World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:17, No:02, 2023

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 can use the large amount and variety of data generated during healthcare services every day; one of the significant advantages of these new technologies is the ability to get experience and knowledge from real-world use and to improve their performance continuously. Healthcare systems and institutions can significantly benefit because the use of advanced technologies improves the 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 protect patients' safety. The evolution and the continuous improvement of software used in healthcare must consider 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's approval. Still, they are necessary to ensure performance, quality, and safety. At the same time, they can be a business opportunity if the manufacturer can define the appropriate regulatory strategy in advance. 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
Conference Title : ICHMTMID 2023 : International Conference on Health Monitoring Technologies and Medical Imaging Devices
Conference Location : Sydney, Australia
Conference Dates : February 20-21, 2023