Veranex

Chemin de Rovéréaz 5
1012 Lausanne, Switzerland

PHONE | +41 21 311 20 59
EMAIL | MDD-training@veranex.com
WEB | www.veranex.com

Introduction to MDSAP (Medical Device Single Audit Program)

TRAINING FACTSHEET

Speaker:
Somashekara Koushik Ayalasomayajula
Quality and Regulatory Affairs Director

Date: January 31st, 2024, Online
Duration: 4 hours | 1:00 – 5:00 PM CET
7:00 – 11:00 AM EST

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:

- Creating awareness by understanding principles and approach of MDSAP program
- Explain the structure and scope of the Medical Device Single Audit Program (MDSAP)
- Understand the main requirements of the MDSAP audit processes and their interrelationships
- Understand legal framework for medical devices in MDSAP jurisdictions

TRAINING CONTENT:

- MDSAP History and introduction

  - MDSAP statement of cooperation
  - MDSAP members
  - Regulatory Authority Council (RAC)
- Regulatory landscape in MDSAP territories and outcomes
  - Benefits of MDSAP
  - Overview of regulatory landscape in MDSAP territories
- MDSAP Structure and scope
  - MDSAP Audit cycle
  - MDSAP process interactions
  - MDSAP audit approach
- MDSAP post audit activities
  - Generalities
  - Non-conformity grading
  - 5-day rule
- Preparatory steps for successful MDSAP certification

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 Assurance and Regulatory Affairs professionals within medical device organizations currently active in participating territories and/ or organizations expanding their market reach to jurisdictions participating in MDSAP.
- Middle Management, Regulatory professionals, or anyone interested in conducting and participating in quality and regulatory audits.

  Prerequisite: Attendees are expected to have a solid background in the requirements of ISO 13485:2016.

PRICE:

EUR 415 incl. course material and certificate

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