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WEBINAR TRANSCRIPT – PART I

The Ins and Outs of Post Market Surveillance Under the EU MDR

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What are the MDR requirements for PMS

The requirements are stated in articles 83-92 of the MDR. These are specifically tied to post-market surveillance, and going through every article, it tells you what you need to do. Let's start with article 83, which defines the PMS system that you must have in place and what you're going to do about it. The PMS system is actually driven by your PMS plan. Your PMS plan is stated in article 84, or Annex III. The Annexes will tell you how you should put things together, whilst your articles tell you what you need to do. So, the articles will tell you what to do, but they won't tell you how, but the Annexes will tell you how or what exactly should be reported into your particular document or report.
Your PMS plan, which drives the system, is the plan that will detail the methods that you're going to use to collect your data, or what are you going to collect, the frequency, and how you will communicate.
The PMS plan should be part of your technical documentation that you will be submitting initially for your conformity assessment to your notified body, and for your technical documentation that is stated in Annex II.

To summarize:

Article 85: Post Market Reports for Class 1

Article 86: PSUR Periodic Summary Update Report with a Safety Update Report

Article 87: Serious incidents and Field Safety Corrective Action Reporting

Article 88: Trend reports - how you analyze the trends, what triggers did you put in place, and what systems you are actually using to analyze the data of your medical device

Article 89: This talks about how you're going to analyze these reports both from a manufacturer's point of view and from the competent authority and the European Commission's perspective

We should all bear in mind that the MDR came as a result of heavy criticism that was alleged against the MDD framework and the key parties involved. So now, competent authorities are supposed to carry out a

detailed analysis of vigilance, analysis of reports that manufacturers or notified bodies have submitted to the electronic system, and that the system is aligned with what is defined in article 92 - the EUDAMED - the European Database for Medical Devices.

Article 92 branches off into article 90, which talks about the competent authorities and the analysis that they will be doing. The member states or the competent authorities will have to work with the European Commission when they're doing extra analysis as well. Then the competent authorities will be assessing article 92, which is the data that has been submitted by the manufacturer into EUDAMED. Competent authorities can then say, let's analyze a particular wound care dressing device that we've got reports of in France, and the trend in the report is not looking good. France could then ask a German colleague how this device performs on their market. Many items are not covered in articles 83 to 92, you've also got your quality management systems with its SOPs, your risk management system, your clinical evaluation plans, and reports (CER) and your post-market clinical follow-up plans and reports (PMCF) and then your summary of safety and clinical performance of your devices (SSCP).

MDR Requirements – Article 83 PMS System

Article 83 describes what you must have in a post-market surveillance system, and this should be established and maintained. The PMS should be part of your quality management system. You must have processes already identified, defined, and written readily available to demonstrate what you are going to do. The key processes that you're going to have to do will depend on your device classification.

Your PMS system is risk class dependent. It must be suited to the activities that you're doing, and it must systematically gather, record, and analyze the data that you're going to capture. It must also define what sort of data that you're going to capture, and the data should be able to cover the quality, performance, and safety of your device throughout its life cycle. It's not just the first two years of putting the products onto the markets, it's for the entire lifetime. For some of these reports you have to do that manually, and for some of these reports, you have to submit them every two years. For some of them, you have to go according to your notified body audit schedule.

Article 84 – PMS Plan

The plan that you put in place must be able to achieve all the things that you have defined as what you're going to do in your PMS system, and the PMS system must power your QMS. All these things are linked together now. Your QMS defines your PMS system, and your PMS system has got the PMS plan. They are all integrated and your PMS plan must be part of your technical documentation. Let's look at an example of literature sources. Now, no two sites that you see will have the same interface, and the format of data that is exported from these sites can vary. There is a need for a systematic process to gather and store information from these databases as a uniform data set.

Why is it part of your technical documentation?

Your notified body that's assessing your products wants to know what you're going to do to maintain the products to continue to be compliant to the MDR, or whatever standards that you are following to make sure that you are putting processes in place. Also, they want to make sure you are actually going to follow these and that the device is going to be compliant and most importantly, users are going to be safe. Additionally, to prove your benefits do outweigh your risks. That's why it will give you the approval or CE Mark. But when it's widely used, what does this benefit risk ratio look like after millions of people have actually used your device?

What methods are you going to use to gather this data?

If you're going to analyze scientific literature, what databases are you going to assess? PubMed or Embase, all these scientific and digitized databases are out there. How are you going to analyze your data? What methods are you going to deploy your methodology to analyze the data? All of these things must be stated in your PMS plan, which is part of your QMS, and you must have your SOPs.

The most important thing here is that the PMS plan must identify your PMCF plan. Post-market clinical follow-up is the heart of your post-market surveillance and there's a big emphasis on post-market clinical follow-up for medical devices under the EU MDR. Basically, for your post-market clinical follow-up, when you are going to market you might have very little clinical data on the use of the device. But now that it's been widely used, how is it performing? What's the safety and performance of it, the side effects that you identified pre-market stage, how are they holding up? Are you seeing a bigger ratio or lesser, the contra indications that you stated - how are they doing?

So you will have a list of objective things that you want to achieve, and some of them could cost a lot of money. It's advisable to space these things out over a period of time. Don't just go in year one trying to achieve everything. It is acceptable if you decide to spread out some of these activities over a five-year period. For example, in year 1, this is what you're going to cover, year 2, this is what we're going to cover as your objective, etc. Then basically feed in your risk elements from the pre-market stage with the data that you've gathered in your post-market stage and reevaluate things. That's a general summary of your post-market clinical follow-up.

Helping You With **Regulatory Operations**

If your organization requires assistance in any of the above EU MDR or FDA requirements, as well as other markets, our team is here to help

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