



이름: 김범민 / Kim, Beop-Min

직위: 교수 / Professor

소속: 고려대학교 / Korea University

기타소속: 범부처전주기의료기기연구개발사업단 /

Korea Medical Device Development Fund(KMDF)

강연 제목: 의료기기 R&D, 어떻게 할 것인가?

Practical Issues for Successful Medical Devices R&D?

#### Abstract:

새롭고 혁신적인 의료기기를 만들기 위해 수많은 의공학 기술들이 개발되고 있다. 하지만 의료기기 산업의 특성상 새로운 기술이 임상현장에서 쓰이기 위해서는 기술의 우수성 외 넘어서야 할 많은 장벽이 존재한다. 보수적인 임상현장, 후발주자로서 증명해 내야하는 새로운 기술의 안전성, 유효성 및 비용효과성, 난해한 규제 이슈 등을 극복해야만 비로소 시작점에 설 수 있다. 결과적으로 의료기기는 연구개발 단계부터 이러한 특성을 충분히 고려하지 않으면 성공적인 결과물을 내기 어렵다. 본 발표를 통해 의료기기의 산업적 특성, 규제와 관련된 정부 및 국제사회의 움직임, 그리고 이를 극복하기 위한 범부처의료기기 사업단의 지원 전략을 소개한다.

#### Brief Biosketch

Beop-Min Kim is a professor in the School of Biomedical Engineering, Korea University, Seoul, Korea. Prof. Kim is also the CEO of the Korea Medical Device Development Fund (KMDF) which has been established by four government ministries to support R&D for the domestic medical devices industry with the budget of US\$ 1 billion during the period of 2020 - 2025. He is an active member of various government committees operated by the Ministry of Health and Welfare, and the Ministry of Food and Drug Safety.

Prof. Kim received the B.S. degree in mechanical engineering from Korea University, Seoul, Korea, in 1989, and the M.S. and Ph.D. degrees in bioengineering from Texas A&M University, College Station, in 1991 and 1996, respectively. He was a pre-doctoral fellow with the University of Texas M.D. Anderson Cancer Center, Houston from 1993 to 1996. From 1996 to 2001, he was with the Medical Technology Program, Lawrence Livermore National Laboratory, Livermore, CA, where he was the staff scientist. From 2001 to 2009, he was an assistant/associate professor with the Department of Biomedical Engineering, Yonsei University, Korea, where he was also the department head and the director of the Institute of Advanced Biomedical Engineering.