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WEBINAR TRANSCRIPT – Q&A

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

## Q: Can you elaborate on the requirements for the authorized representative for products manufactured in the US and are sold in Europe?

A: If the manufacturer is based in the US, then they will have an authorized representative in the EU. Let's get one thing straight - Article 10 of the MDR specifies the obligations of manufacturers and Article 11 goes into the responsibilities of the authorized representatives. PMS requirements are solely the responsibility of the manufacturer but that doesn't mean the authorized representative cannot feed into it. The authorized representative is also obligated to pass on complaints from the market and to pass those onto the manufacturer. So yes, they can feed into it that way, but it's not the authorized representatives' responsibility to gather data, analyze it, and carry out all these duties. If a manufacturer is able to get an authorized representative to help out, then that's fine. But, the reporting requirements to gather data to actually carry out the market surveillance, is solely the responsibility of the manufacturer.

## Q: Can "No PMCF justification" reside within the post-market surveillance plan"?

A: We have to be very careful when it comes to PMCF. There are very limited ways or scenarios where 'no PMCF justification' will actually fly with the notified body. If you're going to use that, you have to make sure that you explain yourself properly. I think no PMCF justification will pertain to legacy devices that are not only legacy devices, because they'd be on the market for 10 - 15 years, but also risks and safety elements that are well-proven and don't have any concerns. Simple technologies, stuff like that. Can that sit in the PMS plan? Yes, it can sit in the PMS plan, but is there a better place for it? Probably. It can also be part of your CER document.

## Q: What are your recommendations for small companies i.e., 10 employees or less?

A: The number of employees doesn't really matter here. If you're a small company, but you've got a class 3 device that can harm patients, then you still need to comply with all the requirements.

I think the only area where I say small companies get some leeway is the person responsible for regulatory compliance - the PRRC. If you are a small company, you don't need to have this particular person within your organization. However, you must have access to this particular person on a continuous basis. If you're working

with a consultancy firm, like Celegence, they will be readily available. You don't need to employ the PRRC as part of your staff in your organization, but if you've got a contract with a consultancy like Celegence, they are deemed acceptable.

## Q: What should we keep in mind for the post-market surveillance requirements for softwares?

A: You've got software as a medical device, and then you've got medical device software, the MDR makes it clear on the classification of softwares if you go to ANNEX 8 - Rule 11.

This rule gives a classification on whether the software is a class 1, class 2, or class 3, and depending on the classification, you go through the reports that are needed for that particular classification. Your software must be classified, and once you classify it, go through articles 83 to 92 to draft the ones that are applicable to that particular class of the device.

## Q: Do the PSUR requirements apply to legacy devices?

A: Yes, PSUR is applicable to legacy devices. From the 26th of May, 2021, all devices on the market need to comply with your PMS requirements. There's no exception to legacy devices.

In terms of PMS requirements and the reports that are needed for PSUR, legacy devices have no exceptions. You have to go through all the requirements and all the aspects that are needed. Treat your PSUR similar to a PQR, a product quality review, which is going into the pharma world  but they should be approached in a similar way.

# 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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