Johner Institut

Seminar Certified Professional for Medical Software

Learning Content

- Regulatory basis for medical devices (including medical device regulation, laws, essential requirements, classification, and conformity assessment procedures)
- Quality management systems and EN ISO 13485:2016
- Risk management according to EN ISO 14971:2019
- Software lifecycle processes and EN 62304:2006 incl. A1:2015
- Usability engineering and EN 62366-1:2015
- IT security basics

Information about the schedule

Day	Content
Day 1	Regulatory basics
Day 2	Document and quality management, risk management, usability engineering
Day 3	Software life-cycle processes (part 1)
Day 4	Software life-cycle processes (part 2), IT security, examination

The seminar will take place **daily from 09:00 am to 05:00 pm** in the specified time period.

There will be a one-hour lunch break each day and small breaks in between as needed.

The duration of the individual learning units depends on the participants' knowledge level and the number of questions that arise. Therefore, no exact times can be provided.

The **examination** will take place **on the last day** of the seminar at approximately **03:30 pm**.

You can find more information and the registration option here