

EUROPEAN DATABASE FOR MEDICAL DEVICES (EUDAMED)

TRAINING FACTSHEET



Date: June 18th, 2024, Online

Duration: 4 hours

Speaker:

Somashekara Koushik Ayalasomayajula
Quality and Regulatory Affairs Director

7:30 – 11:30 AM US Eastern Standard Time

1:30 - 5:30 PM Central Europe Summer Time

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