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강연제목: 취준생이 알아야 할 소프트웨어 의료기기의 인허가 소개

Introduction to Certification & Approval of SW Medical Devices for Job Applicants

Abstract:

There are many types of jobs in SW medical device certification and approval field such as Researcher, Design Developer, Manufacturer, Tester, Regulatory Affairs(RA), Quality Engineer, Quality Compliance and so on. They should be systematic each other in their organizations for getting certificate and selling their medical devices. Especially, it would be getting more essential that RAs have important role in the certification process under MFDS and EU MDR. In this tutorial, we would be discussing why RAs need and what the role of RAs for the certification is for job applicants in the SW medical devices.

Brief Biosketch

Dr. Byung-Woo Lee is currently a senior researcher on the division of biomedical & health in Korea Testing Laboratory(KTL). He is an auditor under GMP, ISO 13485, CE MDD/MDR as well. Dr. Lee received his B.S. from Yonsei University majored in biomedical engineering and electrical & electronic engineering. He got his M.S. and Ph.D. from Yonsei University majored in electrical & electronic engineering in 2011. Dr. Lee worked in TUV SUD which is a sort of notified bodies in EU as an CE MDD/MDR auditor. He focused on the Testing, Inspection, and Certification(TIC) field as a qualifying tester, regulatory affair, and auditor.