

Medical Devices

The aim of this course is to give participants a basic knowledge of the rules and laws regulating the development of Medical Device focusing on how and when to do Clinical Investigation.

Description

- • General
 - MDD - Medical Device Directive
 - National requirements
 - Notified Bodies
 - Reporting - requirements
- Country specific experience of working in:
 - Europe (different countries within EU)
 - USA
- Registration of a product
 - CE-labeling (Europe)
 - 510k/PMA (USA)
 - Classification of a product
 - Risk analysis
 - Instructions for use and labelling
- Clinical Investigations when, where and why
 - When to do a Clinical Investigation
 - Differences between Europe and US
 - Ethical Aspects
 - ISO 14155 -1 and 2
 - Clinical Evaluation
- Group work and presentations

Target group

Those who come in contact with Clinical Investigations with Medical Device both national and international. Research personnel (Clinical and Pre-Clinical), study personnel at hospitals or private clinics and Marketing (how to use Clinical results).

Course leader

- Annelie Andersson, Project Manager

Cost

The cost for the course is EURO 375 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 400 + VAT. The price includes morning and afternoon coffee as well as lunch.

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