Q1 PRODUCTIONS WEBINAR TRANSCRIPT:

How to Start Preparing Your RA QA Team for The EUDAMED Database - Economic Operators & Conclusions with John N. Bradsher

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Responsibilities of Economic Operators

We will now move on to the responsibilities of economic operators, and we will start with the supply chain. At this time, legal manufacturers are compelled to identify distributors and importers in their supply chains to establish the responsibilities with each of them. They are also compelled to identify authorized representatives along with importers and distributors to create provisions, and to ensure traceability for both the upstream and downstream provisions.

This includes EO's that have received devices, and EO's that have supplied devices within their supply chain to the competent authorities for 10 years after the last device was placed on the market. This obligation actually changes to 15 years, in the instance that you're marketing an implantable device. The legal manufacturer, and its economic operators, must cooperate with distributors and importers to achieve an appropriate level of traceability.

The completion of the registration requirement for your economic operators is expected by the date of application in May of 2021. We now know that the EUDAMED registration module for economic operators will be available in late 2020, which allows us about five months for the completion of this requirement.

Requirements for Manufacturers

For manufacturers, many of these requirements may look familiar if you have been marketing in the EU on MDD certificates, and for many of these, you would regard them as essential components for quality management. Specifically, legal manufacturers are expected to establish and document a system for risk management.

They are compelled to make provisions, keep copies of technical documentation, declarations of conformity, and make the certificates available to the competent authorities for at least 10 years after the last device is placed on the market. With that obligation changing to 15 years - in the case that you market implantable devices - manufacturers are expected to establish documents, implement, maintain, update and continuously improve quality management systems that are proportionate to their risk class.

Legal manufacturers are expected to plan, establish, document, implement, maintain, and update a post market surveillance system based on a post market surveillance plan and it will include your technical documentation. They are expected to establish a method for reporting incidents and Field Safety Corrective Actions, as described in the relevant articles. At this time, if they have not already done so, legal manufacturers should consider taking out liability insurance.

More on that topic, in the EU under the MDR, legal manufacturers will be sharing legal responsibility for liability with authorized representatives. Likewise, it makes sense for authorized representatives to consider - if they have not already done so - taking out liability insurance. For these requirements, it is expected that you complete them by the date that you have designated for your QMS audit.

Requirements for the Authorized Representative (AR)

Moving on to the requirements for your authorized representative. These are fewer, but nonetheless important. Legal manufacturers are expected to essentially designate their ARs, as well as to agree upon a mandate of their responsibilities with their authorized representatives.

They are expected to ensure the authorized representatives have permanent access to all documentation required to fulfill their tasks. They also must define the modalities in their agreement between the manufacturer and both the incoming & outgoing authorized representatives (in the event of a changeover for authorized representation).

Suffice it to say, these have all been a specific focus in a lot of discussions, particularly the availability of permanent access to documentation since legal manufacturers regard this as intellectual property and proprietary under many circumstances.

Many legal manufacturers are currently negotiating with their notified bodies about whether they can provide access to redacted copies, or copies of technical documentation that would be sufficient to fulfill all the required tasks, but would not give a technical documentation availability to the full suite of intellectual property from the manufacturer.

This is the time for you to be considering the agreements that you're going to be making with your authorized representative.

Requirements of the Person Responsible for Regulatory Compliance (PRRC)

Now, the person responsible for regulatory compliance is a new role identified by the EU MDR. It is the responsibility of large and medium manufacturers to appoint a person in their organization as the person responsible for regulatory compliance, and they must have demonstrated expertise. It essentially comes down to education and training.

Manufacturers that are smaller, including small and micro manufacturers, have the option to use an outside resource to designate a person responsible for regulatory compliance. On that note, please be aware that changes in your person responsible for regulatory compliance will be regarded as a significant change by your notified body.

As such, you may want to think carefully about the benefits and risks of having a third party nominee for your PRRC, especially if it means you're going to have that person changing over the course of the next many years. Each personnel change will be processed with a significant change now. This requirement for your PRRC's registration is expected to be completed by the date of applicability on May 26th of next year.

We now know that the registration elements will be available in late 2020. So, we will have months to do this in advance of deadlines. You should expect to be done with this step of registration for your authorized representatives, and your person responsible for regulatory compliance, by the day that you have determined with your notified body for your manufacturers MDR certification audit.

Conclusions

This brings us full circle. We've had time to discuss many topics today, and as time permits, we'll have a few minutes now to talk about a couple of the modules that we didn't discuss, including article 57, the electronic system on certificates, and article 73, the electronic system on clinical performance investigation.

As we discussed previously, this first article is the electronic system on certificates. That is article 57, and article 52 in the IVDR, which describes the requirements. That is where you're going to find your certificates for your declarations of conformity and summaries of safety and clinical performance. There will also be a part of that module that will contain the current list of designated notified bodies and how they are designated for each regulation.

That brings us to the electronic system on clinical and performance investigation. This is where the two regulations diverge a little, in regards to the MDR, it's called clinical investigations, and in the IVDR, they are called performance investigations. These are under article 73 of the MDR, and article 68 under the IVDR. Nonetheless, this is the module where you are going to log on to get a single identification number, if you're performing either clinical, or performance investigations in the EU.

That is going to be a go-to resource for those of you in that situation. These two modules are not expected to be available by the date of applicability. We currently are keeping a close eye on when they may be made available, as there are certainly many development projects that are ongoing, and will be depending upon this type of functionality.

Helping You With
The New EU MDR Challenges

Celegence has a wealth of knowledge to help you navigate through the complex regulatory challenges that the new EU MDR bring.

We can assist you throughout the entire process to ensure that you and your business are compliant with all of the EU MDR requirements.

For more information, reach out to us at

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