Q1 PRODUCTIONS WEBINAR TRANSCRIPT:

How to Start Preparing Your RA QA Team for The EUDAMED Database - Overview & Electronic Systems with John N. Bradsher

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

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Introduction

Today we will discuss modules - detailed in articles - 27, 29, 31, 92 and 100. We will briefly discuss EUDAMED modules that are detailed in articles 57 and 73. These are the EU MDR article designations, and where I can, I will provide the correlated in-vitro diagnostic regulation article designations as well.

Many of you may be familiar with the notice of full functionality at EUDAMED, which is not expected until quarter four of 2022, a full two years off, and that is dependent upon a successful audit in maybe the year 2022. There also could be things that put it off to an even later benchmark. One of the questions that we will then address today, is how you as manufacturers are expected to comply with various deadlines that take effect well before that date of full functionality of EUDAMED requirement.

EUDAMED Overview

This slide gives us an overview of some of the functionalities of EUDAMED. Not all of which will have an immediate effect on that date of applicability.

Electronic System on Certificates

First, the electronic system on certificates. This is the article 57 obligation from the MDR, correlated to article 52 from the in-vitro diagnostic regulations. This is the module that will contain declarations of conformity, summaries of safety and clinical performance, and your listing of designated notified bodies. This will have content that is intended to be public facing, including your summaries of safety and clinical performance, as well as other content that is not intended to be facing the public.

Electronic System on Vigilance

Next, is the electronic system on vigilance. This is the article 92 obligation correlated to article 87 in the in-vitro diagnostic regulation, it will contain your post-market surveillance update reports, reports of Field Safety Corrective Actions (FSCA), and serious incidents. This module will also have a mix of public facing and non-public facing information.

Electronic System on Market Surveillance

Moving on, we have the electronic system on market surveillance. This is your article 100 obligation, correlated to the article 95 from the in-vitro diagnostic regulation. This is where you will find your final inspection reports for all economic operators in the supply chain, information on non-compliant products, and information on products that have unacceptable risks to health and safety.

Electronic System on Clinical Investigations

Moving along to the final position, we have the electronic system on clinical investigations. This is the article 73 obligation, and it is correlated with article 69 in the in-vitro diagnostic regulation, where it is called the electronics on performance investigations. This is a module that the legal manufacturer will use if performing clinical or performance investigations in the EU, and this module will generate single identification numbers for clinical investigations. Most of the information that is on this module will not be available to the public.

Now, if we move to the right, we have considered most of these document oriented elements, and to the left, we also have registration requirements, which are shown here. This is a group of modules that will include the registration of economic operators, which is article 31 in the MDR article, and article 28 in the IVDR. It will also include the registration of devices, which is article 29 in EU MDR, and article 26 in the IVDR, as well as the BUDI database, which is article 27 in the MDR, and article 24 in the IVDR.

These modules for registration are said to be slated for availability in late 2020, which should give us about five months in advance for compliance with registration requirements for EUDAMED in advance of that date of applicability in May of 2021.

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.

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