Medidee Services SA
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Impact of the MDR/IVDR on your QMS and technical file

Duration: 1 day

Training objectives:

The following skills and competences are developed:

- Better understand the concept of a risk-based approach into a QMS
- Organizing the validation of software used within the QMS and for production
- Identifying applicable MDR/IVDR requirements and the impact on the quality management system
- Identifying applicable MDR/IVDR requirements and the impact on the technical file

Training content:

- Integration the risk-based approach into your QMS in order to control:
  - Internal and sub-contracted processes
  - Resources and competences
  - Supply chain and process validation
- Validation of software used within the QMS and for production
- Implementation of MDR & IVDR requirements
  - Implement the new structure of the technical documentation
  - Implementation of UDI, and registration of economic operator
  - Implementation of clinical, vigilance and post-market surveillance requirements

The training is delivered by Yann Cailler, Senior Associate at Medidee Services.

Price: CHF 750.-
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