Q1 PRODUCTIONS WEBINAR TRANSCRIPT:

How to Start Preparing Your RA QA Team for The EUDAMED Database - UDI & Product Types of Immediate Concern with John N. Bradsher

celegence

celegence.com

Hi, my name is John Bradsher and I will walk you through the requirements and the availability of EUDAMED over the next 40 minutes.

John N. Bradsher

PhD, RAC, Medical Device Regulatory Affairs & Quality Assurance Expert Celegence

Unique Device Identification (UDI), Definitions (Annex Vi)

Now, moving along to registration. This is the article 29 obligation from the MDR, and the article 26 from the IVDR. The BUDI is a data element that has gotten a lot of attention and has created some anxiety along the way, and without getting into too much detail, the BUDI, like the UDI, is a package of attributes and data. Both will have places that they will be used in common, for instance, the regulatory submissions shown here, each will have unique places where the information is displayed. So for instance, your BUDI will be found on declarations of conformity and on summaries of safety and clinical performance. While a UDI is the type of data you find on primary product labels, implant cards and vigilance communication

One Module of EUDAMED will be the database for UDIs (Article 27/24)

Graphically, we have a UDI which is broken up into two parts, it essentially contains **the UDI-DI: the device identifier, and the UDI-PI: the product identifier,** and these will be provided for reporting serious incidents and Field Safety Corrective Actions (FSCA), which will be provided to patients receiving implants under the MDR.

The economic operators in your supply chain are going to be obliged to maintain electronic records of the BUDI for class III and implantable devices, as well as devices that will be detailed in any implementing act yet to be published. This is an obligation of the economic operators that is reflected as well. With health institutions throughout the EU, they will also be compelled to maintain BUDI records for all class III and implantables,

as well as devices detailed in the implementing act. There is an element of the unknown here in the respect that member states, as stakeholders, may encourage or require healthcare institutions to maintain records of BUDIs for all devices.

This is an area to watch closely because it would be an increase in the amount of effort necessary to be compliant with regulations for registration. We are waiting to see where the various different jurisdictions land on this, and I encourage you to stay in touch with **Celegence, who will help keep you notified and help you navigate through the unknown with respect to this type of jurisdiction specific requirement that may be emerging over the next many months.**

Now for those of you interested in marketing in the UK, including Britain, Scotland and Northern Ireland, the MHRA has issued requirements for products of all classes to be registered with the UK as well, and this is going to be necessary for those who don't have an alternate means of completing it by the end of the year 2020. The grace periods for class III and class II devices have already passed, and the period for the class I devices will pass at the end of December. This legal requirement to register will not affect you if you have an existing relationship with an authorized representative within the UK. Be aware, however, that this is guidance that is based on the concept of a hard Brexit at the end of December of 2020, and as December 31st approaches, things may change as there may be a trade agreement. **The MHRA may provide additional further guidance, suffice it to say, this is an area that is being closely watched as well, and as such, Celegence can help keep you up to date on the requirements as they become public.**

Product Types of Immediate Concern

I would like to move on to product types of immediate concern. Specifically, products that will be marketed on directive certificates after the date of applicability in the EU will be regarded as legacy devices. The MDR does not specifically require BUDIs on legacy devices, but the EU commission has essentially detailed a two-part work around.

First, registration will be necessary according to the article 29 requirements, but it will be possible to complete that registration in the absence of a BUDI using other attribute data and including your UDI. Moving forward with that approach, legal manufacturers will bear a certain amount of risk. In that respect, if there is a Field Safety Corrective Action (FSCA) that occurs with such a legacy device, and it has not been registered by its BUDI, the effective device must be then immediately registered now for the reporting of the serious incident or Field Safety Corrective Action (FSCA).

To me, it looks like the European commission is preparing an on-demand system to handle such events, even before the registration system is available on a broader basis for legacy devices.

UDI Timeline

In contrast to what we just discussed, we will now consider the requirements for devices placed initially on the regulation certificates that are under the MDR, or IVDR. What we see here in this slide is the concept of the end of the window of opportunity to have your BUDIs displayed on your packaging, on your labeling, and other higher levels of packaging. This occurs in the even numbered years, as shown above the register for MDR compliant devices in a reducing risk format, and it occurs in odd numbered years below the register for in-vitro diagnostic regulation regulated devices.

The current dates of applicability for the MDR are May of 2021, and May of 2022 for the IVDR. Since those are only a single year separated, we have this resulting alternation, and the dates that the BUDI requirements will be met for each of the affected risk classes for devices.

There are many reasons why, that as a legal manufacturer, you may choose to be active much earlier than these deadlines when assigning your BUDIs. Specifically, the application to the notified body for conformity assessment is contingent upon completing of assignments of your various products to BUDI groups. Many legal manufacturers are currently active in grouping their devices into various BUDI groups.

This is done so that they can proceed with the necessary negotiation with their notified body in order to determine how many technical files will be needed to be audited for each group of devices. These early moving determinants are the type of thing that many legal manufacturers are currently active with. Do not be swayed to believe that you can wait until these deadlines are near to get started on this type of activity.

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

info@celegence.com

or contact us online at

celegence.com

celegence