



NIHS特別講演会 (殿町#48)

演題

Medical Device Regulation in the US: Challenges and Opportunities



講師

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Food and Drug Administration

要旨

The United States Food and Drug Administration (FDA) is responsible for the regulation of foods, drugs, biologics, medical devices and tobacco products. Within the FDA, the Center for Devices and Radiological Health (CDRH) ensures that safe and effective medical devices reach the public in a timely manner through approving devices for commercialization and ensuring that devices currently on the US market remain safe and effective. CDRH is also responsible for communicating science-based, accurate information about medical devices to the public to ensure that the public is adequately informed of new technologies and potential safety issues associated with existing technologies. This lecture will explain the structure of FDA and basics of medical device regulation in the US; highlight recent FDA initiatives intended to promote medical device development in the US; describe international efforts to promote regulatory collaboration and harmonization with Japan and other countries; and discuss potential opportunities for regulatory science collaboration.

略歴

Dr. Ibrahim is currently serving as a fellow in the 29th cohort of the Mansfield Fellowship Program. She has worked for the Food and Drug Administration for over 16 years in the field of Cardiovascular Devices. She began her FDA career as a computational modeling expert and primary reviewer for devices such as stents, heart valves and devices to treat heart disease in children. As deputy director, she currently oversees medical device review for all cardiovascular devices, including pacemakers, medical mobile applications and other software-based technologies. Her interests include pediatric device development and international collaboration to accelerate medical device access to patients globally. Prior to joining FDA, she completed her bachelor's degree in Bioengineering at Rice University (Houston, TX) and Ph.D. in Bioengineering at the University of Pennsylvania (Philadelphia, PA).

日時

2026年4月9日 (木)

13:30~14:30 開場13:00

国立医薬品食品衛生研究所 2階 共用会議室

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