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WEBINAR TRANSCRIPT – PART II

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

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Article 85 – PMS Report

This report is a summary of all the activities that you've outlined in your PMS plan. It must be focused on the performance, what it will do, and the quality of your device. You have to define how you're going to get your complaints and feedback. You must also identify how you've analyzed the data and what conclusions you've made as well as any trends in both serious and non-serious incidents. What information have you found on similar devices that are already on the market? It must be comparable in performance. All of these things have to be included in the report.

Article 86 – Periodic Safety Update Report (PSUR)

This is applicable for class IIa to class III devices. You've got the summary of activities that you've stated you will carry out in your PMS plan, and you must detail your conclusions that you've made with rationale for the actions that you've taken. If you had to take particular corrective or preventive actions, or if you had to mandate a design change because of trends in information, for example - why did you carry out such an action? Obviously, you must make sure that you define the field safety corrective actions, and for these corrective actions that you are taking there's a fine line between them. If you do carry out a field safety corrective action, you must notify your competent authority and notified bodies, get them involved in the process, and communicate appropriately the rationale for corrective actions that you are taking. For the key content of a PSUR, you are finalizing the activities that you've defined in your PMS plan, some of which will feed into your benefit and risk ratios. You have to update your risk management plan or file as well. When you've done this, what are your conclusions for your benefit and risk ratio? How is it stacking up? What does it look like? Is it getting better or is it getting worse? And, what actions do you need to take?

Your PSUR should have the outcome of your PMCF, and this is very critical. So here, we've got a PSUR that needs input from your PMCF, and you've got your PMCF that needs to look at elements of your CER. The frequency of carrying out the PSUR must fall in line with your CER frequency because your CER will feed into

your PMCF and then your PMCF falls into your PSUR. Now you see how these reports are integrated and annoyingly, some of these processes will be repeated frequently.

Criteria for Serious Incidents - If you get a serious incident that's classified as death or unanticipated deterioration in the state of health, then you have a maximum of 10 days to report it. If it's an effect involving a public health threat, then that's 2 days, and for all other serious incidents, it's 15 days. Take note of these timelines as they have changed from the MDD. Make sure that you've revised your SOPs accordingly. You've trained your staff to report these things accordingly and your sales team should know what the new guidelines are.

Article 88 – Trend Reporting

What is trend reporting? The recording and analyzing of incidents (serious and non-serious) to determine the frequency or severity of the incident. The main thing is which statistical tools are you planning to use? Are you going to use regression analysis? Are you going to use averages? Are you going to use the median? Are you going to use standard deviations? What statistical approach are you going to use? You have to define all of these according to your device classification.

Reports will be submitted electronically via EUDAMED, and for previously reported incidents or faults, these should be communicated by a periodic summary report (PSR). For the PSRs, you must agree beforehand with your competent authority on the frequency and what will go into it. These must be agreed to before a PSR is then submitted.

Article 89 - Analyzing Serious Incidents and FSCA

These are the manufacturer's duties that need to be done after you report an incident - you have to investigate the root cause of the incident, assess the risk to the user, and make changes to the design where it's needed in the manufacturing process or labeling. You must also work with the competent authorities and the notified bodies on the investigation process.

Your competent authority will initiate actions if a manufacturer is not effective in their processes. Post-market surveillance involves a law of relationship maintenance. You know you are dealing with people, from which you can build relationships. Make sure you are maintaining your relationships and that you are doing what the competent authority needs.

Article 90 – Analysis of Vigilance Data

This has to do with the European Commission - the member states and competent authorities analyzing data within EUDAMED for trends to protect public health. They nominate a particular coordinating competent authority to work with the manufacturers to communicate and take the right actions. This is how they analyze the data in EUDAMED, and this is a key function of the new EUDAMED that's going to

come and now you will have access to it. Certain aspects will be available to the public. For example, if you publish a field safety notice, it will be available to the public in EUDAMED. A part of it will be available so users can see what manufacturers are communicating regarding the devices that are being used.

Article 92 – Electronic System on Vigilance and PMS

This is the EUDAMED aspect. It's the database that is going to be used for registering manufacturers and devices. It will be used to track and trace devices that are on the market. Manufacturers will have to register the device in EUDAMED, or get a key called the Single Registration Number (SRN), or the authorized representative will be able to do that.

Devices will have to be registered in EUDAMED using the basic UDI-DI and that's an entirely different topic when it comes to UDI and legacy devices regulations. The European commission will be the data controller for EUDAMED.

Manufacturer's Obligations and Best Practices

- For the MDR, organizations must appoint a person responsible for regulatory compliance. Now, it's actually defined and the qualifications that the person must have are outlined, including the experience that they must have. So organizations need to appoint these people.
- Define your QMS and the systems.
- Define the methods of collecting, monitoring, and reporting.
- Risk management activities according to the ISO 14971. Your hazards - what goes wrong, the severity put in your measures to reduce the risk, the measures afterwards, and post-market activities that are fed into your risk management. Your FMEAs make sure that you can score things and you carry out the benefit risk ratio analysis properly.
- CER and PMCF - article 61, ANNEX 16 of MDR and MEDDEV 271 REV 4, all of these things are in the new MDCG guidelines and have to be produced, you have to factor all of these things in with the five stages of the CER (stage zero to stage four). You have to plan it, what information are you going to gather? The appraisals, the reporting, and how you're going to update all of these things need to be there. State of the art, well-established technologies, and equivalence also must be considered.
- Make sure you've got effective systems in place. Have processes within your QMS that outline how you are going to review the systems. What has been found to work in the past - if your management is engaged with the system, your management reviews will highlight some of these things as well, but don't wait until your management reviews. Whether you do them every 3 months or every 6 months, make sure you are committed.
- Define the roles and responsibly (RACI) – make sure that the appropriate people have the right training in what they're doing.

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

For more information, reach out to us at

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