MPD Training Course: AUDIT4U

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

10:15
- Role of Key Players in Europe: Competent Authorities Notified Bodies
- Where to find the key guidance, you need to answer the exam question
- The standards you can learn from
- The direction of travel
- What is the 'Blue Guide' and why it is so important.

11.15 - 11.30 Morning Break

11.30
- Notified Body Unannounced Audits and the effect on the supply chain
- Differences between Competent Authority and Notified Body Audits
- MDR/IVDR and ISO 13485: 2016 effect on audits.

12.30- 13.15 Lunch and Networking

13.15
- The International Medical Device Regulators Forum (IMDRF)
- Insights about the United States (US) Food and Drug administration (FDA) Inspections
- The Medical Device Single Audit Program (MDSAP) and why this matters so much to those who want to market to Canada.

14.45 Afternoon Break

15.00
- Regulatory impact on audits – what is the direction of travel?
- Strategic audit advice – do you need a holistic approach, especially to risk?
- Auditing – the process for effective results.

16.00
Summary and Q&A

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
on 0121 452 5630 or email VanessaB@MedilinkWM.co.uk

MPD Training Course: AUDIT4U

This one-day course is designed for those who need to better understand what medical device audit is, what it is trying to do, how to do it, and when it is required.

This course is for you if:
You might be new to medical devices, about to get involved with internal audit, perhaps you are thinking of becoming an auditor? Perhaps you are a senior manager who wants to know the fundamentals to help you manage your team?

In just one day, the course will cover:

- Role of the key players in Europe: Competent Authorities and Notified Bodies.
- Where to find key guidance so you can answer the exam question!
- Standards you can learn from.
- What is the 'Blue Guide' and why it is so important.
- Notified Body Unannounced Audits and the effect on the supply chain.
- Differences between Competent Authority and Notified Body Audits.
- MDR/IVDR and ISO 13485: 2016 and effect on audits.
- Insights about United States (US) Food and Drug Administration (FDA) Inspections.
- Comments on the Medical Device Single Audit Program (MDSAP) and why this matters so much to those who want to market to Canada!
- The Direction of Travel!
- What is CE marking and why the 'Blue Guide' matters.
- Auditing – the process for effective results.

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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