⛑️ Vigilance Reporting: The Other Consultants & Easy Medical Device

What is Vigilance Reporting? 🤔

In the Medical Device Directive (MDD) Vigilance and Post-Market Surveillance were loosely defined.

Firstly, let's perhaps say what Vigilance is not. Vigilance is not PMS. However, it does form PART of PMS (incidents). Under the European Union Medical Device Regulation (EU MDR) there is a clear delineation; "Vigilance"; the identification, reporting and trending of serious incidents and the conduct of safety related corrective actions, and "Post Market Surveillance" (PMS); the monitoring of information from various sources used to periodically reconfirm that the benefits of the device continue to outweigh its risks. Anyway…here is some information from MEDDEV 2.12 rev 8 – Guidelines on Medical Devices Vigilance System:

The purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incident elsewhere. This is to be achieved by the evaluation of reported incidents and, where appropriate, sharing of information, which could be used to prevent recurrence, or to alleviate incident consequences.

Incidents that meet reporting criteria specified in the vigilance requirements of the EU MDR found in Chapter VII Section 2 (Articles 87 to 92) must be reported to the Competent Authority (CA) of the member state where the incident occurred. Manufacturers may potentially need to report to other competent authorities where they have devices on the market if an incident meets their reportability criteria.

Is vigilance reporting the same for each country? 🌎

Not really. As said above, the incident must be reported to the Competent Authority (CA) of the member state where the incident occurred, or potentially you may need to report to other competent authorities your device on the market if an incident meets their reportability criteria for occurring elsewhere. If you're in Europe, you have one set of timelines to consider. Other countries such as the USA have different reporting timelines.

💡 Here is a spreadsheet that has a list of the reporting requirements for different countries, it's constantly being updated -

Global Vigilance Reporting Requirement Timelines - Google Drive

https://drive.google.com/drive/folders/1YivbvzoRnTQ0TPSBMOCxo4h6-6jR3kTY?usp=sharing

In the United Kingdom (UK), the Medicines and Healthcare products Regulatory Agency mange reporting through their system called MORE (Manufacturer's On-line Reporting Environment). Here is the link - https://aic.mhra.gov.uk/

In the European Union, manufacturers will have to use EUDAMED. However, the vigilance module is not yet live. So, for now, manufacturs are continuing to use the Manufacturers Incident Report (MIR) form and submit reports to the CA.

Here is a link to a handy document put together by the commission containing the details to submit compelted MIR forms to - https://health.ec.europa.eu/system/files/2023-02/md_vigilance_contact_points.pdf

The Food & Drugs Adminstration utilise the Manufactures and User Facility Device Experience (MAUDE) Database which seems what EUDAMED may be slightly based on since its been around for a while now - https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

How to develop a Vigilance System? 👋

The first thing to consider is what countries you have product placed on the market. From here, manufacturers need to understand the different vigilance timelines and requirements that are in effect. I.e. where are my products on the market? If you sell into Germany, then the EU reporting timelines apply. If you sell into Japan, Japanese reporting timelines apply.

One procedure can work for all, or separate procedures can work per country. There is no right or wrong, as long as effective and conforming to requirements.

As we said earlier, a vigilance process is part of the PMS system. So, it must link to CAPAs, customer complaints, as well as supplier nonconformances.

The most typical scenario is an organisation receiving customer feedback. When customer feedback (positive or negative) is received, the organization BECOMES aware. Becoming aware typically means anyone in an organization first being notified of an alleged deficiency. This could be anyone in the organisation picking up the phone and being given information. So it is important that anyone that has access to communication mechanisms must be aware of the vigilance process or who to notify.

It is from the first notification of this that the manufacturer will be considered as becoming aware, and as a result, the reporting timelines will initiate from the relevant jurisdiction in which the incident has occurred. Other jurisdictions that the device is sold into may also be affected by this.

The organization need to link into their customer feedback processes and have a documented procedure to assess the following but this list is certainly not exhaustive; customer feedback, CAPAs, nonconformances (NCs), trend reports, and clinical findings are good examples of things that have to be considered as whether they meet the criteria of a reportable event. From here, it can then utilize several decision trees for the applicable regions that are in scope of the incident.

Do Notified Bodies (NBs) care about vigilance reports? 📜

Of course they do, however, the CA is more concerned with vigilance reports. It is good practice to notify NBs or your QMS mandates it, but they likely would follow up on the vigilance report on their next surveillance visit.

Due to the NB having assessed the manufacturers vigilance system as part of certification audits, providing the manufacturer is working to their system the NB would be likely happy to verify on follow up. This of course can vary on case by case basis.

How to remediate a Vigilance System?

It depends what needs remediated, but generally, it all comes back to what is said above. Map out the regions you sell product into and understand the reporting requirements. The tool of Who, What, When & Where can be useful to do this as a brainstorming activity. Once you have that, document your procedure/procedures and integrate into your QMS processes such as CAPA, NC etc.,

Where to find the information?

There is lots of information, but here are some of the best places for information on vigilance. You can't go wrong with the official websites, in case things change so here are some useful links that may help:

- MEDDEV 2.12 rev 8 – Guidelines on Medical Devices Vigilance System
- International Medical Device Regulators Forum Vigilance Documentation
- FDA MAUDE Database
- EU Vigilance Contact Points
- MHRA MORE Database
- Global Vigilance Reporting Requirement Timelines

Contact Us

If you would like to ask any further questions, please feel free to get in touch through LinkedIn:

https://www.linkedin.com/in/adam-isaacs-rae/

You can also check out my newsletter at:

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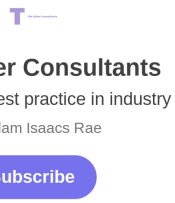

Additionally, you can find more information on the website:

https://www.theotherconsultants.com/