Do you need practical help and guidance on the regulatory requirements of medical device software? Do you want to update your knowledge of IEC 62304 standard and learn about best practices how to utilize standard in practice to cover the compliance – especially in Agile software development ?

"Regulatory affairs expert – controlling the regulatory and compliance requirements related to medicine, diagnostics and medical devices" – ESF project seminar:

Agile Development of Medical Software – requirements and IEC 62304 in practice

Date: Thuesday 8.5.2014
Venue: University of Eastern Finland, Kuopio Campus, Tietoteknia -building, room 1039,Savilahdentie 6B, Kuopio
Organizers: University of Eastern Finland, Aducate - Centre for Training and Development with the Finnish Health Technology Association, FIHTA and USBIMED

Who will benefit? Persons working in medical device industry (diagnostics, medical devices including also medical software). Scientists, teachers and students in research environments related to medical devices. Suitable also for persons who already have experience in software design, but who wish to expand their knowledge of the medical device side.

Course objectives: IEC 62304 standard defines requirements for the software lifecycle, including software development and maintenance. The aim of training is to explore the regulatory requirements of medical SW and how to utilize IEC 62304 in practice to cover the compliance. Agile SW development, frequently asked questions and common challenges will be discussed especially. Practical examples will be presented.

The course is structured to encourage delegates to

- examine particular aspects of IEC 62304 standard and agile development
- solve specific problems
- discuss and develop ideas
- learn from the experience of others

Course fee
190 euros/participants. The fee includes: lectures, course materials, certificate and afternoon coffee.

Registration
Register at www.aducate.fi/lupaosaaja. Submit the registration form by April 23rd, 2014.

Cancellation policy
Cancellation of registration prior to the commencement of the event: 14 days or less, 50 %. If no cancellation, full fee.

For more information:
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Course programme

Chairman: Development Director (Health and Well-being Centre of Expertise) Arto Holopainen, Kuopio Innovation Ltd.

Course instructors:

Robert Ginsberg, Co-Founder and CEO at QAdvis *(main instructor)*

Nils-Åke Lindberg, Co-Founder and VP QA&RA at QAdvis

8.30-8.50	Registration
8.50-9.00	Welcoming words and introduction *Arto Holopainen*
9.00-10.15	Regulatory landscape and Medical Device software
10.15-10.30	Break
10.30-12.15	System/SW Architecture and design ”SW engineering issues”
12.15-13.00	Lunch
13.00-14.15	Software Risk Management
14.15-14.45	Break and Refreshments
14.45-16.30	Software testing, documentation and post market surveillance
16.30-16.40	Closing of course