(국문/영문)이름: 김은철 / Kim Euncheol
(국문/영문)직위: 센터장 / Director
(국문/영문)소속: 한국의료기기안전정보원 /
National Institute of Medical Safety Information
(국문/영문)기타소속: 디지털제품평가센터 /
Digital Product Evaluation Center

국문 강연제목: 디지털의료제품법 시행에 따른 디지털의료기기 품질관리 기준

영문 강연제목: Quality Management Standard for Digital Medical Devices in according with the enforcement of the Digital Medical Products Act.

Abstract(영문):

With the enforcement of the Digital Medical Products Act, a new regulatory framwork has been introducted to establish systematic quality management Standards for digital medical devices. This paper analyzes the key quality management requirements derived from the Act and their implications for the medical devices industry.

The proposed standards integrate digital technology-specific elements such as software lifecycle processes, artificaial intelligence(AI), data security and cybersecurity risk management into conventional medical device quality systems.

Keywords: Digital Medical Products Act, digital medical device, quality managemen system, regualotory compliance

Brief Biosketch (간단한 이력, 연구/대외활동 소개,국문/영문)

- ISO 13485(의료기품질경영시스템) 심사원 / ISO 13485:2016, Medical Device Management System Auditor
- ISO 9001(품질경영시스템) 심사원 / ISO 9001:2015, Quality Management System Auditor
- ISO/IEC 42001(인공지능경영시스템) 심사원 / ISO/IEC 42001:2023, Arificial Intelligence Management Systems Auditor
- 의료기기 기술문서 심사원(Medical Device Technical Documentation Reviewer)