Johner Institut

Compact Seminar Medical Software and IEC 62304

Learning Content

- Qualification and classification of medical software
- Regulatory system
- Requirements of the MDR and IEC 62304
- Software Requirements Specification
- Software architecture and software testing
- ISO 25010 quality model
- Agile software development
- Software engineering best practices

Schedule

Time	Content
09:00 am - 09:30 am	Introduction, expectation of the participants
09:30 am - 10:00 am	Relevant standards, laws and directives, and their interrelationships
10:00 am - 10:30 am	Medical Devices Regulation (MDR, 2017/745), national laws and regulations, basic requirements according to Annex I
15 min break	
10:45 am - 11:45 am	When software becomes a medical device, classification according to Annex VIII
11:45 am - 12:30 pm	Overview IEC 62304, software development process, agile development
60 min lunch break	
01:30 pm – 02:00 pm	Software Requirements Specification
02:00 pm – 02:35 pm	Software architecture and detailed design
10 min break	
02:45 pm - 03:30 pm	SOUP, software safety classification
03:30 pm - 04:00 pm	V&V: unit test, software integration test, validation
10 min break	
04:10 pm - 04:30 pm	Maintenance process, problem resolution, configuration management

Johner Institut

Time	Content
04:20 pm - 04:35 pm	Interaction with risk management according to ISO 14971
04:35 pm - 05:00 pm	Deepening and/or desired topics of the participants (e.g., differences to FDA requirements)

You can find more information and the registration option here