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- -

Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

(<http://Elsmar.com/Forums/showthread.php?t=30317>)

Jim-S

15th October 2008 02:32 PM

Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

Regarding the post-market surveillance required by the EU's MDD, is this requirement similar to the ISO 13485 requirements or does it go beyond them? If a company complies with ISO by compiling information regarding customer complaints & feedback, and then submits the information for review for Management Review, does this satisfy the post-market surveillance requirement?

Marc

15th October 2008 06:08 PM

Re: Question on Post-Market Surveillance required by the EU's MDD

Not my field, but here's a starter:

Existing [MDD discussion threads](#)

Vitali57

19th October 2008 09:51 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Perhaps GHTF post marketing surveillance document under SG2 may be of help?

Al Rosen

19th October 2008 11:34 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

It's the same requirement. ISO 13485 is the harmonized standard used to meet the Quality system required by the MDD. This is discussed in other threads.

MDQSA

5th January 2009 04:14 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by **AI Rosen** (Post 277639)**It's the same requirement. ISO 13485 is the harmonized standard used to meet the Quality system required by the MDD. This is discussed in other threads.*

I wouldn't completely agree with this thought. PMS in the MDD environment is meant to be more pro-active in nature than necessarily what is called out in ISO 13485. So instead of reacting to customer feedback (complaints, etc), companies should be out in the field using surveys or literature reviews or other means to collect meaningful information.

See NB-MED2.12/Rec 1 for more guidance on PMS activities for the EU

SteveK

6th January 2009 04:20 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

I agree with everyone.

However, my NB auditor (in 2008); covering ISO 9001, ISO13485 & 93/42/EEC, 'strongly suggested' an increased emphasis on post-market surveillance 'specifically' due to the 2007 update of 93/42/EEC. Although I've mentioned in another thread (I think!) how difficult it can be to get such feedback e.g. from customers (other than complaints!), I've tried to show I have at least attempted to address/consider this increased requirement for the next audit (partly based on clause 1.1c in Annex X, which then links to clause 8.2.1 paragraph 4 in ISO 13485). It might be repetitive/going over the top/stating the obvious, but I have created a top level P-M Surveillance SOP which captures our relevant lower level SOPs (Complaints, Recalls, Int. Auditing, CAPA, QM Improvement) and other indicators/reviews/forms/KPIs/questionnaires etc that we have in our QM system. So now I have a (single) flag I can wave - during a management review and/or audit.:2cents:

sreenu927

8th May 2009 03:36 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Steve..

Recently we had MDD audit. One comment is to strengthen the Post Market Surveillance System. We have complaint handling SOP, FSCA, CAPA SOPs and customer feed abck form n survey results forms.

The auditor suggested to include publications, scientific literature, competitor's products, etc..and document them.

Now, I am not sure, whether to document all the abovesuggested in a word file n save in a folder or to go ahead with a PMS SOP??

If yes to SOP, could you please advise me the format for the same?

Many Thanks,
Sreenu

SteveK

8th May 2009 07:55 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Sreenu,

I have conducted a literature/publication review for all the medical devices we make. These are the centre point of my 'Clinical Evaluation' (Word format) as part of my Technical File(s). The trouble is wrt post-market surveillance is that these tend to be at least a year old if not more - so it does not make much sense. Not really thought about competitor information, but shouldn't the post market surveillance be on your own products. I suppose if there was a problem with a competitors product it would be relevant, but this would be captured in a Device Alert (a MDA, Safety Notice or Recall in the UK - available on the MHRA site) of some form (i.e. a publication again).

Steve

chris1price

8th May 2009 10:07 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Sreenu

A few years ago, following an FDA audit, I was also asked to perform literature reviews as part of PMS. We listed in a procedure the 6 main journals (covering UK and Worldwide) we subscribed to. These were reviewed monthly for applicable papers and entered into the complaint system when appropriate. A simple spreadsheet was used to show that the reviews had taken place.

My US colleagues also performed a PubMed search on a quarterly basis looking for any papers that we had missed.

At the time, there were few internet forums, so we did not search the internet - however, today it may be more difficult to do this.

Chris

Al Rosen

8th May 2009 01:22 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

From the MDD.

Quote:

an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: ◀

(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the

instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

Where does it say to do this on devices that someone else produces?

SteveK

11th May 2009 03:40 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

As AI and I (and the MDD) have indicated, the post-market surveillance is for your own products. I think the problem is that, other than anecdotal evidence (e.g. from sales staff, medical device related forums etc), how difficult it is to get direct feedback from customers/users in the first place. It is all very well saying use surveys – but how many surveys have you been sent that just end up in the bin (trash)! Auditors must know this – so is this just a tick the box game they must play?:2cents:

Steve

sreenu927

12th May 2009 12:08 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Steve & Chris,

Thanks for your suggestions. But still, am not clear on this PMS.
Is it necessary to have a separate SOP for PMS, if so, what shud be the content?
How to address this issue of PMS?

In NB-MED/2.12/ Rec 1 PMS document, it is mentioned that "...experience with similar devices made by the same or different manufacturer" as one of the sources for PMS. I believe, it is as same as competitor's data.

We have documents for analysis done for complaints, CAPRs, SOP for Vigilant system, exhibitions(of our product), scientific literature(for our product).

Thanks & Regards
Sreenu

SteveK

12th May 2009 03:56 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Sreenu,

Here is what I have done (hopefully to keep an auditor happy, cover my back etc). Within the hierarchy

of documents – QM, SOPs, Work Instructions and so on down the line, I have created a top level SOP for Post-Market Surveillance which basically highlights what I already have in place i.e. to make it bl**dy obvious for an auditor (like in your driving test – deliberately pointing your face at the rear view mirror to show the instructor you are checking behind you!). This SOP indicates that I have SOPs for "Handling Complaints"; "Recall & Advisory Notices"; "Internal Auditing"; "CAPA" and "Quality Management Improvement". It also indicates all the supplementary forms (templates) and inputs (sources of feedback and analysis) that I have available/created – it references MEDDEV 2.12-1 rev 5 etc as well. It may be a little OTT – but for auditing purposes, that is the point – IT SHOWS I HAVE CONSIDERED IT, MADE AN EFFORT!

Steve

sreenu927

12th May 2009 05:03 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Steve,

So, is it ok, if we REFERENCE other vigilance system procedures in this SOP?
Is there any procedure else to satisfy auditor that we have considered all the NB-MED and MDD requirements?
If you don't mind, cud u plz share the template?

I am planning as follows:

1. As mentioned by Chris, prepare a spreadsheet and do literature survey of competitor products (including risk analysis, clinical evaluation of those products) indicating the frequency for the survey.
2. Considering the Vigilance SOPs in 2,3,4 (or so..) points.
3. Semi-annual Analysis of complaints/complaints review (apart from clearing complaints as and when received)
4. Consideration of Annual customer feedback survey. (No idea if there is any particular quantitative requirement for this??)
5. Exhibitions, seminars or talks or training programs to dentists (our customers) shall be conducted as and when required (proof of previous, if any).

Advise me.

Thanks,
Sreenu

SteveK

12th May 2009 07:43 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

1 Attachment(s)
Hi Sreenu,

Reference anything (guidance etc) that is relevant (see attached) in my view. As said before, I believe it is the surveillance of *your* products that is the main goal of the MDD requirement. But looking at other sources of information (as you suggest), at least shows that you are being 'proactive' to an auditor in your quest for feedback. I do not know if the SOP attachment (template) will be much use – as it references my other documents, forms and systems (these I cannot supply).

Hope this helps!

Steve

Marlin

12th May 2009 05:39 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

I too had a suggestion during last year's audit of ISO13485MDD, etc. to come up with a stronger post market surveillance system.

We have used a Marketing Feedback form for a long time. I have begun to collect all the positive forms and file them in the post market surveillance file since they all eventually end up with me for storage. I have to remind the sales personnel and customer service to write up the positive comments. They never fail to give me complaints. We also ask the trade show attendees to document positive remarks for us. My next audit is in June so I will see what the auditor has to say about this system.

Marlin

sreenu927

12th May 2009 11:39 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Dear Steve,

Thank you for the template, yeah, it is a quite useful one, inlines of my draft, but more clear with inclusion of ISO and MDD requirements.

Hi Marlin,
Thanks for sharing the info.

Regards
Sreenu

Roland Cooke

13th May 2009 01:08 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

One of the questions I ask to test the efficacy of a company's PMS system is:

"If your competitor's similar device had problems in the field, how would you learn about those problems, then, how would you determine if those problems might also affect your devices (i.e. possibly in the very near future)?"

I then look to see if the PMS procedure matches the response.

A lot of companies tend to overlook the fact that they have an entire department part-dedicated to PMS. It's called "Marketing".

patmelad

31st August 2009 03:10 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

do you still have that template?

Al Rosen

31st August 2009 07:56 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by patmelad (Post 332996)
do you still have that template?*

If you want a copy just click on the link <http://elsmar.com/Forums/images/attach/pdf.gif> [PMS SOP.pdf](#)
(147.3 KB, 64 views)

zkoulou

31st August 2009 09:22 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Al.
what template? it has been awhile

tec11

21st October 2010 02:31 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Thank you sooo much. this doc was immensely useful to me.

RCW

22nd November 2010 02:42 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

As a contract manufacturer of medical devices, would I need to have a PMS system in place? (Assume ISO 13485 requirements are present.) As hard as it is to get feedback out of the user of the medical device, when you are a level below the company marketing the device, it's even more difficult.

Note: My customers are addressing the advisory notices and are interfacing with the medical device users.

MIREGMGR

22nd November 2010 04:18 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by **RCW** (Post 406863)*

*As a contract manufacturer of medical devices, would I need to have a PMS system in place?
(Assume ISO 13485 requirements are present.)*

No as a regulatory requirement.

Maybe yes as a contractual requirement, if one or more of your customer agreements calls for it.

SteveK

13th January 2011 05:26 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by **SteveK** (Post 312667)*

I suppose if there was a problem with a competitors product it would be relevant, but this would be captured in a Device Alert (a MDA, Safety Notice or Recall in the UK - available on the MHRA site) of some form (i.e. a publication again).

Just as a follow up to my comment about using alerts, FSNs, recalls, safety notices etc (e.g. issued in the UK by MHRA) as a form of PMS i.e. monitoring for medical devices similar to your own, these sites listed may be useful. Obviously it can be a pain to trawl through a lot information to find anything relevant, but at least I can show an auditor a degree of vigilance. I do this by recording the total number of alerts etc for each month and authority on a spreadsheet. Then I highlight any link to the type of devices similar to our own. You may encounter a problem you were not aware of, so then you can update your Risk Assessment file accordingly. For foreign language sites you can use the Google translator. Note for the FDA site since so many alerts are thrown up, I filter these by worst case i.e. causing 'death' (it helps first off to get the 3 letter code for your type of device for the search).

MHRA

<http://www.mhra.gov.uk/Safetyinforma...alls/index.htm>

FDA

<http://www.accessdata.fda.gov/script...UDE/search.CFM>

HC (Canada)

<http://www.hc-sc.gc.ca/dhp-mps/compl.../index-eng.php>

MDB (Malaysia)

<http://www.mdb.gov.my/mdb/index.php?...=69&Itemid=119>

HAS (Hong Kong)

<http://www.mdco.gov.hk/english/recalls/recalls.html>

IMB (Ireland)

<http://www.imb.ie/EN/Medical-Devices...y-Notices.aspx>

Saudi FDA

http://212.100.220.58/services/md_Re...lsDispaly.aspx

Afssaps (France)

<http://www.afssaps.fr/Infos-de-secur...de-securite#dm>

bfarm (Germany)

http://www.bfarm.de/cln_103/EN/medDe.../fca-node.html

Salute (Italy)

<http://www.salute.gov.it/dispositivi...ingua=italiano>

Swissmedic

http://www.swissmedic.ch/rueckrufe_m...Archiv=2010-07

Not all countries publish details of their alert, but if anyone else knows of any other sites that do, please let me know.

Steve

MegSinha

15th June 2011 07:36 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi Steve,

My Company has the PMCF NC from our NB, I am currently working on putting a procedure together but the post related to Post Market Clinical follow up named

"Post Market Surveillance Guidelines or examples of procedures"

(I just joined so can't put the exact link)

In this post Sam says that it is not deemed necessary if duly justified? Do you think its just better do it or it is better to justify why we are not doing it since the product classification is IIa?

Please advise.

SteveK

16th June 2011 04:24 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

The link is:

[Post Market Surveillance Guidelines or examples of procedures](#)

Anyway I believe a "clinical follow-up" relates to implantable/class III products. There is a current case (originally initiated by the FDA) that DePuy (J&J) must conduct a "clinical follow-up" on their metal on metal hip replacements (i.e. on individual patients) - which have now been withdrawn. I think this is the context of the requirement, so I do not see how it could easily relate to a class IIa device. As Sam says, PMCFU is a sub-set of PMS. I would be interested in what your NC actually says. It may be down to how your NB defines PMCFU i.e. for your class IIa device instead that is the problem.

Steve

MegSinha

16th June 2011 01:42 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

This is what exactly the NC says:

... "The procedure on Post-Market Surveillance System was provided. Although it refers to the need to establish "a post market surveillance plan for each product", it does not introduces the notion of Post Marketing Clinical Follow-up as required by the Medical Device Directive in it Annex X - section 1.1. quarter"

... What I figured is that they needed a PMCFU to be a part of our PMS, but as I said in Annex X though is does not state explicitly, it does state that this is required for Class III and implantables, so should I just add a procedure for clinical evaluation or should I talk to them and say that our product is Class IIa, does not require clinical evaluation?

SteveK

17th June 2011 03:40 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by **MegSinha** (Post 438706)*

This is what exactly the NC says:

... "The procedure on Post-Market Surveillance System was provided. Although it refers to the need to establish "a post market surveillance plan for each product", it does not introduces the notion of Post Marketing Clinical Follow-up as required by the Medical Device Directive in it Annex X - section 1.1. quarter"

... What I figured is that they needed a PMCFU to be a part of our PMS, but as I said in Annex X though is does not state explicitly, it does state that this is required for Class III and implantables, so should I just add a procedure for clinical evaluation or should I talk to them and say that our product is Class IIa, does not require clinical evaluation?

You **will** require a clinical evaluation, but this can be done by the literature route (I have have an example document if you do a search on 'humidifier'). I do not think this is the same as a PMCFU for a Class IIa device for the reasons already stated.

Steve

MegSinha

20th June 2011 12:51 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Thanks a lot Steve. That helps!

Compliance Audit Guy

20th June 2011 09:35 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Hi

A very interesting discussion. Wondering if someone knows of a listing of the regulatory requirements by country for drug and device adverse events? Like for a device that a serious injury needs to be reported within X days, near adverse event within X days, a malfunction within x days, etc.

For devices, I am aware of the GHTF SG2 document on the topic but that compares only the requirements in some major regions -- Canada, EU, Japan, US, Australia.

Has anyone put something like this together? Any help would be appreciated.

Thanks!

SteveK

21st June 2011 03:48 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 requirements

Quote:

*In Reply to Parent Post by **Compliance Audit Guy** (Post 439172)*

Hi

A very interesting discussion. Wondering if someone knows of a listing of the regulatory requirements by country for drug and device adverse events? Like for a device that a serious injury needs to be reported within X days, near adverse event within X days, a malfunction within x days, etc.

For devices, I am aware of the GHTF SG2 document on the topic but that compares only the requirements in some major regions -- Canada, EU, Japan, US, Australia.

Has anyone put something like this together? Any help would be appreciated.

Thanks!

For 'Incident' reporting in the UK i.e. to the MHRA:

Serious Public Health Threat: – Immediately (without delay that could not be justified) but not later than two calendar days after awareness of this threat.

Death or unanticipated serious deterioration in state of health: Immediately (without any delay that could not be justified) but not later than 10 elapsed calendar days following the date of awareness of event.

Others: Immediately (without any delay that could not be justified) but not later than 30 elapsed calendar days following the date of awareness of the event.

In my case I have this written in my 'Recalls & Advisory Notices' SOP.

Steve

sreenu927

22nd June 2011 09:46 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

1 Attachment(s)

Hi, see attached for a few Countries, reporting timelines for Medical Device Reporting/Adverse event reporting and FSCAs.

Regards,
Sreenu

Compliance Audit Guy

25th June 2011 12:43 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

Thanks Sreenu,

In a succinct way, a very informative response to my post.

I remain to struggle in determining if there is any structured requirements for India, China, Latin America countries. I would sure appreciate any suggestions on these from you or any one having knowledge in this.

Thanks!

sreenu927

26th June 2011 06:45 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements**Vigilance & Adverse Event Reporting – China**

1. Within 5 working days for an adverse event that caused death.
2. Within 15 working days for an adverse event that caused or may cause serious injury.
3. Adverse events are to be monitored.
4. Provide a procedure for the re-evaluation of medical devices with potential safety concerns and report the re-evaluation results to the SFDA.
5. Adverse event tracking and monitoring records shall be kept for 2 years past the expiration date of the product and not less than 5 years.
6. Submit an Annual report each January to the SFDA summarizing all adverse events that occurred in the previous year.
7. Submit the notification to the Medical Device Adverse Event Monitoring Technical Institution

For India, at this moment there are do defined timelines for vigilance reporting.

List the Latin American Countries which you are looking for?

Regards,
Sreenu

Albena

24th July 2012 12:01 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

Dear, All,

My name is Albena and I'm from Bulgaria. A month ago I've become responsible for writing a PMS SOP and I almost did it. But the main question that occurs is connected to the necessity of preparing a PMS plan for each medical device. I have drafted such a plan, but I'm not sure if it is completed enough. Do you have experience with this part of the game?

P.S. Sorry for my English:(

Cheeky on tour

24th March 2013 05:05 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

sreenu927,

Please can you show me where you found the EC reporting times? I couldn't find them anywhere!!

SteveK

25th March 2013 08:44 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

Quote:

*In Reply to Parent Post by **Cheeky on tour** (Post 515007)
sreenu927,*

*Please can you show me where you found the EC reporting times? I couldn't find them
anywhere!!*

Try going to:

http://ec.europa.eu/health/medical-d...12_1_ol_en.pdf

Steve

SpartanBio

7th May 2013 10:44 AM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

Hi,

During an audit, the auditor indicated that we did not cover the requirements of NBMED/2.12/Rec1 adequately, however I can't find a link to it. Can you anyone help out?

MIREGMGR

7th May 2013 12:18 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

[http://www.team-nb.org/documents/201...ance_\(PMS\).pdf](http://www.team-nb.org/documents/201...ance_(PMS).pdf)

This document of course is a guidance from a third party, not a regulatory requirement per se. I assume the auditor didn't actually describe it to you as a "requirement"...?

SpartanBio

7th May 2013 12:57 PM

Re: Post-Market Surveillance required by the EU's MDD vs. ISO 13485 Requirements

:thanks:

No they didn't site it as a requirement just noted that we didn't address it. Thanks for the link.

The time now is 01:30 PM. All times are GMT -4.
Your time zone can be changed in your UserCP --> [Options](#).

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