Veranex

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UNDERSTANDING EU REGULATORY LANDSCAPE FOR SOFTWARE AS MEDICAL DEVICE (SaMD)

TRAINING FACTSHEET

Speaker:
Somashekara Koushik Ayalasomayajula
Quality and Regulatory Affairs Director

Date: March 5th 2024, Online
Duration: 4 hours | 1x 1:00 – 5:00 PM CET
1 x 7:00 – 11:00 AM EST

About the speaker: Somashekara Koushik Ayalasomayajula is a polymer engineer and an experienced quality and regulatory affairs consultant with 11+ years of expertise in regulated industries. Besides leading Digital Health team, he stands ready to guide organizations through the complexities of quality and regulatory affairs, ensuring excellence in the evolving landscape of medical devices globally. Koushik is ASQ certified Medical Device Auditor (ASQ-CMDA) and holder of RAC Devices from RAPS.

TRAINING OBJECTIVES:

- Understand regulatory requirements applicable in Europe for standalone software as medical device and to medical devices incorporating software.
- Identify and understand classification rules applicable to software in MDR.
- Gain understanding on secure software development practices for medical devices.
- Technical Documentation needed for standalone software medical devices and medical devices incorporating software.

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TRAINING CONTENT:

- Regulatory context & key concepts
- Qualification and classification of Software under MDR (EU 2017/745)
- General product safety requirements (IEC 82304-1) & life cycle management (IEC 62304) for health software
- Clinical evaluation for medical device software
- Requirements related to
    - Risk management (incl. Usability)
    - Interoperability
    - Cybersecurity
    - Data protection and information security
- Conformity assessment routes
- Technical documentation needed for conformity assessment
- Requirements for Softwares using Artificial Intelligence (AI)
- Market access for software providers

TRAINING FORMAT:

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

TO WHOM IT IS ADDRESSED:

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

PRICE:

EUR 415 incl. course material and certificate

Registration: https://education-veranex.talentlms.com/
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