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(국문/영문)강연제목: 의료기기 RA 전문가 자격 소개/Medical Deivce RA Professional Qualification Introduction

Abstract(영문):

The medical device RA expert is a "medical device Regulatory Affair" who has knowledge of the entire process of medical device design, development and Certification, GMP, Clinical trial, Post-Market Surveillance, and Overseas certification. NIDS (National Institute of Medical Device Safety Information) operates a curriculum to cultivate medical device RA professionals and medical device RA certification. The medical device RA expert certification started in 2014 as a private qualification and is divided into level 2 and level 1, and Level 2 became nationally recognized (Ministry of Food and Drug Safety). The test subjects are composed of 5 subjects (Certification, Post-Market Surveillance, GMP, Clinical trial, Overseas Certification), and an average of 60 points or more is passed (under 40 points is fail). Only those with general knowledge related to medical device RA can obtain the certificate. Therefore, when a medical device company wants to hire a related expert, it is possible to check whether the relevant knowledge has been acquired by obtaining the certificate.

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

Tai Gwon Kim is the director of the Human Resources Training Department at the NIDS(National Institute of Medical Device Safety Information) and completed his master's degree in educational engineering at Chung-Ang University.
He started working at LG EDS (currently LG CNS) in 2000, worked at Sun Microsystems (currently Oracle), and the Korea Medical Device Industry Association, and has been working at the NIDS since 2012.
I designed a medical device RA education and certification system, and even promoted the national certification.