이름: 최찬진 / Chan Jin Choi
직위: 팀장 / Manager
소속: 고려대학교 구로병원 / Korea University Guro Hospital
기타소속: 의료기기 사용적합성 테스트센터 / Medical devices Usability Test Center

강연제목: 의료기기 사용적합성의 이해 / Understanding medical devices usability test

Abstract:

The medical device usability engineering process that applies the international standard IEC 62366-1 has been compulsorily applied in Korea since 2019, and has been applied differentially by grade from 2021. The usability process is another regulatory barrier for domestic medical device manufacturers, and it is difficult to implement.

The purpose of this article is to provide an overall understanding of the medical device usability engineering process and explain why medical device usability should be applied.

Brief Biosketch

현재 고대구로병원 의료기기 사용적합성 테스트센터에 근무하고 있음. 한국의료기기안전정보원에서 품질책임자 교육의 강사로 소속되어 있음. 테스트센터에서는 팀장을 맡고 있으며, 평가계획서 작성 및 보고서 작성, 평가 수행의 업무를 수행함.

Chan Jin Choi is currently working at Korea University Guro Hospital Usability Test center. He is affiliated with the quality manager training instructor of the NIDS(National Institutes of Medical Device Safety Information). As the manager of the usability test center, he writes test plan and report, and performs usability test.