이름: 이유경/Lee, You Kyoung

직위: 교수/Professor

소속: 순천향대학교/Soonchunhyang University

기타소속:

강연제목: 임상평가; 의료기기 전주기 종합예술

Understanding Clinical Evaluation; Arts in Medical Device Total Life-Cycle

Abstract

The need to reflect the clinical perspective in the development of medical devices has been a long-standing task of medical device development. MDD and IVDD, which have been applied to the acquisition of CE marks in Europe, have done their lives, and now the era of MDR and IVDR has arrived. According to the definition of MDR, clinical evaluation means a systematic and planned process to continuously generate, collect, analyze and assess the clinical data about a device to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. With the MDR and IVDR, the approval of medical devices seems to have strengthened the clinical perspective and set the direction toward an actual total life-cycle view through the clinical evaluation report (CER) or performance evaluation report (PER).

From the clinician's perspective, it is understood that MDR or IVDR has been considering regulatory approval as the starting point of life as medical devices in the healthcare field. I, as one of the clinical experts, expect the medical devices may reinforce the clinical perspectives under the MDR or IVDR. However, clinical evaluation is quite a tricky task that requires collaboration between clinical experts, methodology experts, and medical device experts. Therefore, the EU has recently established an expert panel to implement the CER or PER system and required them to provide opinions on clinical evaluation reports. Medical device manufacturers, methodology experts, and clinical experts should establish a collaborative partnership to successfully implement clinical evaluation in Korea.

Brief Biosketch

2022-현재, 순천향대학교부속 부천병원 연구부원장, 진단검사의학과 교수

2021-현재, 대한의학회 정책이사 (의료기기), 혁신의료기술위원회 위원장

2019-현재, 순천향대학교 Medical Device APEC Regulatory Training Center of Excellence 책임자

2018-2020, 한국의료기기안전정보원 이사

2013-2019, 보건복지부 신의료기술평가위원