이름: 최수정 / SOO JEONG CHOI
직위: 교수 / Professor
소속: 순천향대학교 부천병원/
Soonchunhyang University Bucheon Hospital
기타소속: Medical Device Clinical Research Center of
Soonchunhyang University Bucheon Hospital

국문 강연제목: 의료기기 이상사례 보고로 본 IMDRF 규제조화의 중요성
영문 강연제목: International Regulatory Harmonization with Medical Device Adverse Event Reporting

Abstract

Medical devices provides revolutionized healthcare development, but can lead to serious adverse events for the affected patients and user. The International Medical Device Regulators Forum (IMDRF) was established to promote cooperation and harmonization of medical device regulations around the world. The IMDRF Guidelines about Terminologies for Categorized Adverse Event Reporting was proclaimed in 2020. Regulatory harmonization of medical device adverse event reporting has advantages.First, safety information that was not known in pre-market clinical trials is helpful in evaluating the safety of medical devices through information exchange between countries. National competent authority report exchange provides timely and appropriate guidance worldwidely. This results in strengthening post-market surveillance. Second, unifying the regulatory requirements for medical devices sold in various countries can save cost and time for manufacturers, which can promote innovation and growth in the medical device industry. Third, if regulatory harmonization for medical device were achieved, users can evaluate medical devices using the same standards.

Brief Biosketch

Soo Jeong Choi is a professor in division of nephrology, department of Internal Medicine at Soonchunhyang University Bucheon Hospital. She received her Ph.D. and M.S. degree in Soonchunhyang Graduate School of medicine. She worked at Harold Simmons Center for Kidney Research and Epidemiology, University of Califonia Irvine in 2016~2018. She recieved commendation of the Minister of Food and Drug Safety about medical device safety management in 2021. Her research interests are adverse event reporting terminology, postmarket vigilance, and international haronization of medical device.