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EUROPEAN DATABASE FOR MEDICAL DEVICES (EUDAMED)

TRAINING FACTSHEET

Speaker:
Somashekara Koushik Ayalasomayajula
Quality and Regulatory Affairs Director

Date: June 18th, 2024, Online
Duration: 4 hours | 1:30 – 5:30 PM CEST
7:30 – 11:30 AM EDT

About the speaker:
Somashekara Koushik Ayalasomayajula is a polymer engineer with 5+ years of experience within the medical device industry in product development and quality & regulatory affairs. Koushik supports our courses related to quality and regulatory affairs, deploying QMS according to ISO 13485, ISO 27001, MDR/ IVDR, integrating MDSAP, GMP requirements and in the preparation of technical documentation of medical devices for global regulatory submissions. Koushik is ASQ certified Medical Device Auditor (ASQ-CMDA) and holder of RAC Devices from RAPS.

TRAINING OBJECTIVES:

- Understanding EUDAMED and its functional specifications
- Interpret EUDAMED data structures, requirements and business rules
- Impact of EUDAMED on QMS of economic operator

TRAINING CONTENT:

- Introduction to EUDAMED
- EUDAMED readiness and time constraints

- Actor registration module
  - User roles and hierarchy
  - Data required for actor registration
  - Obtaining SRN for economic operators (EU and non-EU) - EUDAMED Input screens
- Device and UDI registration module
  - Data required for device registration
  - Data exchange options
- Introduction to vigilance & post market surveillance module
- EUDAMED impact on QMS

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:

- Quality / Regulatory Affairs Manager
- Persons responsible for regulatory affairs and quality management
- Manufacturers, authorized representatives, importers, and sponsors
- Management, and anyone interested in EUDAMED

Prerequisite: Understanding on EU MDR and IVDR requirements is essential.

PRICE:

EUR 415 incl. course material and certificate

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