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ARTIFICIAL INTELLIGENCE (AI) IN MEDICAL DEVICE INDUSTRY TRAINING FACTSHEET

Speaker:
Koushik Ayalasomayajula
Director, Quality and Regulatory Affairs

Date: October 31st 2024, Online

Duration: 4 hours
2:00 – 6:00 PM Central Europe Time
09:00 AM – 1:00 PM US Eastern Standard Time

About the speaker: Somashekara Koushik Ayalasomayajula is a quality and regulatory affairs professional with 7+ years of experience in the MedTech industry. He leads the Digital Health team at Veranex and actively supports medical devices (incl. IVD) and software manufacturers with regulatory strategy, design and development, V&V, management system deployment (ISO 13485, ISO 9001, ISO 27001, MDSAP), auditing, safety and security, Lifecycle management (IEC 62304), cybersecurity and AI. Koushik is ASQ certified Medical Device Auditor (ASQ-CMDA) and holder of RAC Devices from RAPS.

TRAINING OBJECTIVES:

- Understand the scope and structure of EU AI Act
- Understand risk-based approach and related obligations
- AI Quality Management approach to reach compliance, scaling responsible use for AI
- Understand impact of AI regulations on EU medical device regulations

TRAINING CONTENT:

- Introduction to EU Artificial Intelligence Act (EU AIA)
    - Overview of the regulations
    - Subject matter and scope
    - Key provisions
- Compliance requirements for General purpose AI systems
- Risk based classification & prohibited AI practices
- Obligations of providers, importers, distributors and users
- Conformity assessment
    - Harmonised standards
    - Conformity assessment routes
    - EU Declaration of Conformity
    - CE marking of conformity
- AI regulatory sandboxes
- EU Database for high-risk AI systems
- Implementation timelines
- Interplay with EU Medical Device regulations (MDR/ IVDR)

TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)

WHO SHOULD ATTEND:

- AI developers, Product managers and Project leaders.
- Quality and Regulatory affairs employees of medical device manufacturers involving AI.
- Anyone seeking to understand the regulatory requirements of their AI product that falls under the definition as a medical device (under Medical Device Regulation [MDR] 2017/745 in Europe).

Prerequisite: Basic understanding on EU medical device regulatory framework.

PRICE:

EUR 415 EUR incl. course material, recording and certificate

Registration: https://education-veranex.talentlms.com/
Contact: MDD-training@veranex.com