Joint EDMA / Eucomed Workshop on Implementation of a UDI system A focus on US FDA Rules

Thursday, 15 May 2014 - 9:30-16:30

Sheraton Airport Hotel – Zaventem (Brussels)

Background

Unique Device Identification (UDI) systems are rapidly becoming a reality for medical devices and in vitro diagnostics (IVDs). The US Food and Drug Administration (FDA) Rule on UDI, published at the end of September 2013 is the first detailed system from a major regulator to lay out UDI requirements for the medical technology sector, covering both labeling and the UDI database aspects.

With the FDA deadline for implementation (24 September 2014) of UDI on high risk devices fast approaching, it has become urgent for medical device manufacturers on both sides of the Atlantic to start with their planning.

Description

This is the second joint EDMA and Eucomed workshop focusing on questions related to the actual implementation of UDI. This event will specifically focus on the FDA final Rule and the FDA Draft Global UDI Database Guidance.

Jay Crowley, who has held a variety of positions over his nearly 27 years at the FDA, will lead that part of the event devoted to FDA Rules. As Senior Advisor for Patient Safety in the Food and Drug Administration's Center for Devices and Radiological Health, Mr. Crowley developed the framework and authored key requirements for the FDA's UDI system. Mr. Crowley also led the team responsible for the development and implementation of UDI requirements. In addition, **leading medical technology industry experts** will provide their insight into how to deal with the challenges of the UDI system.

We aim to provide manufacturers with answers to practical questions on the US FDA final Rules which will help them optimise their implementation of UDI.

This workshop will be of interest to the individuals responsible for the implementation of UDI within their companies, be it at the level of the labelling, information management, IT infrastructure management or business-related decisions on UDI roll out.

Participants are expected to actively contribute in the discussions of this interactive workshop. It is important that attendees submit questions in advance so that they can be adequately addressed during the workshop. Please send your questions by Monday, 5 May 2014 to Regulatory@edma-ivd.eu.

Workshop highlights

- Get the latest information on US FDA UDI implementation requirements from our keynote speaker Jay Crowley
- Understand what the FDA is requiring for regulatory compliance:
    - Final UDI Rule - Focus on Labelling/Marking
    - Draft Guidance on Global Unique Device Identification Database
- Get insight into how to deal with the challenges of the UDI system by leading medical technology industry experts
- Learn about the policy aspects on UDI implementation
- Exchange views in an interactive workshop where participants can ask questions about UDI implementation in the United States during breakout sessions with feedback from a panel of experts.

This Workshop is open to

- EDMA and Eucomed Corporate and Associate Corporate Members
- EDMA and Eucomed National Industry Associations and industry manufacturer members affiliated with them
- Medical technology industry companies

Are you a member of EDMA?
Are you a member of Eucomed?

Registration Fees

- EDMA and Eucomed Corporate and Associate Corporate Members: **250€** (incl. 21% VAT)
- EDMA and Eucomed National Industry Associations: **250€** (incl. 21% VAT)
- Medical technology industry companies (non-EDMA, non-Eucomed members): **600€** (incl. 21% VAT)
- Industry manufacturers affiliated with EDMA and Eucomed National Industry Associations: **600€** (incl. 21% VAT)

Cancellation rules

Cancellations after Monday, 5 May 2014 and no-shows will not be reimbursed.

Accommodation

If you wish to book a room at the Sheraton Brussels Airport Hotel where the workshop will take place, click on the following link.

A certain amount of rooms are guaranteed for participants until 22 April 2014. After that date, the link may not be active anymore and you may have to contact the hotel directly.

You may register by Monday, 5 May 2014. Registration is completed when receiving a confirmation letter from EDMA / Eucomed.

Please distribute this invitation within your company or among your members.