SPARK EUROPE WEBINAR SERIES 2024

Wednesdays at 4 pm CET

SPARK Europe Education

Is my software a medical device? How to step forward?

HEIKKI PITKÄNEN
CEO
Lean Entries

10 April 2024 | 4 – 5 pm (CET) | Online Webinar

In this online **SPARK Europe Webinar Series**, Heikki Pitkänen will discuss the regulatory landscape of medical software solutions.

After this talk, you will have an understanding on what the rules are and how challenging it is to define which software is or is not regulated by the MDR or the IVDR in EU. We will discuss what are the grounds to classify software into Class IIa or higher, exposing them to Notified Body assessment, or in Class I in remote cases. We'll make a brief comparison to the US FDA and what the regulations mean in practice for medical device software developers, not forgetting AI. For the knowledge transfer, Heikki will use their proprietary regtech platform Entries to explain some of the above principles.

Heikki has over two decades of experience from medical device development. He is the CEO and founder of Lean Entries Ltd., a group of regulatory experts in global medical device regulations providing unique digital regulatory services as well as traditional consulting for the MedTech sector from academies and startups to multinational enterprises.

Online via Zoom| Please register here!

Registration to the webinar is required in advance. Please register no later than **9 April 2024.** Please note that you will receive the Zoom link and access code the evening before the lecture and that access to last minute registrations, cannot be guaranteed.

SPARK is an initiative created at Stanford University, to overcome challenges associated with translation of academic discoveries.

In unforeseen cases, the organizers may change and update topics and speakers.

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