“A Risk-Based Approach to QMS Ahead of ISO 13485 Changes”

Presenter:

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Joe Hage: Hi, this is Joe Hage. As of this recording we have 296,000 members worldwide. And one of the reasons the group continues to flourish is because we have members like Jon Speer, who's the founder of Greenlight Guru. And he's going to share with us information about changes in ISO 13485. Hello Jon?

Jon Speer: Hi Joe, how are you?

Joe Hage: Good, thank you. Now Jon is going to show a picture of himself in slide two I think and it is false advertising because at the end of this presentation he's going to show another picture of himself where he's got this amazing beard. But enough about that, you'll have to stay to the end for that. And Jon I'll mute myself and you can get going, okay?

Jon Speer: All right great. Thanks for the intro Joe.

Joe Hage: Thank you.

Jon Speer: Well good afternoon, good morning, good evening. It sounds like we have people from all over the world today joining us for this presentation that we have to share with you on Risk Management for medical devices. Today we've got quite a bit to cover so I'm going to skip a little bit of the details and the background.

I'll just give you enough to let you know that I've been in this industry since 1998. Served in various capacities from product development engineering, to quality manager, to regulatory affairs, and running my own consultant practice and so on.

And about two years ago I had this wonderful idea to change the medical device world forever, and we started a new company called greenlight.guru. And greenlight.guru is a platform solution provider and we help make medical device product development much much simpler. We improve your efficiency;

we help you get to market faster, while improving your regulatory compliance. And we're going to get into that as well as we get to the presentation.

But today I'm going to talk about; the primary topic is ISO 14971. We're going to dive in to the details of risk management. We're going to also hit on some of the things that are changing in the regulatory world with respect to the topic of risk as well. Whether you know it or not, the world before us right now and the medical device industry is quickly moving toward a risk-based approach. And that's evident with what's been happening with the most recent revision of ISO 13485. So we're going to dive into a lot of these things.

As always when you're participating in these webinars if you have any questions please be sure to type those in and into 00:02:36 the onset we will get to those time permitting as quickly as possible toward the end of the presentation. So without further ado I'm just going to dive in.

So some of this is probably review for many of you. Looking at the attendee list I know many of you are in the industry so I'm not going to dwell on reading through every single definition and ISO 14971. I do encourage you if you do not have that standard that that's something that you need to get your hands on. And it doesn't matter if you're in Europe of United States or Canada or Australia or I think I heard there were some people from Qatar as well.

It is evident that what's happening in the regulatory environment is ISO 14971 is emerging very very quickly as the key standard that will drive the medical device industry, not only from a product development standpoint but also from quality systems standpoint, and we're going to dive into that.

Some key definitions I think that are important for you to understand is the definition of risk. Risk is the combination of the probability of occurrence of harm and the severity of that harm. You have to know that definition because that is key and influential as you go through all of your risk management activities, bringing new products to market, dealing with complaints, capita and other post-market issues. You have to have a clear definition of that term risk.

A few other definitions that are important, and as we get into the process these have become a little bit more relevant. Things like risk analysis, risk estimation, risk evaluation, risk assessment, risk control. I mean we're going to hear the word risk a lot of times today.

And I think that if you've been to any medical device industry conference in the past three to six months you probably have noticed that that's a recurring theme. The word risk is thrown around like crazy these days. So it's important to understand the context of all these different variations of risk. What is a risk analysis? What is a risk assessment? What is risk management? And so on and so forth.

it's very important because sometimes when you get into the regulations like for example if you look at FDA, the only spot in the FDA regulations where they even mention anything along the term ... lines of terms related to risk is in design validation. That's part of the design control regulations in 82030. It makes reference to risk analysis.

Now keep in mind that those regulations were introduced into the market back in I think 1996. So a lot has changed from then until now and FDA has made itself very clear multiple occasions and throughout the preamble to the regulations that what they mean when they say risk analysis is risk management. And while they don't come out and say, "You must follow 14971," FDA is very clear and says, "14971 is a harmonized standard and we endorse it, so you might as well follow it." And that's the same case regardless of where you are in the world. We'll dive in here in a few moments about some of the variations between ISO 14971:2007 and EN ISO 14971:2012.

So let's just get right into it. I'm going to go through kind of a high level overview of 14971. I think it's important for you to know the gist of what standard covers. It covers things like risk management planning, risk analysis, risk evaluation, risk controls, overall residual risk acceptability. It defines the criteria for what needs to be in a risk management report. It defines what you need to do from a production and a post-production standpoint. And it also defines what is involved in a risk management file. So it's very important.

The first piece is Risk Management Plan. So anytime you are to start a new development project or you've got something that you've already launched in the marketplace and now you need to update that particular risk management plan for that particular product, it's very important to understand what needs to go into a risk management plan.

First and foremost one of the things that you need to understand is intended use. And I'm going to speak a little bit here in a few moments about the relationship between design controls and risk management. But I think you all, if you've been through medical device product development you will all understand the importance of that term 'intended use'.

That term 'intended use' is very critical when it comes to product classification with FDA, with European Competent Authorities, with Health Canada and other parts of the world. It's all based on what the intended use of your product is. Well it's also very very important from a risk management perspective. And you need to define that as part of your plan.

The other important concept of a risk management plan is that you're going to identify the risk management activities that you have planned throughout the entire product lifecycle. Now note 'Product Lifecycle' that's the key phrase in that point there. It's not just about the risk management activities that are happening during design and development. It's throughout the entire product lifecycle. Through development, post-production and so on.

And also an important part of a risk management plan is that you need to identify who's involved. What are the roles and responsibilities? Who is the team that is going to be involved in reviewing the risk management plan and risk management activities throughout the entire product lifecycle?

Here's a biggie. The big part of the risk management plan is defining the risk acceptability. I know a lot of times you may have a procedure and that's implemented in your company that if you're following 13485 or FDA's quality system regulations or other quality system criteria, your chances are you have a risk management procedure.

And that risk management procedure likely defines the criteria for risk acceptability. But it's also important that that is included within your risk management plan. You have to define when something is acceptable and when something is unacceptable.

And as we go through this conversation and webinar today I'm going to hit on some of the key differences between ISO 14971:2007 version and also the EN ISO 14971:2012 version. And here's an important point right now and that has to do with acceptability. So if you're following along with, maybe you don't know the difference so I'll give you a brief overview. So basically a few years ago EN ISO 14971:2012 was introduced to Europe as an attempt to basically better align with medical device directives in Europe.

And there were 00:09:17 standard or the normative part of the standard did not change. The only thing that did change in the 2012 version was the addition of three Z annexes. And within those annexes it defined some specific details and I'm going to hit on those as I go through the presentation today.

One of the points in one of these ENXs is this concept of risk acceptability. Always before in the 2007 version and so on there was this accepted concept that you had the acceptable region from the risk acceptability. You had the unacceptable region and then you had this kind of middle zone that many referred to as ALARP or As Low as Reasonably Practicable.

That concept with the 2012 the European version of the standard really went away. And now the expectation is that you're reducing risk as far as possible regardless of where it stands. So that's really important to define within your risk management plan and also within your risk management procedures, especially if you're pursuing products in the European market.

You also need to define in your plan risk control measures. You need to basically make sure that you're verifying those things and that they're effective.

And then you also need to define what happens after you launch your product into the market and you're dealing with production and post-production issues. Like how is that information going to be gathered so that you can continually update the risk management activities throughout the entire product lifecycle. I mean are you going to leverage complaints? Are you going to look at complaint databases and things like FDA mod and adverse events and vigilance reporting? Those are all things that you need to define within you risk management plan.

All right so I'm going to ... I've been talking really fast right now but I want to pause for a moment and give you all a chance to take advantage of a free offer that we're providing right now. And that free offer is you can get a risk management plan template. And all you have to do is go to the URL that's listed on the screen, greenlight.guru/risk-webinar-offer. It's really free, all you have to do is go to that website, click the link and you can download that file right away.

All right so I had hit on, a few minutes ago, the importance of the Risk Acceptability Matrix and I want to dive into that a little bit. As I mentioned the beginning of the talk, I'm a co-founder of greenlight.guru. We are a software solution provider for the medical device industry. One of the things that we just

rolled out just a few weeks ago is a risk management feature set. And yes that risk management feature set does follow ISO 14971. Even if you're going along with the 2007 version of if you're following the EN ISO 14971:2012, it accommodates both versions.

But Risk Acceptability Matrix is one of those things where if you go back to the definition that I had on about risk, probability of occurrence of harm and the severity of harm. This is a very routine allay to define risk acceptability where you have severity on one axis and you have your probability on the other axis.

The terms and definitions that you have for each of these scales that should align with the type of product you have and be commensurate with what's expected to happen for the different things with your particular products.

Like you can see probability you want to define different levels. These scales they can be adjustable and like within greenlight we give you options. You can make a three by three matrix or you can make a four by four or a five by five. It's really up to you to define what those different levels are.

My word of caution for you is to keep it as simple as you possibly can. Sometimes people want to go to 10 point scales where they'll have 10 different choices for severity and 10 different choices for probability. I've lived in those kind of environments where that's what we had in place from a risk management standpoint. But I do caution you to not have too many choices because it can get very confusing. Keep it as simple as you possibly can.

But you can see here within a risk acceptability matrix you need to define where you are ... Where things are acceptable, where things are unacceptable, and what requires a risk benefit analysis. You'll see the RBA acronym that's reference to Risk Benefit Analysis.

Joe Hage: Jon it's Joe, I'm going to interject if you go back to the last slide. My friend Jim asks, "How might the matrix like this be for a software-only device?"

Jon Speer: Joe I missed a couple of words, do you mind repeating the question?

Joe Hage: Of course. How might a matrix like this be for a software-only device?

Jon Speer: Okay that's a great question. A software-only device I mean if this software still uses a med device it's still important to identify the risk associated with that particular medical device. Then again we've got two scales here we've got the probability and we've got the severity. So if that software were to fail, what would the severity of that be? Would it cause death or would it cause serious injury or would it just be a nuisance? Those are typically things that you would define as part of your severity scale.

Then as far as the probability often times probability occurrence likelihood no I'm not a statistician so don't judge my blending of these terms. But often times in the industry we use probability, likelihood, and occurrence interchangeably. And from a software standpoint if you look at a particular hazard,

hazard is a potential source of harm. If you look at how often that happens then that can help you identify from a probability standpoint.

So risk management 14971 00:15:08 risk management really not specific to whether your medical device is software or hardware, electrical or anything it doesn't dictate it's for all medical devices.

Okay, so now this is a ... I want to hit into some of the more details. We're going to start diving into some of the process. So far we've kind of stayed at the 30,000-foot view but now we're going to drill down into a few more of the details.

This particular image that I'm sharing with you right now, this comes straight from the standard. It does say ISO 14971:2007. Note that this is the same figure that is also in the 2012 version. Remember there is no difference between the normative part of the standard. The only thing that's different between 2007 and 2012 are the particular annexes that support the interpretation of the standard.

But as you can see from this chart there's kind of three ... four or five main charts I guess. Not three, four or five but ... So we've got risk analysis and risk evaluation. So those two thing make up what's commonly referred to as risk assessment. I reminded you earlier that there are some important terms and definitions. This is where all these terms sometimes get used interchangeably. I mean sometimes somebody says 'risk analysis' and what they mean is 'risk assessment'.

And sometimes somebody says 'risk control' and what they mean is 'risk management' and so on. So these really get mixed up a lot so it's very very important that when somebody uses the term that you understand exactly how they use it. I would encourage you to all within your organizations start to adopt the common terminology that is defined within 14971. If you don't do keep in mind that the regulatory agencies, FDA and others, they are using the terminology in 14971.

They may say to you, "Show me your risk management report and you may send them a risk assessment. And they're going to be asking you all kinds of questions about the information that is missing because they asked for something different than what you provided them. So the terminology is very very important.

So after you do risk evaluation then the next big chunk is risk control. And it's interesting; I'm going to describe this in a very linear process. And it's just like design controls and product development and so on. It's always described in a straight line but it seldom happens in a linear fashion. So it's very important to understand that there is some hierarchy that is expected but it's important that you capture all of these different parts and pieces from a risk management standpoint. And going in a straight line doesn't always make sense.

So once you have risk control then ... Risk control really is about reducing the risk that is evident as part of your product. And we're going to talk about this here in a few moments but it's very important for your risk management and your design control efforts to be in sync with another. In fact, I might even postulate that those are two slightly different perspectives of the exact same process. And I'll dive into that here in a few slides.

But risk control is about reducing the risk. Once you've done that then you need to evaluate the overall residual risk acceptability and that's for the entire product. So up until this point what you've looked at is individual risk associated with particular hazards and hazardous situation. And now at this stage we're looking at all of these things together, the entire 00:18:45 in its entirety and determining if the overall residual risks are acceptable or not.

You define all of these details in a wonderful risk management report. And then from there you're continuing to monitor, manage, mitigate, address any risk from a production and a post-production standpoint once you've launched into the manufacturing and sales of your product.

This chart's a little busy. Don't worry about reading every single block at this ... in this particular view; I'm going to break it down into digestible chunks here in the next few moments. But this also comes from the standard. I encourage you to not reinvent the wheel. Many people when it comes to risk management they think that they have a wonderful approach and idea, and you might be right. But I would encourage you to as best and as quickly as possible to start adopting what's defined within 14971.

And not just regurgitate what's stated in the standard but put it to practice, put it to use. Make sure you understand what all these steps mean and interpret how your organization is going to follow these things. The more in alignment you can be from a 14971 step it's really going to make not only your product development life easier but also your quality system life easier especially with the coming changes of ISO 13485.

So let's dive into some of the details. I'm going to spend first a few moments on risk assessment and remember risk assessment is the combination of risk analysis and risk evaluation. And I like to bundle these things together because there's a natural flow. If you think about when you start a project and remember when we defined our risk management plan, we're identifying the intended use of that particular product.

And part of the intended use is how is your product going to be used? What are you going to market is as and so on. And as part of your risk analysis you need to identify what are foreseeable hazards. What are things ... And hazards are a potential source of harm, so what are all the hazards that can happen for your particular product?

Now a lot of people, I'm going to say right now, they misuse this risk assessment. One of the things that a lot of people are doing for risk assessment is they're doing an FMEA. And while you may have FMEA in use at your organization, and I'll just remind you FMEA Failure Mode Effects Analysis. FMEA is not risk management. Now FMEA is a good tool for reliability but FMEA evaluates failures. What happens if something breaks? Now this is another key point where the term matters.

The definition for hazards is a potential source of harm. It doesn't say that something had to break for it to be a source of harm. You can use a medical device entirely correctly and there will still be hazards. FMEA is about when something breaks, it's a single fault failure. So that would imply doesn't happen the way it's supposed to. This is one of the flows of using FMEA and saying that you're following 14971.

But after you've identified the foreseeable hazards you need to estimate the risk for those hazardous situations. And remember risk is the combination of probability of occurrence of harm and the severity of that harm. And that's why that matrix that we showed just a few slides ago was severity on the X axis and probability on the Y. This is where you start to estimate that.

And then from there you need to determine whether or not risk reduction is required. And this is when you define where those acceptable regions are. Now if you're operating in an EN ISO 14971:2012 environment, all risk regardless of where they are reduction is required. Now if you're in a 2007 world as far as the standard is concerned, you need to define where the acceptable region is, the ALARP region is, and the unacceptable region. And determine what to do next based on your definition of what is acceptable from a risk standpoint.

Now I'm going to dive into risk control and all I've done is that I've split out the different sections of that busy chart that I've showed you a couple of slides ago into the digestible chunks. So at this point we've made a decision whether or not risk reduction is required. And the way we're going to reduce our risk is we're going to identify these things known as risk controls or risk control measures. Some people refer to these as risk mitigations or something along those lines. Again I encourage you; I actually beg you please follow the terminology that's in the standard. As long you're all speaking the same language it's going to make life a lot easier on this topic of risk.

But you identify those risk control measures. And it could be things like you have to do a specific test. Maybe you have to update a particular design input, and this another key point where risk management ties into design controls. Things like design outputs and design verification and design validation activities, those are all very good candidates for risk control measures so keep that in mind, there is tie into the design control side of things.

Once you've done that, identify what your risk control measures are, then you need to determine if you can actually reduce the risk. And if the answer to that question is no, then here's a concept known as risk benefit analysis. You need to, you have an opportunity you can say, "I can't reduce my risk any further." But now you can evaluate the medical benefits that your product provides to the patient versus the risk that opposes. And if you have a rationale to support that decision and your organization is willing to accept the risk associated with making that decision then you have the opportunity to document this as a risk benefit analysis.

Here's another point where the two versions of the standards are different; I want to highlight that. The 2012 the European version of 14971 it requires that you do a risk benefit analysis for every single risk. It doesn't matter if your risk is determined to be acceptable, if it's reduced as far as possible or what have you. You have to do a risk benefit analysis for every single item.

All right, so let's go back to our flow chart kind of keep walking through that and see how things are going here. So risk reducible if the answer to that is yes then you need to implement those risk control measures. And then you need to make sure that you verify that those risk control measures are appropriate and are actually doing what you said that they were going to do from a risk reduction

standpoint. And then from there you're going to look at the residual risk, you're going to evaluate that severity, you're going to evaluate that probability again. And then it's possible when you implement risk control measures that you have possible introduce new hazards or hazardous situations. So if that happens then you need to basically go through that process again. You need to identify hazards for those new things that came up and you need to take it through the same rigorous process that we're going through.

And then once you've confirmed that all hazards are identified then you get to go to that next step of the risk management process. Before I get to that I want to remind you a little bit more about what a risk benefit analysis is. This is an important concept, and the big important of this is because of what came out in a European version of the standard a few years ago. Requiring everything, every risk have a risk benefit analysis. And again you're just going to weigh the medical benefits that your product provides versus the risks that are posed right now. So that's an important thing to realize.

All right, so after you've done your risk controls, now you need to do an overall residual risk evaluation. Up until this point we've looked at individual hazards and the risk associated with that. Now we're looking at the entire finished product and determining whether or not that is acceptable or not. So you need to ... Again you'll see that concept of risk benefit analysis that's why I wanted to hit on that specifically a couple of times.

That's going to come in again at the end here where you're looking at the overall product. You need to once again determine how that risk benefit fits into the whole occasion. Once everything has been reduced and acceptable and/or you have a RBA or risk benefit analysis, now it's time to finalize that risk management report.

All right so in that report, some specific details that you need to capture, you want to hit all those risk benefit analyses. You want to make sure that you've addressed all the risk acceptability for your product. You want to make sure that all the activities that you identified in your risk management plan have in fact been addressed and captured and so on. And you also want to make sure that you have the right resources within your organization.

Generally if somebody put you high up in the food chain of a smaller organization it's probably going to be CEO. But somebody who has the authority, the executive responsibility within your organization to basically review and improve and accept the risks that are identified in that particular report.

And then the last big part of the continuing product lifecycle process that risk management is has to do with production and post-production information. You want to make sure that you have the processes in place that can feed into your risk management for your particular product after you've launched into the marketplace.

It's things like making sure your 00:28:39 capered process can feed into your risk management. And that your complaint process can feed into your management. That customer feedback feeds back in and all of these other things that you're using on a day-to-day basis from as part of your quality management system. They all need to feed back into the product lifecycle process for risk.

And as I get, I'm jumping the gun a little bit, but here in a few slides I'm going to talk to you about what's happening at 13485 and why this concept of a lifecycle process with respect to risk is not only important for your product development, design, manufacturing efforts, it's also going to be important for your quality management system efforts as well.

Okay, I've hit on a few points where ISO 14971:2007 and EN ISO 14971:2012 there are some variations between these two things. I'm going to spend a moment or two reviewing those particular differences just to ... I know I added those in the context as we were going through different topics but I wanted to give you a moment to absorb what those things are. And I'm not going to go through every single nook and cranny nut and bolt detail of all the nuances. Just know that if you want some entertaining reading for a couple of days just go to Joe Hage, as you all know he's part of the Medical Devices Group on LinkedIn.

Often times there will be a discussion about risk management on either the main Medical Devices Group or some of the sub-groups like it's common in the QA and RA group that there will be a risk management discussion. But there's some lively reading on this topic. There's a lot of debate. A lot of people are very passionate and adamant about what is and is not required from a risk management standpoint. But just if you have any doubts at all you can always reach out to me and I will be sure to help point you in the right direction. If I can't answer your question I know the three people who can.

Joe Hage: Thanks for the 00:30:53 Jon, I'll put a link to the QA RA group for everyone. I've already added a link to the webinar offer you made and I am getting your slides up live on the website. You have quite a queue of questions here so let me know when you want to take a break for some of those early ones.

Jon Speer: How about we go ahead and hit a couple of questions now Joe?

Joe Hage: Okay, I'll do it. Let's see. Mark asks, "Is the new module able to accommodate strictly quantitative risk management processes?

Jon Speer: I'm not sure I know exactly what Mark is meaning by that. I think I know who Mark is though. That's the interesting thing is Joe because he sent me an email the other day. But the way we set up the risk module in greenlight.guru is we allow you to define the scales for probability and we allow you to define the scales that you have for severity as well. If you want some recommendations we have default descriptions for each of those probability and severity of scales out of the box.

Joe Hage: Okay.

Jon Speer: But it's a fairly standard approach.

Joe Hage: He adds that the latest version of the standard from ISO is 2007. The English version or the EN version 2012 has not been released by ISO. Which you probably know but I'm reading it aloud for everyone's benefit.

Jon Speer: Yeah the standard is known as EN ISO. It's not released throughout the entire world. It is a European-only version. You can only get that standard through organizations like BSI and there are a few others.

Joe Hage: Maya asks, she always has a problem defining probability. How do you define probability?

Jon Speer: Well probability it's always a difficult scale to define. Often times there's an implication that there's some sort of rate or occurrence that is defined or tied to probability. And when you're a brand new ... you've got a brand new device that there's nothing like in the market, it's really hard to determine if how you can have one-in-a-million chance. So a more common practice that's used is try to tie some qualitative descriptions. And I think if you can use some agreed upon within your organization some descriptions that make sense, then ... and assign those particular levels that's going to be really important within the organization.

If somebody wants to have be able to quantify that probability scale, then you're going to have to have some sort of supporting evidence for the values that you estimate for probability. And if you've got a brand new device you can rely on history of use of maybe competitive or predicate devices that may be on the market. You may be able to search things like the more database from FDA and other vigilance reporting channels that exist to try to determine that.

But it really is really difficult and I wish I had a better answer to that. That's why it's very important when you go through risk management that it's not a solo activity. That you have a team representing the various functions within your organization participating in the event. It's good to have sort of voice of the customer if you have can have end-users participating in that that's important too. But realize that when it comes to probability it's the probability of occurrence of harm, it's not just the probability or occurrence and then-

Joe Hage: Let me build on that with Dan's question and then one more and then I'll let you return.

Jon Speer: Okay.

Joe Hage: Dan writes, "I'm used to risk-based analysis being an analysis of the overall product. Are you saying that the analysis needs to be done for each line item, hazard plus hazardous situation equals harm?"

Jon Speer: Yeah I mean if you take a literal interpretation of the standard it's very clear that you need to estimate the risk for each hazard and hazardous situation. And again risk is defined as the probability of occurrence plus the severity or the probability of occurrence of harm plus the severity of that harm. So like I said if you're following the standard literally then the expectation is that you're identifying risk for every single hazard and hazardous situation.

Joe Hage: Then a number of questions having to do with FMEA. One writes, "The matrix is typical for FMEA but not for other models." That's from Robin.

Jason says, "Can you specify the difference between risk management and FMEA process that use similar risk charts?"

So a couple of things, oh and then here's a third. Sebastian, "If not using FMEA how do you objectively quantify risks during assessment and then enter into the matrix?"

Jon Speer: All good concepts and I think I can sum it up with a couple of statements. As I mentioned earlier I mean FMEA it's a good tool but FMEA it seems that something bad happened that there was a failure. If you're taking FMEA literal FMEA includes there's a lot of terminology confusion between FMEA and ISO 14971. But FMEA includes things like failure modes, causes of failure, severity, occurrence, detection.

And I think that that's one of the big differences from FMEA and ISO 14971 standpoint is really about FMEA is a failure mode tool and it assumes there's something broke and now you need to determine what caused that and what is the severity occurrence detection. And usually what's calculated from that is what's known as our risk priority number. The most common practice for an FMEA is to multiply those three terms.

If we go back to 14971 the definition is risk there's nothing about detection and the definition of risk, it is the probability of occurrence of harm and the severity 00:37:19. It's the combination of those two things.

And again risk management is your product can be used exactly as you ... Well basically what I said in that last minute is FMEA is what happens when stuff fails, and risk management is what happens when stuff as medical devices are used. You can have hazards and your product is used correctly. FMEA only-

Joe Hage: So in the meanwhile I am going to entertain the troops with a link to the QA RA group which I've now put out there for the entire audience. This is 00:38:02 saying thank you Susan, thank you very much. I sent a link out to the QA RA group for folks.

Jon Speer: All right Joe can you hear me now?

Joe Hage: I can. Are you on the phone?

Jon Speer: No, I'm not on Nick's computer.

Joe Hage: Okay, well someone might want to dial up just in case but I'll go back on mute and why don't we resume the presentation where you were. Thank you Jon.

Jon Speer: All right, sounds great. All right so let's spend a little bit of time talking about risk management and the relationship between risk management and design controls. Right now we've talked a little bit about intended use and the importance of intended use with respect to design controls and also from risk management standpoint.

It's an important piece because intended use defines how your product's going to be used. It's important because it defines how your product is going to be cleared from a regulatory perspective as well.

So I'm going to show you a chart here that dives into ... This is kind of a flow if you will. I know there is some questions about how do you flow from through a risk management process and what are the various steps. And we kind of hit on that earlier from a 14971 standpoint but this is kind of ... This is a slightly different view of that, and I've shown in here a couple of spots where design controls tie in.

So moving from left to right and throughout the entire process I want to show you how risk management and design control really are the same process but from slightly different perspectives. Both design control and risk management are intended to do one simple thing in my opinion. And not one simple thing not really simple of course but that simple thing is to prove your medical device is safe and effective for the intended use. That's really what you're trying to do from design control and that's really what you're trying to do from a risk management standpoint.

So we have to realize these have very very similar intent behind them. But moving through this flow you can identify the hazard and hazardous situations and then from there there's a tie-in at that point to that different design control. So things like user needs and design inputs. There's a relationship between hazard, hazardous situations, user needs and design inputs.

From there you identify foreseeable events that lead up to a hazardous situation. You define that particular harm what could happen and what is the source. You can see through this flow that there's just this aligns with your product development process or it should align with your product development.

You identify the probability of severity of that harm, you estimate the level of risk is it acceptable, unacceptable and so on. You go through the risk control. I mean again this is stuff we've already talked about from earlier, from earlier slides.

When you get into risk control measures this is where you'll start to identify things like design outputs and design verification and design validation. These are all design control activities. And of course if could be other risk control measures but there's a direct linkage to design control and risk management.

In fact, I was in an ISO surveillance audit about six months ago and the auditor in this case she wanted to see our design control activities. She wanted to look at the user needs and the inputs, the outputs and so on. And then she shifted over and she said, "All right, then show me your risk management," and so we pulled our risk management file. And then she says, "Well why aren't these two things integrated?" And I'm like, "Well they're separate." She's like, "No no no, you have that all wrong. They're entirely the same. You need to make sure that these things dovetail together."

And I think that's very important for industry to understand right now. The regulatory world this was an ISO audit, and I've heard it come from FDA. And it's going to be more evident as the new 13485 rolls out. The expectation is that risk and design they're really the same process. It's like two different sides of the same coin; it's very very important. But you can see how that kind of flows through.

Just a few more points about that. We already talked about the intended use, how important that is between both risk and design. We talked about risk management being a total product lifecycle process.

Well guess what, so is product development. There's the design control piece that happens to bring a new product to market but then once you've launched into the market now you have things like change control and the managing your device past record and complaints and capers 00:42:52. Well guess what, those all feed back into your design control process. So both design control risk need to be handled as product lifecycle processes.

Also very very important that we start shifting towards using risk management as a tool. I've seen some cases throughout my career where maybe risk management wasn't treated as a tool. I've seen plenty of cases where risk management was treated as a checkbox activity. But I'm here to tell you that risk management is not a checkbox activity.

Now I can share a short story. I was a young engineer, I think I was 23 maybe 24, I was working on one of my first medical device projects. I'd gone through design controls, documented my design and development plan, all of my inputs and outputs and verification activities. And I was approaching the point where I wanted to transfer into production. And then I had an oh-crap moment. I said, "Oh crap! I haven't done my risk management activities yet."

So I went and spent the next few hours at my desk and I created my risk management documentation. And I did it all by myself and I got it all done in the course of a couple of hours. And I was proud that I got my risk management activities done. But the problem is it didn't add any value. Risk management is supposed to help you improve the safety and the effectiveness of your medical device. And I learned pretty quickly that it really did suck to spend a few hours doing an activity just to check a box. But I got to check the box but that was the last time that I ever treated risk management that way. And I hope you're not treating your risk management process that way either.

It's very important too that in addition to what you're looking at from a risk management standpoint as you're going through design and development and the manufacturing of your products, other people will be evaluating your decisions that you make from a risk management standpoint as well. Whether you're ISO-certified or you're registered with the FDA or some other regulatory body, there's a good chance that there's going to be inspectors and auditors coming in.

Or it might even be a supplier coming in to evaluate your processes and doing audits and inspections. And guess what, they're going to look at your risk management documentation; hopefully you have it. And they're going to maybe challenge you and make sure that when you went through that process that you understood the value of being thorough and complete with risk management and not just checking a box on your form and saying that you got something done.

So now let's spend the next several minutes talking about what's about to happen with 13485. You'll notice that the nomenclature here includes an X as far as the year is concerned. I saw that recently as this is the ... It's an unknown, it's not entirely clear when the new version of 13485 is going to be live. Most signs are pointing to 2016. And the current version has been there published since 2003. So the way standards work is usually every five or seven years they roll out and they get updated so the 13485 frankly is long overdue for an update.

Now I've done some analysis of the 13485:201X and there are a few I would guess I'll put them in the category of major changes. The big adjustment here for 13485 is this concept of risk. I mean I've only said risk probably 122 times so far in this webinar but 00:46:51 I've already hit on what's happening from the FDA perspective and the EU perspective. Well guess what, 13485 is also evolving to be a risk-based approach, and not only from a product standpoint but also from a quality management systems standpoint.

It uses the premise and the foundation that's been laid by ISO 14971 and just continues to build upon that. And I think that's really really important for you to understand is the risk-based approach is now going to start getting into different aspects of your business rather than just the product development manufacturing efforts that you have underway.

But some of the big areas where that's the major changes from a 13485 standpoint and the next version are things like regulatory requirements. I would say that's probably the biggest driver towards this new revision. Keep in mind the current published version has only been out or it's been out since 2003. If you think about your time in the medical device industry and the regulatory environment, I can speak for myself anyway, a great deal has changed in the regulatory environment since 2003.

And frankly the standard 13485 is really out of date in some respects with what's happening from a regulatory perspective. So there needs to be some catch-up work, and that's really what's driving a lot of these changes.

But there's an expectation that throughout different processes in your quality system things like purchasing and suppliers that you're actually evaluating the ability of your resources to deliver products and components and services and so on that will allow you to design manufacture safe and effective medical devices. So that's really really important part of this new version of 13485.

Some other details that you should be aware of. The term "risk" and "regulatory" in the current version of ISO 13485:2003 is mentioned some 50 times. I think that it blooms to well over 200 times in the draft version that's scheduled for release probably in 2016. I already hit on some of the regulations, better alignment with regulations. But also a lot has changed in the industry as well so the 13485 revision is going to better align with some of the industry best practices. And again this concept of risk, risk-based QMS that's now going to be ingrained throughout.

The other big shift here is ... has already actually. The 9001 and 13485 both of those standards used to be in alignment. And both of those were scheduled to be revised in a similar timeframe and it's two different groups that were working on these different standards. But the 9001 version has actually already been published and it's going in a pretty different direction from what we've seen so far from the draft 13485. So that's important.

So sometimes contract manufacturers who've carried dual registrations, it's been pretty easy up until this point with 9001 and 13485. That will become a bit of a challenge from this point going forward.

A few other details that are important to realize about the changes. It's just given some more flexibility. You have an opportunity to identify different parts of the standard that maybe are not in application depending on better aligned with like design firms and contract manufacturers and other service providers. They may not be entirely applicable across the entire standard but there might be some clauses where they are applicable. So that just gives a lot more flexibility.

And just a couple of other terminology changes that you should be aware of. Things like product quality, well that's now referred to as product safety and performance. Again the concept of risk is pervasive throughout this standard.

But anyway that kind of hits on a lot of details of some of this. But it's an important thing to think about ... Oh I guess I have one more. The other things that have changed again this is more of a regulatory. Things like UDI, the Unique Device Identification there's been a lot of movement since the current version of 13485 has been published. So there's some criteria in 13485 the new version that aligns with the way that's moving as well.

But also some more emphasis on design and development activities especially when it comes to transferring to production keep in mind that risk management and design controls those are product lifecycle process so it doesn't stop once you transfer the production. So ISO 13485 they recognize that and they're making some adjustments to that as well.

It's important to think about what is the impact of this standard and how is this going to affect you. I think the good news here is if you already have 13485 in place and/or are compliant with FDA quality system regulations. I think the overall impact will be fairly minor. I think that assumes that you're starting to move towards more of a risk-based approach. That you really need to emphasize and stress the importance of 14971. That is, as far as I'm concerned, the best standard there is in our industry. It's prescriptive enough and it provides ample detail to help guide you through what is expected from a risk management standpoint.

And the good news is I happen to know of software solution provider known as greenlight.guru that has the only ISO 14971 software solution on the market today. And it's the only software solution that exists that integrates design control and risk management as one seamless process. So if those things are important to you, I'll let you know how to get a hold of me once again here in a few moments.

But the overall impact of this new standard is I think is going to be slight. It's expected to be published in 2016 and there will be a three-year adoption inquiry 00:53:17 which is already ... That's a pretty standard approach for standards like these.

Just a couple of thoughts on risk-based quality management system. What does that mean? Well here's how that is impacted. Things like management review and training and calibration and purchasing and all these other quality management system elements, the expectation is that throughout those processes that you're actually using risk-based decision-making process like in a management review. What happens if something fails? What is the impact? What does that mean? Does that mean you have

to go redesign a product? Does that mean you have to do a recall and so on? So it's really applying that risk thinking to your overall business processes.

Last thing I want to share as I mentioned if you're at all interested in getting a software solution that aligns with 14971 either the 2007 or 2012 version the only one on the market frankly that also integrates with design and development, then here's how you find out more information about greenlight software.

So I appreciate your attention today. Joe I think we have time for a few more questions.

Joe Hage: Well so yes we do, just four minutes to the top of the hour. We will continue to record, we will be asking these questions and we will record them so if you have to drop off we understand but we will continue. I just shared a link to today's slides in the checkbox so you should be able to click through for that. And it also has a link to the free risk management template download.

I guess my first question is for the world, do you guys prefer Jon with the big beard or the small beard? That's a personal question. You're welcome to write your answer in the chat box.

Jon Speer: And Joe this is a picture of our greenlight management team. This is 00:55:16 a lot of old white guys but we've all been around the block before, we've all been in startups and we know what we're doing. So we've got a kickass team behind us that is developing the best software known to man and it's like no experience I've ever been a part of.

Joe Hage: Well Bill wants you to discuss documentation of risk management within the context of post-release engineering change.

Jon Speer: I love these risk questions; they're very deep. So Bill as far as post-production document there's the current practice that I've seen in a lot of companies right now is there are things like cappers and complaints and some of these post-market processes. There's usually a section on like a capper form or a section on a complaint form that says something like, "Hey, did you update your risk management? And yes or no. And if no provide justification.

That really is, that's an archaic practice. Really what you need to have is a risk management file that is living and have the ability that when you get a complaint or a capper or a non-conformance or some post-production event, that you're actually able to go in in real time and update that risk assessment and risk management activities that you've conducted. If you have something that resulted in a harm or changes the probability of occurrence, you should have the opportunity to go in in real time, make that change in your risk management file.

The trouble is most people bury the risk management file in a file cabinet once they launch the product into the market. And that the people who are responsible for post-production don't have the skills or the training on keeping risk management activities up-to-date and current.

So the best option is to make sure that your file is living and always represents the current version of your product.

Joe Hage: Nicole asks, "Do we need rationale for our risk acceptance, and how do we document it?"

Jon Speer: Rationale for risk acceptance, yeah. I mean a lot of the world is already moving whether they have products in Europe or not, a lot of people are moving towards some of the concepts that are in the EN 2012 version of 14971. And with that there's this expectation that you have risk controls identified for everything. And a big part of what the standard defines is basically making sure that you verify the effectiveness of your risk control.

So as far as documenting your rationale really that's what risk controls are about. And if you're in that 2012 environment let's say, the expectation is you have a risk control for every single item, every single risk. So if you use that mentality or that approach then in effect you do have rationale documented for all of your risks.

Joe Hage: Jen asks, "Does product disposal fit into the risk management strategy? Trash can be a major issue in Europe."

Jon Speer: Yeah, that's a really good question too. There's an expectation that you have defined what happens during the entire product lifecycle. And that also includes what happens when it gets thrown in the garbage. Whether it's a disposable single-use product you need to think about is that going to be thrown into a landfill somewhere and is it going to have toxic leachables that are released to the ground and then to the environment?

So those are actually things that should be incorporated as part of your risk management activities.

Joe Hage: Cecilia asks, "What are the usual job titles for those who work in risk management in the ISO 14971 standpoint?"

Jon Speer: I don't know if there's an actual job title per se, I mean sometimes there are people who have the title of "Risk Manager". But I think it's important to realize that risk is not one single person within the organization's responsibility. It is an enterprise-wide responsibility. If you do have somebody that is given the title of Risk Manager or given that responsibility realize that they really should be a facilitator more than anything else. That everyone in the organization plays a part in the risk management process.

Joe Hage: Good answer. Mr. Shaw asks, "The challenge for software failing as it relates to probability is it either fails or it doesn't, bug or no bug. So how do you determine a probability scale for software?"

Jon Speer: I mean that's again a pretty specific question, I'd have to know a lot more about the intended use of that particular product and what are the possible failures that can result, what kind of harms can result and so on to be able to better advice that. So Joe if you want to let him know that he can reach out to me that would be great.

Joe Hage: Yeah he heard you, and he can certainly do that.

Simon asks, "How do you verify the risk control measure works?"

Jon Speer: All of these things are always challenging of course but as far as verifying your risk controls what you have to do is be able to have objective evidence to be able to support your decision. Once you've implemented a risk control measure then really the next piece after that is about identifying or re-evaluating the residual risk. So you need to re-evaluate severity. Usually severity doesn't change unless you've done something to redesign and completely mitigate that out of the equation. Usually what you're impacting is the probability piece from a risk control standpoint.

So you should have supporting rationale and objective evidence to be able to back into your justification for your ratings. It's not always easy and it's sometimes hard based on sample size and so on and so forth. But it's really ... That's why it's important to have this to be a team activity and to back into as much objective evidence as you can.

Joe Hage: For Khalid, no I don't think Jon can talk any slower, but we will have a transcript. So as long as my transcriptionist can understand him you will be able to read what he said later; sorry about that.

Mark says, "Could you please define hazard versus failure modes at FMEA?"

Jon Speer: I can define hazard pretty well as is in 14971. Hazard is a potential source of harm. I don't have all the definitions in 14971 memorized but I don't remember failure mode being defined in 14971. You have to look into a specific FMEA type of text to define that, but in my experience failure mode means something broke or something failed that's ... The name is actually pretty descriptive.

Joe Hage: Elliot says, "You mentioned that FMEA is only a tool and does not fully address performing a risk assessment. What should we use in its place?"

Jon Speer: Elliot that's a great question. First and foremost if you're still on the screen you can see there's a link to greenlight.guru/risk-webinar-offer. I can encourage you first to go there and to request the demo of the greenlight software because we have designed a workflow that aligns with 14971. And it's much about what we talked about today where there's just a natural progression hazard, foreseeable events hazard situation harm, estimating severity, estimating probability, identifying risk controls.

Yeah sorry Khalid I'm talking really fast but I've got a lot to offer and I want you to take advantage of this time and this great opportunity that we have at greenlight.guru. But Elliot I would encourage you to at least check out that demo and you're going to have access to these slides today and after the webinar. So you'll have an opportunity to kind of see a workflow that I recommend you put in place from your risk management standpoint.

Joe Hage: I'll ask patience of the group. Apparently sending 300 and somewhat people to get the slides at the same time is something my server was not anticipating. So if it's spinning a little bit it'll be better soon.

Marcus, my friend, is here and he asks you, "Do you have experience with software-based solutions for documentation of risk management such as Qware in Germany? Do these solutions cover all of the requirements of 14971?"

And on the side you'll have a chance Jon to meet Marcus at 10x, he's already signed up.

Jon Speer: Awesome, cool. Well Marcus I don't know what Qwares is, the name is not something I'm familiar with. I do know this, there's only one software solution that aligns with 14971 and that is greenlight.guru.

Joe Hage: Okay. Ann asks, "Can you address how contract manufacturers are affected by this and how should they approach risk?"

Jon Speer: Yeah I think that's important, that's a really good question Ann. Contract manufacturers at least here in the US they most definitely have to register with the FDA as such. And that theoretically means that you're subject possible FDA inspection. If you're outside the world there are similar ramifications. Generally outside the US the contract manufacturers will pursue either 9001 or 15485 certification. I suspect today that that's going to make the most sense especially if you're a contract manufacturer in the medical world to definitely have the 13485 certification in place.

But because of that if you're on the FDA register you're subject to inspection by FDA. FDA is going to expect that you have risk management documented and defined. Now it may not be from the product standpoint because your name doesn't go on the finished product labels for those particular devices. But you should have the manufacturing processes, you should have the risk management activities identified for those things.

And if you're on a 13485 role we already hit on briefly today that that standard is evolving too to being a risk-based QMS approach. So if you're certified to 13485 the expectation is that you're also going to need to incorporate risk management throughout your entire quality management system.

Joe Hage: Okay. My friend Jim's back with a question, "For 13485:201X, you stated the entire QMS should involve risk-based approaches to the QMS process. Could you give an example or a walkthrough of a risk-based approach to a QMS process? Perhaps to a simple process like control of documents or control of records?"

Jon Speer: That's a pretty specific example, it's a pretty detailed request actually. I mean the 13485 standard-

Joe Hage: Maybe if you can do a topline and then follow-up with Jim directly.

Jon Speer: ... make sure that your process from a quality management system, have you identified risk-based approaches. So in the example that was asked for on documenting the control some example of areas where risk-based approach is important is what happens to your documents? Where are they stored? Where are they kept? Where are they maintained? Who has reviewed and approved those documents? How do you manage revision history and all those sorts of things.

So in a lot of respects if you're following good documentation practices and you're following the definitions on 13485 for document control and record management and also FDA, there's a good chance you probably already have many of those risk-based approaches defined. But you have to think about things like disaster recovery and 01:08:10 of documents are missing. Or you find out during an audit that there's a missing signature, I mean those are all risks from a compliance standpoint that you need to define what you're doing about that.

Joe Hage: Importantly people did weigh in on the beard question. "We have big beard rocks." "Big beard." "Small beard." "Small beard." "No beard." "Where are the women?" "Small beard." "I like John with the big beard better." So I don't know that we have any kind of consensus there I guess you're going to be kind of left to your own risk management-

Jon Speer: All right, or maybe I'll just shave half my face.

Joe Hage: I think that there's a risk management element about having that much facial hair. I don't know if you want to address that in this conversation.

Jon Speer: Well Joe I don't have any hair on top of my head so I think a balance is out.

Joe Hage: Fair enough. Hans wants to know, "Risks should be reduced to levels as possible not as low are reasonable. Does that mean risks should be reduced to unreasonable levels?"

Jon Speer: This is where the two version of the standard are different. I mean the 2007 says "As low as reasonably practical". The 2012 version says, "As low as possible or as far as possible." I've seen both of those used almost interchangeably. That's a really loaded question, I mean there are some people who have argued that very topic and have said that as far as possible is impractical and unreasonable. And that's really something that is, it's very difficult to put in practice.

How can you possibly reduce everything as far as possible? And that's one of the like I said, the contentious points of that particular detail and the Z Annex and the 2012 version. And plenty of people are arguing that very topic right now and I don't have a sound yes this is the answer for that particular topic.

Joe Hage: Okay. Linda asks, "We are a contract manufacturer that does not design product. We manufacture to customer specifications and finished medical devices and are ISO 13485 and FDA-registered. How do we define intended use and harm hazards for the products we manufacture?

Jon Speer: Okay, well I mean we all still play a part in the risk equation whether a designer or a manufacturer or what have you. If I'm a contract manufacturer there's a probably a good chance that somebody has provided me with a product design somewhere along the way. So as part of that process then I need to be aware of what that product intended use is and how it's designed and so on. Not so much from a design standpoint but to make sure that as I'm manufacturing it I'm not introducing hazards as part of my manufacturing process that can negatively impact intended use.

Joe Hage: Next question. Susan asks, "Is there a risk management for dummies out there to help groups go step-by-step through their first process?"

Jon Speer: Susan yes. Send me an email I'll get it to you.

Joe Hage: Jon, let me write that out. Is it jon@ or jon.?

Jon Speer: It's on the screen, it's on the screen right now. Jon.Speer@greenlight.guru.

Yeah Joe we're coming out with the complete guide to risk management in about a week or so, so tell them this not a dummy but we'll get her the complete guide.

Joe Hage: Okay. I remember reading someone asking if your system is validated. Is your software validated?

Jon Speer: Yes.

Joe Hage: Yes, okay.

Jon Speer: Yes.

Joe Hage: Rich said that his software question is so big that I think he needs to follow up with you directly so look for a-

Jon Speer: Okay that's fine.

Joe Hage: ... a note from Rich.

Khalid asks, "Can we use information for human factors and usability evaluations to define our risk acceptability criteria?

Jon Speer: Oh absolutely, absolutely good idea. And those activities can also be used potentially as risk controls as well.

Joe Hage: Richard asks, "Is there a hard copy template for assessing and resolving risk?

Jon Speer: I guess, I mean I'm not sure exactly what that means but-

Joe Hage: I'm not sure either I hope you did.

Jon Speer: ... did it mean-

Joe Hage: Richard if you'd like to send a follow-up note I'll read it aloud. Joe I'm sorry I have to leave Jon that was great okay. Another vote for big beard, good.

Jim writes, "I disagree with your marketing pitch, but Qware from Germany is fully integrated with EN 14971." So 01:13:56 Jim.

Jon Speer: Yeah I'm just I'm not aware. I haven't heard of Qware and I don't know anybody that uses it so I guess that greenlight is the only software solution that aligns with ISO 14971:2007 and EN ISO 14971:2012. And fully integrates design control activities with your risk management. And that I am for certain.

Joe Hage: Rich asks, "I understand that FMEA alone not sufficient for risk management, but as the combination ... Pardon me ... but is the combination of hazards analysis DFMEA and PFMEA sufficient to satisfy the requirements of analysis evaluation and control. If not what are the tools that are needed?"

Jon Speer: Yeah I'd have to look at Rich's process to understand exactly whether or not that would work. I mean there's a possibility yes but sometimes people say FMEA and they don't always mean the same thing as the next person that says FMEA. So I would say without knowing specific details then there's a possibility of course.

Joe Hage: As people leave they're giving their final votes. We have, "A big beard is sexier," and, "Big beard for Jon." That's for you.

Jon Speer: I can sign an eight by ten if anybody wants one.

Joe Hage: What's that?

Jon Speer: I can sign an eight by ten picture with the long beard if anybody wants one-

Joe Hage: 01:15:29 are included with all, for all webinar participants. Okay.

"In what way is ISO 9001:2015 and the new 13485:201X not aligned from both?"

Jon Speer: Aligned or not aligned?

Joe Hage: In what ways are they not aligned?

Jon Speer: Yeah they used to be in complete alignment but 9001 is for general manufacturing and 13485 when it was introduced several years ago was specific to med device. And now that 9001 has been revised, they both have incorporated more risk-based terminology and approaches as far as concerned. But they just hit a fork in the road. Again 9001 is for general manufacturing is not for med device and 13485 is for med device. So I would say the biggest area where they're not in alignment is just that piece alone.

Secondly, 13485 is moving towards better alignment with the regulatory environment in the med device industry.

Joe Hage: Okay I'll stop us in 12 minutes at the half hour and if you answer in short spurts we may be able to get through these questions.

Mr. Jayne asks, "What does the risk/harm definition consist of? Only safety injury or should it also contain non-injury product risks?"

Jon Speer: Yes. I mean harm can be certainly include injury or some sort of adverse event or something like that. But it can also incorporate nuisance, it can also incorporate things like damage to equipment and things along those lines. So it doesn't always have to be just an injury type of descriptor.

Joe Hage: You may have answered this but for Terry, "What is the best way to evaluate overall residual risk based on risk levels of all risks?"

Jon Speer: Yeah that's you would have a similar risk acceptability scale that you would have defined for your severity and your probability. And when you look at the overall product you're basically using that same acceptability scale for that overall product. But if you look at it in aggregate you wouldn't spice 01:18:17 in the individual hazard level, you would look at the product in its entirety and determine from an overall standpoint is that product safe? Is it effective? Do the medical benefits outweigh the risk in all your levels and at a point where your management and your executive hours within your company accept the risk that are applicable to your product?

Joe Hage: Nick I can hear you typing. Gordon from Montreal asks, "Are including warnings in the IFU an acceptable risk control?"

Jon Speer: Well it depends, you said Gordon, where's Gordon based?

Joe Hage: He's in Montreal, Canada.

Jon Speer: Montreal, Canada so if Gordon's following the 2007 version of the standard there is an expectation that you can use labeling as an effective risk control. This is an area where 2012 version indicates that labeling is not accepted as really a risk control measure.

First and foremost it has to be inherent by design and safety measures incorporated into the product. The expectation is that the labeling is part and parcel with designing, developing and manufacturing a medical device. So if that information is contained on your product label and your instructions for use it should have been there anyway, it shouldn't be a way to reduce risk.

Joe Hage: Scott asks, "With respect to harms, how do you deal with questions about misuse especially as we have human factors requirements about that? Pointing at training materials isn't always a good answer in an audit. Your ideas?"

Jon Speer: Misuse is a tricky tricky topic. The ISO 14971 does address and deal with foreseeable misuse, and that you should identify hazards that are associated with that for sure.

But as far as like intention there's two different types of misuse: there's intentional and unintentional misuse. But you really need to identify the hazards that are associated with misuse of your product. And this is a case again where as noted the human factors could be strong supporting evidence to be able to show from a risk control standpoint that your product has effectively identified.

Joe Hage: Marcela asks, "Can a risk control measure be a test?" She writes parametrically, "Part of the design verification. Or the risk controls are implemented in the design software labeling training and the testing is only to verify the implementation of the controls?"

Jon Speer: I suppose both scenarios there's ... I mean that's a pretty specific example I suppose both scenarios have potential. Like I mentioned earlier generally risk controls are things like direct tie-ins to your design controls things like design outputs, design verification, design validation. Again it's a pretty specific example, I suppose either scenario mentioned could work 01:21:43 a risk control.

Joe Hage: Mark wants to know if there's a preliminary draft of the new ISO 13485 available somewhere. If you have it-

Jon Speer: I think there is, I don't have it. I think I saw that on like VSI's website. If you search for I think it's called DS 13485 may say 201X, I can't remember exactly. But if you just do the search on the internet for that you can find that. I think you have 01:22:14 though. If you have a notified body already starting to work with right now you may connect with them and see they can provide that draft to you.

Joe Hage: And Mark will have notified body TUVSUD on this time next week talking about the new CE marking rules. I would be surprised if they don't have a copy of it.

Louis asks, "How will the new ISO 13485:201X affect silicone components manufacturers?" Perhaps too specific for you to know on the spot.

Jon Speer: I do not know.

Joe Hage: Okay, follow up with Louis.

Jason wants to know, "Do you have any insight on new industry testing standards in regards to ISO 10993 biocompatibility and leachable extractable risk evaluations?

Jon Speer: Tell Jason I do not have the specific insights on 10993 but I know of three experts who do if he wants to reach I'll be happy to make a connection.

Joe Hage: That sounds reasonable so Jason please email Jon.

Andy wants to know, "Can you point out any differences in risk management processes as described for 13485 versus the new 9001:2015 revisions?" We might have asked that question but if you could recap that quickly.

Jon Speer: I'll give a slightly different answer this time I'll say 01:23:42.

Joe Hage: Okay.

Jon Speer: I have always focused on 13485; I don't have all the ins and outs on 9001. I've been very focused on med device topics so I don't have the specific details of where they're different. I can just tell

you that 13485 they're shifting to better align with med device industry best practices and regulatory environment.

Joe Hage: Okay. What methodology have you seen to address risk benefit analysis for individual residual risk?

Jon Speer: It depends on what the particular item is. Generally if you have some supporting evidence, some sort of test or some sort of analysis or maybe you can use market research and so on. There's a lot of different tools and techniques that can be used to support your medical benefits outweigh your risk.

I mean there's no way I can be specific enough to address that exact question. But testing works, market research works. There's a lot of other ways that also are acceptable.

Joe Hage: We have Binceng 01:25:03 saying asking if Jon has done a thorough risk assessment of his beard. And he thinks that we'll find out that no beard is much safer thus a lower risk. While Keith Anderson on the other hand throws caution to the wind and advises you to stick with the big beard. Let's see.

Jon Speer: Yeah it's about to be winter time here in the next few months; I need to keep my face warm.

Joe Hage: Okay, well that's something right there. Does your software also include a post-market surveillance review model to check if the initial risk profile seen ... pardon me ... is seen when commercialized.

Jon Speer: The short answer is yes we allow the risk management file to be a living entity throughout the entire product lifecycle. I mean if you click the link on, go to the that's on the screen to schedule a demo to learn more about how that looks.

Joe Hage: If risk is the probability plus severity of harm, how does record retention or document control weight in?

Jon Speer: Okay, I was just thinking about the context of that. That's probably back to the earlier question. But using ISO 14971 as the backbone from a risk standpoint within your quality system and you think about probability occurrence of harm and severity of harm being the definition of risk. If you look at it from a doc control standpoint what's the probability ...

I'll give you one example, what's the probability that a critical record in your system is missing a signature? And if that's the case what is the severity of that? Are you going to get a 43 observation from FDA? Are you going to get a non-conformance from ISO? So those are factors that you can throw in as far as doc control and concepts of risk.

Joe Hage: Jack wants to know in what stadium your basketball photo was taken.

Jon Speer: That's in Banker Life Fieldhouse in Indianapolis, Indiana.

Joe Hage: Let's see. Great webinar, okay. Slides slides leaving. It's a beautiful day. Well okay we're at the, I think there's maybe a half dozen questions I wasn't able to get to. But Jon and company you'll have a record of all the questions that were asked and on behalf of those who tuned in today please make a point of answering them individually if you can.

Jon Speer: Yeah we'll do Joe thank you.

Joe Hage: Final thoughts after 90 minutes from me. First thank you, this was very informative. I know it is when 200 people are still around at the 90-minute mark. So thank you very much; this is very informative. I will have a transcript made up, I will have the video online later today. And I am on with my host right now, Theresa at my server so folks try again in about five minutes for the slides and I will send out an email in perhaps an hour's time with a link to the video as well.

Jon Speer: Jon I'll see you in person in May at the 10x Conference, looking forward to shaking your hand. And as I'm sure most people on the call are, I'll be curious to see what kind of facial hair you'll be spotting.

Joe Hage: All right, great Joe.

Jon Speer: Thank you everyone, and tune in next week for CE marking with TUV SUD.

Thank you Jon and company. Bye for now.