MDSAP Medical Device Single Audit Program

Presenter: Edna Falkenberg - TÜV SÜD

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 morning has 280,000 members worldwide. I'm grateful for members like Edna and the folks at TÜV SÜD because they know lots of things that I know nothing about. The Medical Device Single Audio Program is one of them.

I was talking with one of the folks and they mentioned this to me and I said, "I don't know what that is." I'll take a guess and say that there are a whole bunch of members in the group who like me could use an education in it.

So Edna, who's calling in from Massachusetts today, say hi.

Edna Falkenberg: Good morning, good afternoon and good evening to everybody.

Joe Hage: Yeah, and I have a hard time hearing you a bit so if you can talk a little closer to your mic. When I asked the TÜV SÜD folks, "Who is the expert in MDSAP?" they said, "You want to talk to Edna."

So let's talk to Edna, I'll put myself on mute. I'll be here in the background and enjoy the program. Edna thank you; take it away.

Edna Falkenberg: All right, thanks Joe for the introduction and thanks everybody for joining. Before I start with the topic for today's webinar, the MDSAP Medical Device Single Audit Program, I would like to give you a brief overview about TÜV SÜD.

TÜV SÜD is one of the world's leading technical service providers of testing in perfection certification training solutions. We actually focus on providing tanguil business value through our services.

We are actually headquartered in Munich, Germany. TÜV SÜD is a multinational corporation with a raft 00:02:03 office and laboratory network in over 800 locations around the globe.

Clients benefit from a winning combination of German technical excellence and local in-country experts familiar with local market standards and regulations.

In the US, TÜV SÜD America was founded in 1987 and we are here in Massachusetts in Peabody and we are the North American subsidiary of TÜV SÜD AG.

TÜV SÜD America Inc. provides a complete service portfolio through our division: the Product Services, Management Service, Industry Service, Chemical, Oil and Gas and Global Risk Consultants.

The next slide actually gives you a snapshot of our locations in the Americas region. Our medical divisions are headquartered as I said in Peabody, Massachusetts. We have a second location where our medical business is located at New Brighton in Minnesota close to Minneapolis. And the third location is San Diego in California.

Today I would like to talk about the Medical Device Single Audit Program. I actually have been actively involved in this program since last year and performed a couple of audits under this program. A couple of these were observed by regulators from the authorities FDA, Health Canada and the Brazilian ANVISA.

Today I would like to cover a little bit about the background and overall objective of the Medical Device Single Audit Program. Would like to give you some details about the pilot and the expected transition. As well would like to focus a little bit in regards to the regulators acceptance of the MDSAP program and of all the resulting audio reports.

We'll focus briefly about the MDSAP Process and the Audit Sequence, the so-called Audit Model under the Medical Device Single Audit Program.

We'll focus a little bit in regards to differences between current audits. If you're currently audited under the ISO 13485.

Then we'll talk in regards to the non-conformative grading which is different to what you are used in regards to current ISO 13485 audits.

Then I will go into the definition of unannounced audits under this program.

And briefly at the end give you an overview about what are your benefits in participating in the pilot program and as well who can participate in the program. What do you have to do?

To give you a little bit background in regards to this program and actually how it was developed, it's actually coming from the IMDRF, the International Medical Device Regulators Forum. Which was actually conceived in February of 2011 as the program to discuss future directions in medical device regulatory harmonizations. Which to be honest has been discussed for quite some time in the past couple years.

Doing this forum as well as the Medical Device Single Audit Program was one of the topics to be discussed.

The voluntary group of medical device regulators from around the world came together to build on the strong foundation work of the Global Harmonization Task Force which actually was replaced by the IMDRF.

The goal was to accelerate international medical device regulatory harmonization and convergence to promote an efficient and effective regulatory model for medical device. Which is responsive to emerging challenges in the sector while at the same time protecting and maximizing public health and safety.

This slide gives you an overview who are actually the Management Committee Members of the IMDRF. As I said, the IMDRF is a voluntary group of national regulators from around the world. And the stated goal of this group is to accelerate international medical device regulatory harmonization and converge it.

Current IMDRF Management Committee Membership includes representatives from medical device regulatory authorities of the following countries as you can see on the slide. It's the US, it' Brazil, China, the European Union, Japan, Russia and the US.

As well participants in the IMDRF discussions also include representatives from the Asian Harmonization Working Party, known as AHWP. Which is a complimentary body to the IMDRF that covers more than 20 additional national economies.

As well one observing body in the IMDRF is currently the World Health Organization, WHO. Which is documented as an official observer to the IMDRF Management Committee.

So you can see on this slide and as I said it's quite quite a range of participants here which 00:09:23 and Harmonization in regards to the regulatory requirements in the medical device industry.

This slide gives you actually a brief overview of the current IMDRF work items. And as you can see the fifth bullet point here is the Medical Device Single Audit Program. Actually four out of these six work items are still in progress. Two out of them have been finally closed out which are the requirements for recognized standards and the roadmap for implementation of UDI system. These two items are actually were closed out. So there remains four open work items and one of them is as I said the Medical Device Single Audit Program. Which actually the working group established in 2012. The group was built to create actually the Medical Device Single Audit Program.

The overall objective of the Medical Device Single Audit Program is to develop, manage and oversee single audit program that will allow at the end a single regulatory audit of a medical device manufacturer recognized by MDSAP-recognized auditing organization. And to suit if one of the recognized auditing organizations for MDSAP with the goal to satisfy the needs of multiple regulatory jurisdictions.

The current participants in the pilot program of the Medical Device Single Audit Program are four parties. It's the US FDA, it's Health Canada, the Brazil ANVISA, and the Australian's TGA.

Currently Japan is acting as an observer in this program. And they actually haven't indicated when they plan to participate in the program but at least they participate currently as an observer and hopefully Japan will join the program as well very soon.

Currently under the terms of the pilot program, participating regulatory authorities will accept audit reports of medical device manufacturers quality management system based on audits conducted by authorized auditing organizations.

The audits will be based on the requirements of ISO 13485, medical devices quality management systems requirements for regulatory purposes.

On top of that, we need as well to cover any country-specific requirements of medical devices of those regulatory authorities participating in the Pilot Program. That means FDA, Health Canada, Brazilian ANVISA and Australian's TGA.

Additional regulatory requirements need to be covered during those audits to include such things as registration, 00:13:33 lifting, licensing, post-market recalls or field safety notices, 00:13:43 requirements and others which might fall into the additional requirements from the regulatory body.

The overall objective of the Medical Device Single Audit Program is as I already said to develop, manage and oversee a single audit program that will allow a single regulatory audit of a medical

device manufacturer conducted by an MDSAP-recognized organization to set aside the need of multiple regulatory jurisdiction.

So the MDSAP will not require changes to country-specific regulation. The basic is the ISO 13485 plus regulatory-specific requirements from the participating countries.

So what are the goals for the Medical Device Single Audit Program and what are the key strategies? I tried to summarize it a little bit in this slide. So the goals are to have a single audit to set aside the regulatory requirements of multiple participants. And as well to create a program to be or to have more effective, efficient and less gruesome regulatory oversight of the quality management system of a medical device manufacturer.

With the goal to have a single audit and to have inappropriate regulatory oversight and reduce regulatory burden for everybody. Which at the end results as well to more efficient and flexible use of regulatory resources.

We will have a greater global alignment of regulatory approaches and technical requirements.

Another goal was to promote consistency, predictability, and transparency of regulatory programs worldwide.

And as well leverage existing conformity assessment structures.

So as a summary, a single audit by an auditing organization would at the end benefit patient health and patient access. Leverage regulatory resources. As well minimize medical device manufacturing disruptions due to multiple regulatory audits. Specifically to mention multisite companies which could have a number of audits per year and have these disruptions in their schedule all the time throughout the year.

As well to provide global benefits both on short term goals and longer-term goals by the IMDRF regulators.

Plus a single audit would provide a standard set of requirements and set of documents for performing regulatory audits of medical device manufacturers.

And actually a set of documents and procedures actually has been developed in the MDSAP working group. Which are actually available on the FDA MDSAP website. These documents are actually really available for everybody who's entrusted in the program. So you will find there's a lot of useful information on that website.

The pilot program actually started in January of 2014 and is now underway. Several certification bodies are in the pilot program. And actually to become a recognized auditing organization, a

certification body has to undergo a certain procedure to actually become recognized. That actually includes initial office audits which we underwent last year in the US and in our headquarters in Germany.

It's included as well witnessed audits by the regulators and as I said I was involved in two witness audits in the past couple of months. And as well we have to have surveillance audits doing this pilot program. So it's pretty much like a usual certification for a manufacturer. We have to undergo as well an initial audit and have as well surveillance audits throughout a three-year cycle.

As I said already pilot program countries are the US, Canada, Brazil and Australia. And the pilot will finish at the end of 2016, it's after three years.

Once the MDSAP is fully implemented, it will replace the CMDCAS in Canada.

As I said Japan is involved in the pilot program as an observer. It's unclear when they actually will join the program, but we're hoping that they will join as well pretty soon. We got to Europe it's at the moment completely unclear if they will join the program or not.

The following slide gives you a little bit an overview in regards to the acceptance of the outcomes of an MDSAP audit from the perspective of the regulators. They have actually brought up some discretions regarding the acceptance of audit reports. I tried to summarize some specific conditions in regards to each of the participating countries.

But actually in regards to the USA, the FDA will accept the MDSAP Pilot program reports as a substitute for FDA routine inspections. However, the FDA will not accept MDSAP for initial visits or "for cause" inspections. So initial visits or "for cause" will still be done by the FDA.

And another condition is an organization must sign a contract for an MDSAP audit before FDA routine inspection is announced, otherwise the inspection will still occur and performed by the FDA.

For Canada there are not much differences. Health Canada will use the MDSAP in the same manner as CMDCAS. So if you submit 00:22:18 we actually not after the audit submit the audit report, Health Canada it will accept the MDSAP.

For Brazil, Brazil actually the ANVISA plans to use MDSAP pilot audits in lieu to ... of premarket inspections by ANVISA to grant ANVISA's GMP certificate to manufacturers intending to put class III or IV medical devices on the Brazilian market.

Actually undergoing an MDSAP Pilot audit may accelerate ANVISA's GMP certification process. I guess many of you know there is a three years backlog for ANVISA to conduct their own audit and participating at the end in the MDSAP could accelerate your time to get your product on the market.

Australia, the TGA will take into account MDSAP Pilot audit reports when they consider whether a manufacturer has demonstrated compliance with the Australian Conformity Assessment procedure. And for considering whether to issue or maintain a TGA Conformity Assessment Certificate in relation to manufacturers of kinds of products prescribed in the regulation.

Actually under some circumstances a manufacturer may avoid year routine TGA inspections at their premises.

The TGA will accept MDSAP certificates as evidence of compliance with the ISO 13485:2003 where the Standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Let's take a quick look into Japan and the MDSAP program. As I said already Japan has been an official observer and active participant in the Pilot Program. And they have actually as well contributed to the development of MDSAP documents in 2012, that means since the beginning.

Japan recently amended their regulations in the end of 2014 which became effective November 2014. And actually the amendment of the medical device regulations in Japan are becoming more aligned now with the 13485 though 100%. And as well in that case as well becoming more aligned with the MDSAP documents and GHTF documents for Nonconformities and Audit Reports.

As of today, Japan does not have full access to reports as they are not yet a full participant in the Pilot Program. And as I said earlier they have not clearly indicated when they will participate so it is at the moment still open.

But Japan is evaluating the following possibilities at the moment. For manufacturers intending to put medical devices of class II, III and IV on the Japanese market, an MDSAP Pilot audit report might be utilized for desk review instead of a premarket inspection performed by PMDA or a registered certification body in Japan.

So that means that they actually won't go on site to do an inspection. They will take the audit report and might perform a desk review in their office and not come to your facility.

Also an MDSAP audio report might be utilized in this manner for a periodical post-market inspection.

And as well here pretty much the same as it was as I mentioned for Brazil. Undergoing an MDSAP Pilot audio may accelerate the Marketing Authorization with fewer burdens as well as reduce some burden for a post-market phase.

Europe and the Medical Device Single Audit Program as I said it's still unclear whether Europe will join or not. The hope is still that Europe will adopt the IMDRF documents for use in their regulatory system.

However, at the end it's unlikely that Europe will ever be a full participant in MDSAP because of the difficulty in getting confidentiality agreements with the additional 28 countries in Europe. So that might be a hurdle to climb over to get the agreement of all 28 member states.

As I said, the MDSAP documents are freely available. So for everybody who's interested to get more details for the procedure, feel free to visit the FDA's website. You will find the audit module document and the companion document which details the audit task for each processes. I will go into that in detail in a little bit.

It gives you as well the overview about the forms the auditors are using in regards to audit reports which look a little bit different when you're used to ISO 13485 audits at your company that audit report is totally different. So it's wise to visit the website and take a look into the existing document published there.

So let's take a look into the audit approach of an MDSAP audit. The approach is quite different than what you're used to in regular ISO 13485 audits, and as well the sequence of the audited elements is different. The sequence actually was developed and designed to allow for the audit to be conducted in a logical, focused and efficient manner.

The audit will begin with management. Management includes the management review, quality objective, quality planning, training activities.

Will be followed by the process Measuring, Analysis and Improvement. Which includes corrective and preventive actions, internal audits, complaints, improvement activities in the company.

Followed by Design and Development and Production and Service Controls.

Sometimes we're sure a corrective action or a complaint could affect all of these areas. That means if you have a corrective action where you need to do a design change or as well develop

a process change in the production. So actually the all sequence is intended to build a flow in the audit process starting from management review activities into improvement. Then from improvement into design and development and production and service controls.

Plus we have a supporting process which is Purchasing which actually can be audited and shall be audited toward the cause of the audit in all these processes mentioned as well.

In addition, the MDSAP audit process has two supporting processes. One is the Medical Device Adverse Events and Advisory Notices Reporting. And the other one is the Device Marketing Authorization and Facility Registration.

And these two topics are as well to be audited during the course of the audit. Whereas the management and Device Marketing Authorization and Facility Registration can actually be audited in tandem. As well the second process measuring ... Measurement, Analysis and Improvement can be audited in tandem with the Adverse Events and Advisory Notices Reporting.

The supporting process of Purchasing can actually be audited in conjunction with either Design and Development or Production Service Controls. Whereas as well second option is actually to divide the audit tasks within the process. But in that case you might have two audit teams or actually two auditors auditing the same elements at the same time. Which might be difficult to keep the communication of the auditors in alignment. So it's better to audit different tasks within an audit team.

Actually by following the MDSAP audit sequence, audits performed for MDSAP will be conducted in a consistent manner across auditing organizations. There has been an audit model developed, and each process is made up of a number of audit tasks. So when we have the time later and look into the Audit Model document published on the FDA's website.

You will see that under each of the processes I just mentioned in my previous slide, there are numbers of audit tasks to be followed doing an audit for each of these processes. And the Audit Model will direct the auditor performing the audit to confirm specific evidence for each task.

And as well for each task there is reference to the applicable clauses of ISO 13485, and actually if applicable, specific regulatory from the four participating countries.

On top of that, there is a focus on Risk Management throughout the audit while performing the audit under the MDSAP Program.

And again following this model audits will be conducted in a logical and efficient manner with the attention to the interaction beefing the processes.

So the goal is not to audit all these processes standalone. Actually it's important to build the connection between all of these processes. That actually at the end enables as well auditors to determine whether systemic quality management systems nonconformity are present at a company or not.

Just to give you an example of an audit task which you will find actually in the Audit Model document, we clearly have here an audit task verify that the quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.

And as I said under each audit task you have to reference to the clause of the ISO 13485 and to the respective regulation. If they are the same, that means the ISO 13485 clause is the same like the regulation from TGA, ANVISA or the FDA, then you won't find any additional country-specific requirements mentioned.

If there are specific requirements from one of these four participating regulatory bodies, then you will actually find the description of those additional requirements listed under each audit task.

This might be as well helpful for you in case you decide to participate in the Pilot Program to identify where you actually have gaps in your quality management system.

As a summary, what are the MDSAP Audit criteria?

As I mentioned before, and I just see I have a typo here, it's the ISO 13485:2003. Plus the GMP requirements of the regulatory bodies. Actually here depending on where you sell products. To add MDSAP to your quality system or to your certification actually is certification ordered if required. Which is considered as an initial certification.

The MDSAP is based on a three years audit cycle. And actually as I said we need an initial audit or an initial certification to add MDSAP to your certification. And this initial audit is actually a complete audit of a medical device manufacturer's quality management system consisting of a Stage I and Stage II audit.

The duration at the moment roughly calculated for an initial or a recertification audit is approximately six days. The duration for a surveillance audit roughly spoken will be five days.

The initial audit is followed by the partial surveillance audit in each of the following two years and a complete recertification audit is in the third years to be performed.

There might be under this program special audits conducted by the regulatory authorities and unannounced audits. Doing or actually within the audit cycle, the unannounced audits, and I will give you more details about that in one of my later slides in regards to the waiting of Nonconformity.

As I mentioned already in regards to old mandates, in the past all were 00:41:17 doing regular ISO 13485 audits all the time is based in these days on employee headcount. Actually under the MDSAP Program, audit time is based on tasks.

So as I said throughout the six days for a single-site company. Roughly six days for an initial. Roughly five days for a surveillance audit.

But as well there will be additive and subtractive adjustments. It's based on what is applicable to your company.

And as well doing the Pilot Program data will be collected and there might be an adjustment in regards to the man-day requirement system at the end of the Pilot Program. But at the moment we have it based on the audit task. And the audit task as well when you look 00:42:24. And it will set website based on audit time calculation sheets. And each audit task is connected to a certain amount of time. So actually there are minutes assigned to each audit task.

Looking into Nonconformity, if you're certified to ISO 13485 at the moment you might be used the grading minor nonconformities and major nonconformities. Actually under the MDSAP Program, nonconformities are graded using the GHTF document SG3/N19 document. And actually the grading is a grading from one to five.

So nonconformities are graded in regards to the impact of the quality system. And as well there are certain escalation rules where actually additional gradings are put on top of that. So under this program, major and minor nonconformity this definition is gone.

To give you a little bit overview but really not in detail because otherwise I would spend more time. I will explain quickly how the grading of nonconformities is done under the MDSAP Program.

As I said this is coming from the N19 GHTF document. And the grading of nonconformity is first defined on the quality management systems impact. What actually is the X axis of the grading matrix shown here? This is actually related to the incidence of the QMS clause on medical device safety and performance.

And the x axis of this graph is showing the Occurrence of the finding and is actually divided into two categories, first and repeat. So First means it's the first category addressing a

nonconformity in this particular sub-clause of the 13485:2003 identified for the first time. And the first time is defined as not observed in the two previous QMS audits which evaluated the same sub-clause.

And the second category is Repeat. That actually identifies its repeated finding throughout the last audit in your organization. So actually for example we have a finding in regards to training. Training is actually sub-clause 6.2. This is considered as an indirect quality system impact. In that case it will end up in the one. If it's First, we will add nothing on top of that. It will be a one, it will be a grading one the first occurrence. And in indirect impact it will be grading of a one.

As an overview in regards to the definition of indirect and direct Quality Management System impact, you will find here the definition in regards to this. Everything in the clause 4.1 through 6.3 as seen as "enabled". "Enablers" making it possible or feasible for the Quality Management System processes to operate.

For that reason these clauses are considered to have indirect influence on medical device safety and performance.

Whereas clauses 6.4-8.5 are seen as having direct influence on design and manufacturing controls. They are considered to be a direct Quality Management System impact. Because they are considered to have direct influence on medical device safety and performance.

A little different as well is the Nonconformity Response Timing under the Medical Device Single Audit Program. So actually you have 15 calendar days for all nonconformity grades to respond with a correction plan, root cause and correction.

Corrections and depending on the grade of your findings for grades four and five, the response time is actually it's 30 days, 30 calendar days after the audit. You need to provide the certification body with evidence of effective implementation of correction and corrective action.

I mentioned earlier that under the MDSAP Program there are unannounced audits. As well as regulatory authorities themselves can perform special audits including unannounced audits anytime if deemed necessary and within the purview of its jurisdiction.

And as well the auditing organization that means your certification body like TÜV SÜD shall carry out unannounced audits if previous audits indicate serious and/or frequent nonconformity.

Unannounced audits actually have to be performed when an organization has findings in the grade of five. And as well if a company has more than two findings in the grade of four. This

actually will trigger an unannounced audit within six to nine months after performing the MDSAP audit.

But actually the unannounced audits will be on top to the normally scheduled audits.

The unannounced audits for the nonconformities and the gradings more than two, fours and five are actually intended to close out only to close out the findings and see whether the corrective actions are implemented and effected.

Just to give you a brief summary to the differences as I mentioned. The grading of nonconformities are considering the impact to the quality system, no longer differentiation between minor nonconformities and major nonconformities. But in case you're so used to this definition roughly said grading one to three it's more or less minor findings gradings above four. Actually four and higher is pretty much considered or actually comparable to major findings in the past.

The audit report under the program includes regulations from Health Canada, FDA, ANVISA and the Australian TGA. Only as applicable to your organization.

Major differences as I said it's the audit sequence, following the audit processes as outlined in the old model. And at the end all MDSAP reports must be submitted to all regulators as part of the program. And here regardless of the outcome, all regulators will be reviewing the report.

In the future there will be a database set up for this report so that regulators can read the reports, the nonconformities, the grading and look for trending in the nonconformities for a certain company.

00:52:56 list I'll give you an overview in regard to participating in the MDSAP Pilot Program and benefits for companies. At the moment any manufacturer may participate if the product falls under the scope of at least one of the participating regulatory authorities. And subject to their quality management system requirements.

It doesn't matter where a manufacturer is located, a manufacturer may be located anywhere in the world if you fulfill the requirements and your products fall under the scope of as I said one of the participating regulatory authorities. You may participate and only the MDSAP-participating countries will have direct access to the audit report at the moment.

As I mentioned earlier, some of the audits under the Pilot Program they'll be witnessed by the regulators. Only for the purpose to evaluate the auditing organizations and not the manufacturers.

As I said I was taught of two audits where the regulatory authorities witnessed us but actually there was no interaction with the manufacturer which really creates the purpose of observing the auditors and evaluate the auditing organization to be capable to perform this audit.

And as well one benefit in participating in the Pilot Program is your ability to provide feedback to the regulators and as well influence the future of the program at the end of the Pilot phase.

In case you are due for a routine inspection, you potentially can reduce inspection expenses and resources assignments and reduce with that as well a number of audits. And save at the end as well money for not allocating so many resources to a number of audits. So you have one audit combined for four regulations so that can reduce as well the allocation of resources for your organization.

For actually an upgrade to the MDSAP during regular surveillance cycle, the auditing organizations will need to conduct recertification audits. As I said to get under this program where recertification or initial certification if necessary.

Manufacturers cannot select which of the four regulatory schemes to include within the audit scope. Meaning you cannot have an MDSAP and task as only audit the requirements of for example Australia and Brazil. If you're currently all for selling into the US and Canada.

On the other hand we would not audit you to any regulatory requirements that is not applicable to your organization. But if it is we must include all regulatory requirements for any of these jurisdictions.

That's the end of my presentation. Unfortunately I almost used my hour. Thank you very much and in case you have any questions.

Joe Hage: Oh boy do they have questions! There's quite a queue here.

Edna Falkenberg: Oh oh!

Joe Hage: You've really kicked something off here. So for those of you who have an hour and have to run, don't worry I am recording everything and we'll record the questions and answers. But those of you who can stay on I can stay on for another half hour, Edna are you available to stay.

Edna Falkenberg: I am available yes. I will make myself available.

Joe Hage: Well then let me jump right in. First question from JD. He says, "We're a relatively small company less than 50 employees. From what we have read and heard about MDSAP, the

audits are relatively long about one week, and expensive. Could you let us know if MDSAP will be resized to account for the company size?"

Edna Falkenberg: Actually there's one exception for I think the number of employees towards up to I think the maximum was 15 employees as far as I can recall correctly where actually reductions can be made. But that's it at the moment. At the moment every company is pretty much considered the same under the program with the audit task.

And if you have or if everything is applicable under your quality of management system, you are treated the same as a company with more than a thousand employees and so on. Unfortunately there is not much difference made between a small and a big company at the moment.

Joe Hage: Thank you. Next question comes from Pedro. What validity does GHTF documents have now that the IMDRF replaced them?

Edna Falkenberg: So actually there's a few documents still used under the GHTF Program as as well there's one of the documents I mentioned is the grading system for nonconformity. This is actively used under this program.

So there is at the moment for certain documents no difference made. So we are actively using a GHTF document yeah.

Joe Hage: And he also wants to know if the EU is participating in this program because it's not listed among the participants.

Edna Falkenberg: Correct. At the moment the EU is not participating in the program as well not as an observer like Japan. There's still hope that they will jump on this program but at the moment no, Europe is not included.

Joe Hage: Jen asks, "If a company..."

Edna Falkenberg: Crosstalk 01:00:29.

Joe Hage: I'm sorry, I thought you were finished.

Edna Falkenberg: Go ahead yeah.

Joe Hage: Jen asks...

Edna Falkenberg: Go ahead.

Joe Hage: "If a company is audited by TÜV how is it recognized by the four participating countries?

Edna Falkenberg: So actually at the moment we are participating in the Pilot Program. We are recognized as 01:00:52 organization. So a the company decides to participate in the Pilot Program, we come in, perform the audit. And at the end you will get new certificates indicating all applicable regulatory requirement on a new certificate. And for example, Health Canada fully recognizes MDSAP certificate instead of a CMDCAS certificate.

Joe Hage: Okay. Magda asks, "What about MDD? Will we have to do MDD and MDSAP at the same time by the notified body? That is will there be an extra couple of hour cost?"

Edna Falkenberg: Actually at the moment yes. Since Europe is not included in the MDSAP Program yes. MDD needs to be audited on top of that. And as well for certain areas additional time needs to be added yes.

Joe Hage: Eddie wants to know, "What about the additional requirements to ISO 13485 by other countries such as Canada? Would you require them to withstand as well under MDSAP?"

Edna Falkenberg: Yes, actually the additional regulatory requirements in addition to the 13485 yes are audited during the MDSAP audit. And clearly as I outlined in the MDSAP Companion document to be audited. Yes, additional requirements from each country are to be ... 01:02:43.

Joe Hage: Megan wants to know, "What is China's involvement in the program?"

Edna Falkenberg: China is currently not involved in the program. They are a committee member in the IMDRF but they are not actively involved currently in the program.

Joe Hage: David wants to know, "Do the various regulatory agencies have the ability to override an audit finding classification?"

Edna Falkenberg: They don't. There's actually just an 01:03:17 audit in exchange of the nonconformities with the participating regulatory bodies. But they do not overwrite the classification of the findings.

Joe Hage: Leah asks, "If an FDA deems an MDSAP inspection to be violative, then could a company receive a warning letter?"

Edna Falkenberg: At the moment under this program no.

Joe Hage: JD came back and said that, "Edna said MDSAP covers the ISO 13485 plus specific requirements imposed by member countries. What happens when the equipment fails a

specific in-country requirement imposed by a country? In this case does the organization fail the MDSAP Audit?

Edna Falkenberg: If you do no fulfill one of the country-specific requirements you will end maybe in a finding. But it doesn't that necessarily mean that you fail the MDSAP Audit. The MDSAP Audit is pretty much when you're familiar with the ISO 13485 audits you will get a finding but it doesn't necessarily mean that you fail the MDSAP Audit. You have as well the response time to findings and once this has closed out you will get your certificate.

Joe Hage: Alain says, "This sounds like it will be more burdensome for us in Europe. Currently our EU-notified body audits against 13485 and CMDCAS but we will need to separate audits if Europe doesn't join the program. Do I understand this correctly?"

Edna Falkenberg: No actually you can combine MDD with the MDSAP, so actually you can do it at the same time.

Joe Hage: She said, "You also mentioned having to sign a contract. Please elaborate."

Edna Falkenberg: Actually we have two suites. We have so-called audit agreements with our customers and before joining the MDSAP Program you need to sign an audit agreement with us. Which actually outlines that you are intending to participate in the MDSAP.

Joe Hage: Thank you. Chris asks, "Are IVD products included in the scope of MDSAP?"

Edna Falkenberg: Yes. Under the 13485 requirements quality system requirements, IVD products are as well included under the MDSAP program yes.

Joe Hage: He also asks, "FDA 820 regulations note internal audit reports, management reviews, and supplier audits are exempt from disclosure from FDA during inspections. They aren't typically made available during ISO 13485 audits. Are these records being reviewed by MDSAP? Are the details of the records disclosed in the audit reports?"

Edna Falkenberg: Yes, actually during the MDSAP audit we are looking at those records like management review reports and presentations for example in the audit reports and resolve. Actually in the audit report you will not see what we look at. Actually different to usual audit reports you might be used to from your certification body.

Under the MDSAP Program we do not lift the records we look at the in the audit report templates giving to us by the regulators. We only lift a number of records to look at. So no one actually will see which records we looked at. We only see a number of records.

Joe Hage: Edna, Robert asks, "How would a virtual company be assessed? No manufacturing on-site and no warehousing."

Edna Falkenberg: In that case for sure we will do a review of the quality agreements you might have with your manufacturing partner. If deemed necessary there might be a possibility to actually go to your supplier and audit specific tasks at your supplier. But sure it's 01:08:41 to start with the quality agreements in place with your partners.

Joe Hage: Hillary asks, "I understand MDSAP fees are by discretion of AOs but do you expect them to be significantly higher?"

Edna Falkenberg: I don't think so.

Joe Hage: Andrew asks, "We're a medical device manufacturer in Barcelona. We're interested in the program because we want to add our products to US and Canada. How do we do that?"

Edna Falkenberg: Very simple; sign up for the Pilot Program at one of the participating audit organizations. For sure prefer at TÜV SÜD and start the process.

Joe Hage: Edna do you have a link that I can share with the audience to start to get registered?

Edna Falkenberg: Absolutely. I can...

Joe Hage: And Lisa I know you're silently on the phone. If you have it you can either send it to me or there's a way on chat to send it out to the entire audience.

Philip asks, "Are we getting the presentation?" Yes we are getting the presentation and I'm going to send it out to everybody now. I already have it uploaded.

Stephanie asks ... You may have addressed this one. "Are IVDD products included or just MDD?"

Edna Falkenberg: IVD is also included.

Joe Hage: Okay. Mehela 01:10:27 asks, "If we participate in the program, will the 13485 CMDCAS be replaced by MDSAP?"

Edna Falkenberg: Yes.

Joe Hage: Rapheal asks or Raphael pardon me, asks, "During the Pilot Program what are the options for Brazilian companies to register US company devices in faster and more agile fashion?"

Edna Falkenberg: So actually the Brazil ANVISA fully recognize the MDSAP Audit report to issue GMP certificates in Brazil. So you can use the MDSAP report to accelerate your product registration. And as well to get past on the market in Brazil with that report because Brazil fully recognizes instead of GMP inspection performed by the ANVISA themselves.

Joe Hage: Chris asks ... Oh pardon me, there's a follow-up question here, "That means we would have to sign an agreement with TÜV?"

Edna Falkenberg: With TÜV or whomever you choose as a certification or auditing organization, yes.

Joe Hage: Chris asks, "Regarding the post-audit activities, does the manufacturer receive the same information an audit report as the regulatory authorities?"

Edna Falkenberg: Yes, you will get the same audit report they are getting. You will still get an audit findings list. You will not get the so-called Nonconformity Exchange form which is an exchange form between the auditing organization and the regulatory authorities which actually just includes details of your findings in the same way you're getting on your findings list.

So actually there's more information which you are not getting but the regulatory authorities will get. So actually you will get the same information.

Joe Hage: Juan asks, "What is the mechanism which may trigger ISO 13485 certification to be discontinued? Is there a real deterrent for companies to comply?" An increase of audit interval is not sufficient in his opinion.

Edna Falkenberg: Can you repeat the question?

Joe Hage: He wonders if the ... Let's see, let me see if I can rephrase it. Is there a real deterrent for companies to comply because he believes that an increase in the span of audits, how often audits happen, won't be sufficient. What's the mechanism to trigger ISO 13485 certification?

Edna Falkenberg: So actually the ISO 13485 audit cycle is a three years audit cycle. One certification or recertification audit plus two surveillance audits in the three years and continued the following three years in the same manner.

So there are typically no additional audits under the 13485. And as well currently there are no unannounced audits under the ISO 13485 unless you are certified as well under the MDD which requires as well unannounced audits in the three years cycles. But that's it.

Joe Hage: David asks, "In the event of an audit finding, which group judges the adequacy of the response?"

Edna Falkenberg: It's the same process as you might be used to. Actually it's the auditing organization the lead auditor and audit team who receives your audit responses and evaluates whether they are appropriate or not. So it's still the same process. It's the auditing organization and not the regulatory.

Joe Hage: The next question comes from me. Have you ever been so many questions so quickly?

Edna Falkenberg: No.

Joe Hage: Okay, that was an easy question. Magda asks, "Are reports submitted by the notified body or the organization?

Edna Falkenberg: By the notified body or auditing organization, yes.

Joe Hage: Eddy asks, "Can you clarify what it means that an initial certification is required? Is an ISO 13485 certification coming from the notified body?"

Edna Falkenberg: Actually to add MDSAP is actually considered an initial certification even though you're already certified again for 13485. So the requirement it's really to have a stage one and the stage audit performed where actually the stage one audit can be an offsite documentation review which actually only focusing on the requirements of the regulatory requirements you are applying for.

Joe Hage: Mark asks...

Edna Falkenberg: So there could be the potential to have... Yes.

Joe Hage: Mark asks, "Are clinical evaluation reports a requirement of this process? If so who creates it the manufacturer or the notified body?"

Edna Falkenberg: The manufacturers have to create it.

Joe Hage: Robert asks, "How does a manufacturer challenge an AO finding?"

Edna Falkenberg: Can you repeat it?

Joe Hage: How does a manufacturer challenge a finding?

Edna Falkenberg: How manufacturers challenge a finding. It's still the same process you might be used to. You will get a finding from the auditing organization for sure. There's still ... We have an appeals process where actually you are able to appeal against the finding if you don't agree with the process.

But usually as well doing an audit there should be not a surprise for a company at the end of an audit in regards to a finding. So the typical approach to raise findings is clearly to let a company know right away if an auditor finds an issue in the quality management system and if you have thoughts during the course of the audit.

Joe Hage: Pedro says, "Medical device companies are paranoid when facing FDA audits because of the power of the federal agency. How is this going to change with single audits?"

Edna Falkenberg: Actually with this program we perform the audits on behalf of the regulatory authorities much different, not much different in regards to the audit process you might be used. When you are certified we're just adding additional requirements and exchange at the end of the report these regulatory authorities. And to be honest unless there are no product-related issues which might cause the FDA coming back to your company, you should be on the same side.

Joe Hage: There are multiple ISO standards and guidelines for risk management. Which documents will the MDSAP follow?

Edna Falkenberg: It's the ISO 4971 for risk management.

Joe Hage: David asks, "How would an audit be conducted and reported if a manufacturer wishes to combine an MDSAP with an ISO 13485 Audit?"

Edna Falkenberg: It will be actually the approach under the Medical Device Single Audit Program because the base is the 13485. So we will check the compliance of the 13485 plus the additional requirement. But the approach will be following the Audit Model under the MDSAP Program.

Joe Hage: Leah asks, "Is it anticipated that Health Canada will force medical device manufacturers to participate in MDSAP by 2018 in lieu of their current CMDCAS? Will there be alternatives if manufacturers choose not to participate?"

Edna Falkenberg: No at the end Health Canada will ... there will be only one way to get a CMDCAS certificate or at the end an MDSAP certificate under the Canadian requirements because Health Canada clearly was stating once the MDSAP Program is implemented they will go away from the standalone CMDCAS program. So there is no way for the Canadian requirement around 2018. Not to participate in the MDSAP Program you need to have it under the Canadian requirement.

Joe Hage: Since companies don't currently pay for FDA audits but do pay for ISO audits, will companies pay for MDSAP audits?

Edna Falkenberg: Yes, companies will pay for MDSAP audits.

Joe Hage: Mark asks, "What is the availability of the Audit Model document?"

Edna Falkenberg: The Audit Model document can be found on the FDA's MDSAP webpage. There's actually a link I provided in my presentation. Just go to that website and you will find the Audit Model document as well the Companion ... so-called Companion document. And as well the document for calculation on-site audit time. So this website gives you a good overview about the documents and as well as the requirements.

Joe Hage: Leah says, "Currently manufacturers typically don't share internal audit results with FDA but do share 13485 CMDCAS certification. How will internal audit results be handled in the MDSAP Program? Will they be reviewed and assessed in MDSAP Audits?"

Edna Falkenberg: Yes, and some audit results will be assessed during the MDSAP audit program.

Joe Hage: Do manufacturers receive the same information as the agencies?

Edna Falkenberg: Yes.

Joe Hage: What will be the impact of the revision on 13485?

Edna Falkenberg: There might be a law coming of the revision of the MDSAP Audit Model document to align the processes and requirements with the audit tasks.

Joe Hage: You may be pleased to know that I can now see the remaining questions on one page.

Edna Falkenberg: Wow!

Joe Hage: Yeah. JD asks, "We heard that some organizations will be transition. Can you provide timelines? When will organizations such as FDA, HC, ANVISA, and TGA no longer accept CMDCAS audit reports? Please provide insight by country."

Edna Falkenberg: I only have the insight in regards to CMDCAS right now in regards to the transition. It's 2018. I certainly can find out more information and provide to the participants or attendees later in this week.

Joe Hage: Yes I'll be able to send something out to the full group.

Edna Falkenberg: Okay.

Joe Hage: Pedro asks, "How is industry going to be trained in this program?"

Edna Falkenberg: The best part here is there is no official dedicated training or preparation for manufacturers available right now. There was always specific trainings for auditors made available by the FDA. But unfortunately for companies there is nothing available on the market right now.

Joe Hage: Pedro may I suggest that you get in touch with Edna after this recording? That might help.

Edna Falkenberg: Absolutely, absolutely.

Joe Hage: Mark asks, "Combining all these regulations in an audit seems like the creation of a new quality management system standard. Has that been considered by IMDRF?"

Edna Falkenberg: No, it has not been considered to create a new quality management system standard. They just tried to take the 13485 as the basis and add the additional requirements to it. Which in most of the case in regards to the 13485 requirements there are not many tasks where actually additional requirements are needed by the four regulatory authorities.

Joe Hage: Okay Edna. As entertaining as that was here comes the speed round. I've got six questions remaining in five minutes, you're ready?

Edna Falkenberg: All right.

Joe Hage: Eddy says, "What if we manufacture of do subcontracting, would our subcontractors be subject to the MDSAP Audit?"

Edna Falkenberg: As I said earlier the first approach would be to verify your quality agreements you have in place with your subcontractors. In case there are some concerns there might be a possibility that the auditing organization visits as well your subcontractor.

Joe Hage: What will the AO do for six days? You can't look at a quality agreement for six days.

Edna Falkenberg: Right, right. At the end, actually at the end ... But actually there are a lot of tasks. Well actually as well we can reduce time if production is not clearly applicable we can reduce time. So that might be not six days on site where we exclude the production activities so the time might be shorter then.

Joe Hage: If we have FDA clearance already will we be fast-tracked on ANVISA?

Edna Falkenberg: You have to actually either to have the MDSAP report to actually accelerate your ANVISA application.

Joe Hage: Which leads to his next question, "If we have an MDSAP certificate, how do we get it?"

Edna Falkenberg: The MDSAP certificate you will get after successful completion of the MDSAP Audit which includes as well the closure of the findings in case there were findings during the audit. So once you have closed everything out, the auditing organizations will issue the MDSAP certificate.

Joe Hage: Smooth sailing now. Two minutes for ... Three minutes for two questions.

Edna Falkenberg: All right.

Joe Hage: Chris asks, "What information is on the Nonconformity Exchange form that's provided to a regulatory authority that is not provided to the manufacturer?

Edna Falkenberg: So actually there is no different information on the exchange form then on the findings list you are getting from the auditing organization. So the exchange form includes the description of the findings, the applicable clause under the 13485. Plus the evidence where the finding was raised. It includes a little bit more information in regards to the regulatory requirements written again.

So actually they require us to have really a full picture in regards to the regulatory requirements. Plus the grading in the 01:28:44 list we have to indicate whether the finding is closed or still open. As well they won't see anything in regards to your corrective action and the implementation. The only thing that they are seeing is whether we indicate the finding as closed or it's still open. If you're...

Joe Hage: You took a lot of time with that answer. That leaves us one question.

Edna Falkenberg: I know, and as well just to add that the Nonconformity Exchange grading form or the exchange form is as well available on the FDA website.

Joe Hage: Mehela asks your final question, "Who sends the inspection report to each regulatory body, manufacturer or certified body?"

Edna Falkenberg: It's the auditing organization.

Joe Hage: Edna I don't know how you like to treat yourself. I don't know if it's like getting your nails done or going out for an ice cream Sunday or if you like to drink. But whatever it is I think you deserve it today.

Edna Falkenberg: Thank you very much.

Joe Hage: That was quite an adventure seeing you raise through all of those questions. Now with everyone's patience ... Pardon me I'm going...

Edna Falkenberg: ... enjoyed it.

Joe Hage: ... to send out a link out to you for everyone to download the slides. Here it is in the chat box. And I will send an email out to everyone who is still on the line and those who registered but could not attend to download these slides. As I said, the replay will be ready I hope later today, and I will have the entire talk transcribed.

Edna Falkenberg, when they said that you were an expert in this program, they were right. Thank you very very much for educating the Medical Devices Group today.

Joe Hage: Thank you.

Edna Falkenberg: Be well everyone. Thank you for joining us.