MPD Training Course: MDD2MDR

AGENDA

Please note all timings below are for guidance and may vary during the day as required.

9.30
Registration & Refreshments

10.00
Welcome, Health & Safety and Introductions
Vanessa Bailey, MWM & Trevor Lewis, MDC

10.05
Introduction to the EU Regulations for Medical Devices
- What is and what is not a medical device
- Who is involved
- The EU, Directives and Regulations, MEDDEVs, Guidance and Standards
- CE Marking and Essential Requirements
- Eudamed database and GMDN

The Medical Device Regulations (MDR)
- Introduction to and impact of the new Medical Device Regulation
- Key considerations – what do you need to be aware of, including time lines
- How does this change what we need to do?

11.15 - 11.30 Morning Break

11.30
How to Classify Your Medical Devices
- Medical Device Directives (MDD) definitions and considerations
- Examples of device classification
- Borderline products
- Classification under the Medical Device Regulation (MDR)

How to Choose the Conformity Assessment Routes
- Optional routes for each class of device
- What is required for each Conformity Assessment Annex
- Changes with the Medical Device Regulation

12.45 - 13.15 Lunch and Networking

Compiling Your Technical Documentation for a Medical Device
- What you need for a Technical File
- What level of risk is acceptable?
- Who audits the technical documentation?

DID YOU KNOW?

Medical Device Directive defines the term "medical device" as *any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its human body with action that is ancillary to that of the device*, that device shall be evaluated and authorised in accordance with this Directive.

The MDR (European Medical Device regulation) defines the term "in vitro diagnostic medical device" *as any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information...*

Contact Vanessa Bailey, Events Co-ordinator
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AGENDA Continued

How to Label Your Medical Device
- Directive requirements
- Use of language and symbols
- Translations
- Electronic labelling
- Unique Device Identification (UDI)

14.45 - 15.00 Afternoon Break

Brief Comments on the Clinical Evaluation of Medical Devices in the EU
- Current Directive requirements and standards
- When is a clinical trial needed
- Understanding how the MDR has changed expectations
- What is needed for the Competent Authority and Ethics Committee submissions

MDR
- Considerations for the transition
- Managing the gap and time line dangers
- Action Plans – do you have one?

16.15
Summary and Q&A.

16.30
Close

This course covers in one day:

- What is and what is not a medical device
- Who is involved
- Insights into guidance and standards
- What is CE marking and why the 'Blue Guide' matters
- An introduction to the MDR, key considerations and timelines
- Understanding the role of economic operators
- How to classify your device under both the MDD and MDR
- How to choose a regulatory route to market and why a quality system approach is important
- What is required in technical documentation
- Labelling insights
- Brief but vitally important comments on clinical evaluation**
- MDD2MDR planning considerations

**please note comments on clinical evaluation have to be limited and is strongly recommended that delegates wanting in-depth training on this register for other more specific Medilink courses.

MEET THE TRAINER

Trevor Lewis

Trevor provides medical device and in vitro diagnostic companies with a diverse range of services from strategic research, business planning, regulatory affairs (EU & US), quality systems through to all kinds of business development issues and related training.

He has provided training of national regulatory authorities and senior officials in European Union (EU) medical device directives, especially in India, China, Egypt and Turkey but also all MEDA countries on behalf of the European Commission.

Trevor has provided guidance and advice on medical regulation implementation to Canada, the Republic of Moldova, Hong Kong and China.

Several previous clients, initially engaged with at the start-up stage, have grown and developed into successful businesses that have been sold and provided substantial returns for their founders and investors

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