for this guidance?

**Jon Speer:** You know Robin, it's an excellent question. Anytime you're talking about legislative and regulatory bodies, it's a crap-shoot. I mean the only thing that I'm certain of is there's an election in the United States in early November that aside from dates as far as when legal bodies and regulatory bodies and legislative bodies are going to harmonize something, I don't know that that's been published that I'm aware of. I know also in Europe there is significant changes happening to the medical device directives and IVD directives. These are becoming regulations in Europe. I've heard that that's anticipated to be going to full effect as soon as this year but could even creep into 2017. So I don't know that that date's been set.

**Joe Hage:** Eckhart asks, are you able to name some companies who are early adapters for better engineering efficiency and live under the new 13485 regime?

**Jon Speer:** Eckhart that's an excellent question. I'm going to confess. I'm not aware of any company off the top of my head who has implemented and been certified to ISO 13485:2016 yet. The practice varies from one registrar to the next. So I would recommend if you're not certified, I would recommend contacting some of these ISO registrars. I mean there are several out there. If you need a list of who those options are, get a hold of me. I'd be happy to suggest a few contacts. But they won't be the best guidance to companies who have gone through the certification process.

**Joe Hage:** My buddy Rick Stockton is on the line and you met him at 10x. He asks, as a medical designer consultant, pardon me. As a mechanical designer consultant, what is my best path to preparing to have design documentation that is most readily transferrable to my client's QMS?

**Jon Speer:** Oh wow. I was waiting for the twist to the question. Did you tell him to ask that question Joe?

**Joe Hage:** Why is that like a lap for you? Is that what you wanted?

**Jon Speer:** No. All these questions have of course nuances but the interesting twist to that is if you're responsible for designing development activities, it's important that medical device companies realize that even though they may outsource that as a service to a company like Mr. Stockton or is he a doctor or a mister? I can't remember. He's pretty smart.

**Joe Hage:** Mister. Doctor.

**Jon Speer:** Mr. Dr. Stockton, the expectation might be outsourced to a company. The medical device OEM, the company who's putting their name and label on the product and selling that under their brand still needs to adhere to and ensure that they have design and development and files and design history files that show with objective evidence and documentation that the process has been followed.

So if they've outsourced that to Mr. Stockton then they should be expecting that he's able to provide objective evidence to that. Now there is a bit of a … and I'm sure Mr. Stockton is going to do that as well. Make sure that his process is in place aligned with design and development and design controls, best practices and deliver that as a package to the company. But it can be sometimes companies look at this as, "Oh well I hired a supplier to do contract design services or a contract manufacturing services. So as the medical device company, I kind of wash my hands of bit and I don't have to do anything more about that."

Remember when I talked about some of the changes to the purchasing and supplier controls, there's an expectation that you identify and assess the risks that those suppliers provide because they're providing you with services but you need to make sure that you've done the proper due diligence, qualification evaluation of the suppliers and that you get the documentation and objective evidence that you need.

Remember, you're going to be sitting across from the auditor or that FDA inspector. So make sure that you have the proof and evidence at your fingertips.

**Joe Hage:** I'm going to give you a special succinct challenge because we have at least a dozen or two more questions and we're running short on time. So with that in mind, JD asks, is there a gap analysis available comparing ISO 13485:2016 and 21 CFR 820?

**Jon Speer:** There is. And JD, it's very very easy to do at this point. You see that link on your screen? Greenlight.guru/qms-audit-checklist? All you have to do is click that and we'll get that to you. It's a special gift to the listeners of this webinar.

**Joe Hage:** Sarah asks, if you make devices that do not qualify as medical devices that is used for the environment or for animals, do you have to conform to the ISO standard for all your products including design controls?

**Jon Speer:** Well, ISO 13485 is … sorry. You're asking a very interesting question. ISO 13485 is specific to the medical device industry and I could speculate a few twists and turns on Sarah's question. I don't know if her company has any medical devices at all or no medical devices at all but I'll answer it the first way where their company has a portfolio of products. Some of them are med device. Some of them are non-med device. Some of them maybe for other uses.

If her company has put in place and is certified to ISO 13485, the expectation would be that their quality management system adheres to that and that their company follow their quality management system. So that's the first way I'll answer that.

The second scenario is Sarah's company has no medical devices. They only focus on animal and non-medical device applications. Well, 13485 may not be all that applicable. It may be something that she wants to put in place because it's a pretty good standard that defines best practices. She may also want to consider something like an ISO 9001 if she has zero medical devices in her business. And if you have a quality management system, again, the expectation is that you follow that. So for design control and design and development, that's got to be dependent on which version of ISO you put in place and whether or not you're under the jurisdiction of FDA or other regulatory bodies.

**Joe Hage:** Eliot asks, with the increased focus on risk management of products and processes, is it your understanding that there would need to be a risk analysis and changing from one method to another? For example, switching from FTA, pardon me, to FTA from FMEA?

**Jon Speer:** Yeah. Eliot that's a really insightful question. So risk management as a practice there is really … there's an overview that describes the different phases and stages of risk management. Starts with planning. Goes through analysis, assessment, evaluation control, risk reduction, so on and so forth.

As far as the items that you mentioned, FTA is fault tree analysis, FMEA is failure mode effects analysis. Those are very specific tools that you use to conduct certain steps in the risk management process. If you're only using one of those tools like maybe you only have Fault Tree in place then you're calling that risk management, then your risk management process is not in alignment with 14971. If you only have FMEA in place, your risk management process does not meet ISO 14971.

So you'll be exposed. You'll be something that you want to sure up and clear up if that's the case. But as far as being able to use Fault Tree versus FMEA, I would expect that you will have a toolbox so to speak that list a number of different tools that you may use for various scenarios and cases. You want to pick the right tool for the right situation. Don't shove every single risk management scenario through one toolset but do make sure that you have an overarching approach when it comes to risk that aligned with 14971 and that's the key thing.

**Joe Hage:** Bill asks, can you comment a little about the ability for your software to meet electronic records requirements in both the US and Europe.

**Jon Speer:** Bill, we got you covered. I mean that's the simplest I could put it. The entire platform is built around the best practices and expectations when it comes to Part 11 when it comes to

electronic recordkeeping, electronic signature, revision control, all of those things are baked in and built into the greenlight platform because that's a requirement if you're going to sell a eQMS solution into the medical device industry. You better know what you're talking about. And folks, I want you to understand just because a company sends their Part 11, you need to challenge them a bit. You need to ask the hard questions. You need to ask them what that means to them because sometimes they don't go beyond the service. But here's what Part 11 means to you. You need to have a … I can't do 100% of the Part 11 in software validation for you. Some of that you'll have to do on your end. And one of the things that you'll need to make sure is that you have test, results and protocols and the ability to do some testing on your end to be able to make that claim that your software is validated and yes we have that. We have IQPQ documentation and protocols and test cases. We can set up test environments. We provide that to you. We'll walk you through that entire process.

**Joe Hage:** Michelle asks, how can you integrate this with the paper-based system that's already established?

**Jon Speer:** Michelle, that's a fantastic question. Some of the companies, they're looking at making the improvements and improving their efficiency and some of those companies like you realize that paper is the most expensive process and the most time-consuming and one of the most riskiest approaches. They make that decision each and every day. And so we have part of our customer success team, one of their challenges with you will be to establish a quality plan. Just those five steps that I mentioned earlier. One of those steps is determine scope, determine the gaps, assess the situation and so we'll put together a quality plan. We'll work on a transition and moving everything from paper into a greenlight.guru platform so that you can use that paper, start a bonfire and roast some hotdogs.

**Joe Hage:** Sound appetizing. Steven asks, does the new standard have any changes around what FDA calls SOUP (software of unknown providence)?

**Jon Speer:** Yeah the 13485 standard doesn't really go into that per se. I mean there are a lot of hooks so to speak or references to other industry standards like I mentioned the 6366 from usability 6304. There's references there from the software design and development perspective. Validation is expected as well.

So there are some expectations but nothing explicitly defined quite to that nature.

**Joe Hage:** Okay. We have a couple of questions so I won't read them but they all relate to how 9001 and 13485 relate to one another and are there conflicts?

**Jon Speer:** Well I mean generally speaking, there … it used to be that ISO 9001:2008 and ISO 13485:2003 were very much in sync with one another. Almost clause for clause. Something

happened in 2015, 9001 changed. It's now 2015 and really the layout, the format of that standard also changed and that was one of the big decision points that the working group for 13485 had to determine.

Do they also change the layout of the 13485 standard to stay in alignment with 9001 or do they continue to stay in alignment with basically the format, the methodology, the layout of 13485:2003. And the decision was made to stay in line with 13485:2003.

So once the format is a bit different from 9001:2015 to 13485:2016. However, 2016 does have an Annex B in that standard that basically describes and defines the similarities and differences. So there is a roadmap in the standard.

**Joe Hage:** Okay and then for risk management, are both now … I don't have that right. On risk management, is product risk management and product project risk management both covered during the entire development phase?

**Jon Speer:** You said product and process?

**Joe Hage:** Product and project.

**Jon Speer:** Oh project. Oh okay. Products, that's very much an expected behavior with respect to making sure that your processes meet ISO 14971 and you're ensuring that the product is safe and effective. As far as project risk management, that's really more of a business approach per se and technically speaking, that's not required or covered as part of ISO 14971 or even ISO 13485 per se. However, I would as a product manager, a person who's done this before, I would highly recommend that project risk management be incorporated into your processes. It's just a different methodology.

**Joe Hage:** Okay. I'm going to have to make this be the last question. There are at least a dozen I didn't get to. Jon, while I'm doing that, why don't you go ahead and put up your email address on the screen so people can write you directly and Jon will get a copy of everything that you have asked. So they'll be able to follow-up with you directly.

Sarah asks, obviously all the changes to 13485:2016 are important but after conducting the gap analysis, is there an area or two that you would prioritize as being most critical for a successful transition?

**Jon Speer:** Sarah that's a really really insightful question and Joe, while I buy myself some time to think about Sarah's question, my colleague Nick has said that he put my email address in the chat window so that if anybody wants that, they can do so and for those of you that are taking notes, it's [jon.speer@greenlight.guru](mailto:jon.speer@greenlight.guru). But Sarah, I would say the big thing is really that gap analysis is going to be key. Because I don't know what your current process is. I don't know how

you do with respect to compliance. I don't know if there have been issues in previous audits and inspections before. So those are going to be your guide. I would say your internal auditing process, your external audits, those are all going to be insightful to give you some tips and pointers of which areas are going to be most impacted by this transition to 2016.

I could tell you right away, risk management is obviously by now one of those areas that are going to be key and one of those areas that many many companies need to improve upon as far as making sure you have continuous risk management throughout the entire product lifecycle. That's one of those areas that tell us apart a little bit. Most companies are very good with risk management during the design and development process. Not as good once the design transfer happens.

So that would be an area and then this other area that emphasize today's traceability. Making sure that you have traceability of all of your design and development activities. That's key and a lot of companies struggle with that approach which is clear when you think about FDA, number 1 reason for 43 inspectional observations still to this day, 2016 is related to design control. So keep that in mind.

**Joe Hage:** Jon, thank you for a great event. We have a full 50% of the people who signed up still online. A half hour overtime. So you offered a lot of great information and we have recorded this. We'll make it available for everyone and any final thoughts Jon?

**Jon Speer:** Well just to say Joe, anybody that asked the questions that we didn't get to today, feel free to contact me. Again, it's [jon.speer@greenlight.guru](mailto:jon.speer@greenlight.guru) and you can find out. If you didn't get my email address, jot it down. Go to greenlight.guru. Go to contact us and submit your question there and I'll be happy to respond to your question as best as I possibly can, okay?

**Joe Hage:** Jon Speer ladies and gentlemen. Thank you everyone for joining us. We'll see you online soon. Bye for now.