Medidee Services SA
Chemin de Rovéréaz 5
1012 Lausanne | Switzerland

PHONE I +41 21 311 20 59
EMAIL I training@medidee.com
WEB I www.medidee.com

Person Responsible for Regulatory Compliance (PRRC) – EU & CH regulations

Duration: **4 hours | 1:00 – 5:00 PM CEST | 7:00 – 11:00 AM EDT**
Date: **April 25th 2023, Online**
Speaker: **Koushik Ayalasomayajula**

Training objectives:

- Understand the regulatory context of PRRC roles and responsibilities in both EU and CH regulations
- Understand the qualification needed for selecting the PRRC within an organization
- Understand in what situation(s) the role of the PRRC can be outsourced
- Analyze the impact on the QMS documentation

Training content:

- Regulatory context & qualification requirements
  - Review of Article 15 requirements of MDR (EU 2017/745) and IVDR (EU 2017/746)
  - Review of Article 49, 51 requirements of Medical Device Ordinance (MedDO)
  - Review of Article 42, 45 requirements of Ordinance on In Vitro Diagnostic Medical Devices (IvDO)
  - Requirements regarding PRRC's qualification
- Implementation of the requirements
  - Analysis of the roles and responsibilities of the PRRC
  - How to implement in practice the requirements from EU & CH regulations
  - Outsourcing and sharing the roles and responsibilities of the PRRC
  - Liability
- Impact on QMS documentation
  - Job description
  - Quality Manual
  - Human Resources process
  - Pos-market Surveillance and Vigilance processes
  - Design and Development and Manufacturing processes

Medidee Services SA
Chemin de Rovéréaz 5
1012 Lausanne | Switzerland

PHONE I +41 21 311 20 59
EMAIL I training@medidee.com
WEB I www.medidee.com

Prerequisite:

- Understanding of Quality Management Systems as per ISO 13485
- Understanding of medical device regulatory framework in EU and CH

Training format:

- Presentations with interactive discussions
- End of training assessment

Price:

- EUR 415 incl. course material and certificate

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

Contact: training@medidee.com