Q1 PRODUCTIONS WEBINAR TRANSCRIPT:

Best Practices for UDI Implementation and EUDAMED Submissions -

Dr. John Bradsher's Presentation

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Structure and Availability of Modules

Currently, we have the actor registration module available to us, and this was made available to the community as of the 1st of December 2020. UDI modules will be available as of May of 2021. Now, as with all of these modules, they are going to be voluntary until the date of full functionality, and at that point, they will mention the date of applicability and their use will become mandatory for all economic operators.

Economic Operators

Now, registration is necessary for four types of economic operators, including manufacturers (MF), authorized representatives (AR), importers (IM), and system & procedure pack producers (PR). It is not necessary for the distributor. Be aware of that as you go through this process, it will be necessary to do a separate action for each type of role that you are filling. If you have one facility, which includes both functions as an importer and a system procedure pack producer, you will be required to do two separate registration activities in order to fulfill both of those roles.

Registration of Actors

The person that does the registration online is automatically assigned a pair of informatic type roles, including what are known as local actor administrative roles (LAA) and a local user administrator (LUA) role. The local actor administrator is hierarchically the superior role, who is also the person that manages the organization's sales grants access.

Data Fields, Actor Registrations and Non-EU Manufacturers

The local user administrator is involved in granting requests for use on a daily basis for the organization, and as a multinational organization, you may need to make this available to the local user administrator and multiple individuals. The local area administrator to facilitate transitions such as that could have contractors, for instance - performing the registration for the local administrator roles, which would also need, for instance - be assigned to permanent employees whenever the contractors would depart. This is a large module and it is important that you conform to your particular needs as a manufacturer as you get online and perform the function of registration.

The crucial information that you are going to require is a relationship with the authorized representative and specifically, what you need from the authorized representative is the single registration number (SRN). Without that single registration number from an authorized representative, you as an economic operator will not be able to process anything.

You will enter that as a data field in one of six such data fields that are required to complete the process registration. That relationship is also available in a document that you upload to the site that shows that you have an agreement between yourself and the authorized representative, and that the document must provide a date for its validity.

We have further identification provided in several of these spots, some of these are include more specific information that you may want to organize before you get ready to perform your registration. Among those pieces of information, perhaps a little bit more obscure - you will need your value-added taxation information about a tax number if you have one. It is known as your economic operator registration and identification number, which is obtained from customs agents and is used to facilitate.

You will have additional data fields necessary to complete this process. A lot of identification is provided throughout the process, and you are going to have your person responsible for regulatory compliance nominated. This person should be aware that this is a modular type of role which can be divided amongst various individuals or legal persons to fulfill different roles for regulatory compliance.

Once you have completed these data fields then you are able to finish the process and it will create what is known as a single registration number (SRN), and that is a two-character economic operator type code, and then a nine-digit numeric code, which altogether is your single registration number. This is the number that you will use for numerous different documents interacting with the notified bodies as well as the European Commission. You will have it present in your files, and you will have it present in your post market surveillance reports and summaries of safety clinical performance. So this is a crucial number that you will be required to have in the EU MDR era.

Ongoing Registration of Economic Operators

Remember here, your goal is to explain your decisions and the rationale for decisions to the notified body in an audit. So this is really providing essential protection for yourself.

Geographically, economic operator registration is going on currently and it depends on your relationship with an authorized representative in one of the 27 EU countries shown here in blue. As we are on the topic, the European economic area is somewhat different and larger, including Norway, Iceland, and Lichtenstein. But the EU does not include Switzerland, Turkey, or Great Britain. Now that Great Britain is outside of the EU, organizations within the U.K. that are interested in EU market access are required to register with EUDAMED. This registration is once again dependent upon your relationship with an authorized representative.

Economic Operator Registration in the United Kingdom

Brexit has given us a lot to think about, and specifically, the countries involved Scotland, England, Wales, Northern Ireland will now be under a separate regulatory regime overseen by the MHRA. They have decided that in order to ease the difficulty on legal manufacturers, they will be allowing CE marked products to be imported into the UK until the midpoint of 2023 June 30th. So we have about 40 months of allowance for legal manufacturers to continue to sell in the UK with a simple CE Mark obtained from the EU. That gives us a lifeline. If you are a class III or Class IIB manufacturer you are required to register by the 30th of April. For Class 2A, it would be the 30th of September and for Class 1 it will be December 31st.

In order to stay on the market in the UK, you are going to need as a manufacturer something very close to what is needed for the EU and EUDAMED. You must designate a responsible person in the UK (UKRP) and then you will register through that relationship. You will register with the MHRA and upload the agreement between yourself and your registered person. The role of the UK registered person (UKRP) combines the roles in the EU as the authorized representative and the person responsible for regulatory compliance. The UK responsible person fulfills both of those roles and will need to be located within the UK in order to facilitate a prompt response to the public health league.

Conclusions

The UK and EU are moving to a regime that will require separate labeling. There is a 42-month allowance for products with CE marks to be sold in the UK. The EU is not allowing reciprocal treatment. So there are no provisions, nor expectations of a provision in the EU for you to sell on products that have a UK conformity assessment or a Northern Ireland conformity assessment. In fact, they will be restricting availability of the market such that products with the UK or Northern Ireland conformity assessment will not be marketable in the EU. This means that these two jurisdictions are essentially moving into separate labeling regimes and that one downside to this whole transaction.

Thank You!

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