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New Advanced Medical Software Technology Challenges and Evolution of the Regulatory Framework in Expert Software, Artificial Intelligence, and Machine Learning

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Abstract : Software, artificial intelligence, and machine learning can improve healthcare through innovative and advanced technologies that are able to use the large amount and variety of data generated during healthcare services every day. As we read the news, over 500 machine learning or other artificial intelligence medical devices have now received FDA clearance or approval, the first ones even preceding the year 2000. One of the big advantages of these new technologies is the ability to get experience and knowledge from real-world use and to continuously improve their performance. Healthcare systems and institutions can have a great benefit because the use of advanced technologies improves the same time efficiency and efficacy of healthcare. Software-defined as a medical device, is stand-alone software that is intended to be used for patients for one or more of these specific medical intended uses: - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease, any other health conditions, replacing or modifying any part of a physiological or pathological process–manage the received information from in vitro specimens derived from the human samples (body) and without principal main action of its principal intended use by pharmacological, immunological or metabolic definition. Software qualified as medical devices must comply with the general safety and performance requirements applicable to medical devices. These requirements are necessary to ensure high performance and quality and also to protect patients' safety. The evolution and the continuous improvement of software used in healthcare must take into consideration the increase in regulatory requirements, which are becoming more complex in each market. The gap between these advanced technologies and the new regulations is the biggest challenge for medical device manufacturers. Regulatory requirements can be considered a market barrier, as they can delay or obstacle the device approval, but they are necessary to ensure performance, quality, and safety, and at the same time, they can be a business opportunity if the manufacturer is able to define in advance the appropriate regulatory strategy. The abstract will provide an overview of the current regulatory framework, the evolution of the international requirements, and the standards applicable to medical device software in the potential market all over the world.

Keywords : artificial intelligence, machine learning, SaMD, regulatory, clinical evaluation, classification, international requirements, MDR, 510k, PMA, IMDRF, cyber security, health care systems.
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