

Developing Software for Medical Devices (Remote presentation)

Tuesday, 21 March 2023 14:00 (30 minutes)

Medical devices will almost always be driven by software components. Development for this field of work requires special considerations for patient safety and data privacy and is thus governed by rules alien to other deployment scenarios. The European Union is about to switch to a new regulation framework, the Medical Device Regulations (MDR), replacing the far less comprehensive Medical Device Directives (MDD). The new rules will have a significant impact on software development in the future and, while providing more patient safety, come at the price of significantly increased complexity and thus cost. Other regions in the world either follow or, to the contrary, have relaxed some regulations. The presentation discusses current regulations and difficulties in different areas of the world from the perspective of software development, with the focus and starting point of the new MDR.

Primary author: Dr BERLICH, Ruediger (Gemfony scientific)

Presenter: Dr BERLICH, Ruediger (Gemfony scientific)

Session Classification: Health & Life Sciences (including Pandemic Preparedness Applications)

Track Classification: Track 2: Health & Life Sciences (including Pandemic Preparedness Applications)