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Combination Products: Seeking a Notified Body Opinion according to MDR Article 117

Transcript - Q&A

Q: Can you elaborate on the lack of notified bodies and the lack of expertise in this area?

A: There is indeed a lack of notified bodies, with 20 at the moment. Bear in mind, the notified bodies went through a redesignation process from the MDD to the MDR, so some are still going through the process with relevant competent authorities in order to be designated under the MDR. If you Google "EC NANDO" it will give you the list of notified bodies that are available to certify under the MDR. There also are the MDCG codes that have been released in the document 2019/14. You will be able to assess the notified body, whether they can actually carry out work on your particular device family. Go to the EC's website to check on the approved or certified notified bodies and then you can approach them, and they will be able to help you from there.

The second part of the question about it's the expertise of the notified bodies - they are going through a re-designation process. They are going to be assessed according to the requirements and if they have the resources to do it. Some of the notified bodies have set up new teams in order to carry out work under the MDR. I have no doubts that if they are on the NANDO list and if your device family is listed, then yes, they will be able to carry out the assessment for you without a problem.

Q: Can you expand on the need for CER for a combination device?

A: This is a very hot topic when it comes to combination products & the need for a CER. Now the GSPRs themselves, you have to make sure you are compliant with your clinical data. Now, let's look at it this way. What is a CER? The CER is how the manufacturer demonstrates that the device that they've got on market, or coming to market, is compliant to the essential requirements under the GSPRs under the MDR. You need to use clinical data. By demonstrating compliance to the GSPRs using clinical data, it is a form of clinical evaluation, but it doesn't need to be in the format that we know as a clinical evaluation report.

If you were to ask me, do you need a clinical evaluation report when you are demonstrating your GSPRs for an article 117 notified body opinion? The straight answer will be no. However, you must make sure that your GSPRs are compliant, and you must demonstrate that with clinical data. Clinical data also comes in many ways, it's either from a clinical investigation, post-market surveillance, or from a scientific literature review, which you get in a clinical evaluation report. So, you don't need to draft it as a clinical evaluation report in that sense, but by demonstrating compliance to your GSPRs, using clinical data, and having that clinical evidence, you are compliant to the requirements and that's what you need to do.

Q: What do we need to keep in mind in terms of timing and costs?

A: The first thing you need to do is assess your budget for your product. When it comes to the time, your regulatory pathway, when you want to go to market, you need to think of it in reverse. Starting right from the end when you want to go to market, you need to plan it backwards to where you are now. You must understand what is going to take the longest, and then attack those simultaneously as you're completing the other relevant tasks. For timing, it could take a good 4 to 6 weeks in order to engage with a notified body, for them to accept you as a client, and then to put your technical documentation through. You need to assess your current documentation for any gaps, and you have to then upscale your documents to make sure that they're compliant to the MDR. This will take time. For example, it could take in the region of 12 to 15 weeks to fix your technical documentation. Then, you have to approach your notified body.

As you are addressing your gaps and finalizing your technical documentation, that is when you will know you are ready to submit your technical documentation. In that case, you'll be able to reach out to your notified bodies and that could take a good on average around 3 to 4 months to get your notified body opinion. Then to your competent authority for your MAA submission, so you have to factor all these things in when it comes to timing.

When it comes to costs, reach out to a handful of notified bodies, and depending on your preferences, whether you've worked with them, the market that the product is going to, and look at the NANDO list. So, reach out to three to five of them and get your quotations and the timelines, but understand how busy they are.

Q: Do you have any recommendations for seeking a consultation on this matter?

A: Notified bodies do not consult. If there's any consultation that you need, then reach out to the consultation agency. You can come to Celegence and we'll be happy to assist you accordingly.

Q: Can you provide clarity on the amount of information, and the required level of detail that is necessary for the consultation?

A: This is your technical documentation that meets the requirements of the GSPRs. Go through the GSPRs and make it very clear what is applicable and what is not applicable, and for the ones that are applicable, make sure that you can demonstrate that with clinical data. This is data that has been generated by the use of the device, either in development testing, pre-production testing and production testing, and post-market surveillance information. Make sure it's clinical data that demonstrates the clinical evidence and ultimately, the clinical benefits to the patients and the users. If you're able to demonstrate with clinical data, clinical evidence, and the clinical benefit, and you assess your risk from all areas, then you'll be in good shape.

Helping You With **Regulatory Operations**

We can support manufacturers of combination products to ensure that their essential documentation and clinical evidence complies under the new MDR

For more information, reach out to us at

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