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State of the art engineering of medical software and Mobile Medical Apps according to MDR, FDA and IEC 62304 requirements

The presentation gives a small insight into the medical software engineering process, while focusing on the following five main questions:

- What are the requirements for medical software and Mobile Medical Apps to fulfill the MDR?
- What should be considered when designing a software architecture that should meet the MDR, GDPR and FDA Cybersecurity requirements?
- What is the most efficient way to engineer and maintain a medical software that should be released in multiple regulated markets?
- What are the main criteria to decide if a medical software component should be engineered from scratch or based on an unvalidated SOUP component?
- Should multiplatform apps for Android and iOS devices be engineered native or by means of a cross-platform framework like Xamarin?

In addition to answering these questions, the paper provides a brief overview of the challenges of developing medical software and highlights possible solutions based on realized projects.

Link:

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