MedTech Europe online training on the Unique Device Identification implementation

Tuesday-Wednesday 26-27 January 2021
Online training

This is a 2 days' training from 2 pm CET to 6 pm CET each day

THIS TRAINING IS FREE OF CHARGE AND OPEN TO THE EMPLOYEES OF:

- MedTech Europe Corporate Members
- Corporate Members of National Associations affiliated to MedTech Europe
- Notified Bodies
- Member State competent authorities with a special attention to the Medical Device Coordination Group's UDI subgroup members

Please distribute this invitation within your company, organisation or among your members. **If you do not fall under any of the categories above, MedTech Europe reserves the right to cancel your registration.**

You will receive the webinar details via e-mail by 22 January 2021.

Please register by Wednesday, 20 January 2021 using the following link: https://www.eventbrite.co.uk/e/medtech-europe-training-on-the-unique-device-identification-implementation-tickets-132073492371

About the workshop

Regulation (EU) 2017/745 ('MDR') and Regulation 2017/746/EU (IVDR) introduce the unique device identification (UDI) system as a new concept to be implemented in Europe. MedTech Europe offers this training opportunity on the implementation of the UDI for industry, national competent authorities, and notified bodies to support a harmonised application of UDI in the European Union.

This workshop aims to give an overview of the new requirements and dive into more depth on specific topics of general interest:

- UDI legal requirements and timelines
- UDI application (labelling, direct marking, symbology, issuing entities' rules)
- Implementation of UDI into manufacturer's quality management system audited by a Notified Body
- Implementation of Basic UDI-DI
- UDI data elements to be registered in EUDAMED
- Differences between the EU and US UDI systems

Participants are requested to submit their questions[1] in advance in writing to regulatory@medtecheurope.org; these will be answered to the extent possible during the Q&A sessions.

[1] Please note that company specific questions will not be addressed.

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draft Agenda

Tuesday, 26 January 2021 – Day 1 (2 - 6 pm CET)

Welcome and opening address
Scope of MDR/IVDR
Kevin Taylor - *Chair, MTE EUDAMED WG, Johnson & Johnson Supply Chain*
Katalin Máté - *Manager Regulations & Industrial Policy, MedTech Europe, coordinator of MTE EUDAMED and UDI WGs*

Description of the main changes from Directives to Regulations, and where UDI fits into EU legislation.

General overview of EUDAMED
Kevin Taylor - *Chair, MTE EUDAMED WG, Johnson & Johnson Supply Chain*

This session will focus on the modules and implementation timelines of the EUDAMED database, the role of UDI and Basic UDI-DI in the database and the concept of UDI-DI triggers.

Implementation and assignment of Basic UDI-DI
Céline Bourguignon - *Cardinal Health*
Olga van Grol-Lawlor - *Boston Scientific*
Katalin Máté - *MedTech Europe*

Introduction to the concept of Basic UDI-DI, data elements associated with it, consideration for assigning a Basic UDI-DI (with a decision tree) and its relation to regulatory documents and UDI-DI.

Q&A session

Differences in legal requirements: older-than-legacy, Legacy and Regulation devices

Wendy Jackson - *Boston Scientific*

This session will discuss the difference between Older-than-legacy, Legacy, and Regulation devices and how this relates to EUDAMED device registration.

Fundamentals of UDI – overview

Definition of UDI-DI, -PI, direct marking

DI triggers and product lifecycle

Frank Matzek - *Biotronik*

UDI follows a precise set of requirements where knowledge of the definitions – and what triggers the need to establish new DI – is critical. This session will cover the essentials.

Application of UDI: labeling and direct marking, symbology and Issuing Entities rules

Jackie Elkin – *Vice-Chair, MTE UDI and EUDAMED WGs, Medtronic*

Mary Gray - *Chair, MTE UDI WG, Johnson and Johnson*

Medical device unique device identification system requires meeting the MDR regulatory requirements while adhering to Issuing Entity standards. This session will focus on an overview of the requirements for Issuing Entities, the identification of the accepted Issuing Entities, the application of Issuing Entity symbology for medical device label and direct mark of reusable devices related to the MDR format requirements.

Q&A session

6 pm End of the Training Day1

Wednesday, 27 January 2021 – Day 2 (2 - 6 pm CET)

Welcome back

General EU UDI regulatory requirements and timelines

Common regulatory concepts and applicable UDI rules: medical device, accessory, component, configurable devices, software, label, package, shipping container, IVD kit, systems and procedure packs

Jay Crowley - *USDM Life Sciences*

This session will focus on the UDI requirements under the MD and IVD regulations for labels and packages as well as the application for system, procedure packs, configurable systems, and software. It will also cover the various exceptions in the regulations.

Q&A session

Differences between the EU and US

Differences in definitions

Leverage from data submitted in the US – comparison

UDI-DI triggers

Dennis Black – *Becton Dickinson*

Kevin Taylor - *Chair, MTE EUDAMED WG, Johnson & Johnson Supply Chain*

This session will focus on the differences between the US FDA UDI regulation and UDI under MDR and IVDR. We will not go into detail for every data element but will cover a number of specific examples and provide an overview on the approach manufacturers may want to take to determine their own interpretations and data strategy

Implementation of UDI into manufacturer's quality management system audited by a Notified Body

Lifecycle management of devices

PMS/Vigilance reporting

Jay Crowley - *USDM Life Sciences*

Mary Gray - *Chair, MTE UDI WG, Johnson & Johnson*

UDI is a new MDR requirement and is one that is or needs to be embedded within the lifecycle of a medical device. In this session we will review the aspects of MDR and specific areas within a manufacturer's quality system where UDI should be incorporated to ensure compliance from manufacturing controls to PMS/Vigilance reporting.

UDI implementation by a company

Grant Hodgkins - *Smith & Nephew*

This session explores the journey to create a holistic, global UDI solution by using the EU MDR/IVDR regulation as a catalyst for change. Looking beyond US and EU UDI, a more scalable, repeatable, and cost-effective model was required. We will review the strategy taken to globalize our solution path, provide updates on implementation status, and review some early successes and challenges, including how to design a solution in an ever-changing global UDI landscape. We will also provide perspectives on how to address unique

challenges of the EU MDR/IVDR regulation related to Basic UDI or BUDI-DI, Certificates, and Economic Operators.

Q&A session

6 pm End of the Workshop Day2