

GRIPS-Mansfield Foundation Joint Seminar

“Overview and Challenges of Medical Device Regulation in the United States”

米国における医療機器規制の概要と課題

Friday, December 19, 2025 12:10-13:10 Online (Zoom Webinar)

*To join the Seminar, please register at the [Registration Form](#) below or

QR code on the right by 17:00(Japan Time) Wednesday, December 17, 2025.

You will receive an invitation e-mail from the Zoom online system.

https://grips-ac.jp.zoom.us/webinar/register/WN_yc2vJt5UT16Kddq5tu256Q



Speaker:	Nicole Ibrahim (Mansfield Fellow) ニコール・イブラヒム (マンスフィールド・フェロー) Deputy Director Office of Cardiovascular Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health Food and Drug Administration (FDA) U.S. Department of Health and Human Services 米国保健福祉省 米国食品医薬品局 (FDA) 医療機器・放射線保健センター 製品評価及び品質室 循環器医療機器審査部 副所長
Moderator:	Taichi Ono, Professor and Director of Healthcare Policy Concentration, National Graduate Institute for Policy Studies (GRIPS) 小野 太一 政策研究大学院大学教授・医療政策コースディレクター
Description:	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; highlight recent FDA initiatives intended to promote medical device development in the US; describe international efforts to promote regulatory harmonization with other countries; and discuss expertise and potential career pathways in the organization. Nicole Ibrahim, Ph.D. (Bioengineering, University of Pennsylvania) 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).

Taichi ONO, Ph.D. (Economics, Osaka City University)

Professor and Director of Healthcare Policy Concentration, National Graduate Institute for Policy Studies (GRIPS), Tokyo Japan

Before becoming tenured professor of GRIPS in 2020, he has worked as a senior official at the Ministry of Health, Labour and Welfare about three decades. He has assumed various positions including Director-level positions at Health Policy Bureau, Health Insurance Bureau as well as Equal Employment, Children and Family Welfare Bureau. He has also been First Secretary (Health and Welfare) at the Embassy of Japan in the United States between 1999 to 2002. In 2022, he published a book titled as “Formulation of Social Security in Post WWII Japan – Advisory Council on Social Security and its Expert Members” from University of Tokyo Press.

***Language: English**

***Admission: Free**

***This seminar will be off the record.**

For registration and inquiries, please contact

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(Mr. Asahi/ Ms. Sawanaka)

The National Graduate Institute for Policy Studies

GRIPS was established in October 1997, superseding the Graduate School of Policy Science (GSPS) at Saitama University, which was the first graduate school for Policy Studies in Japan. GRIPS is a government-sponsored graduate school and research institute which has been restructured into an entirely new and unique entity. GRIPS aims to be an international center of excellence for the education of future leaders in the policy arena, for the advancement of policy research, and for the systematic collection and dissemination of policy-related information. In order to accomplish these aims, a Graduate School, a Policy Research Center and a Policy Information Center have been established. GRIPS is the first graduate school without facilities for undergraduates in Japan in the wider disciplines of social science. GRIPS is located in Roppongi, Tokyo, with easy access to the political and business headquarters of Japan.

GRIPS degree programs are designed to attract outstanding students and thoroughly prepare them for distinguished careers in policy setting. After a period of thorough preparation since its foundation in 1997, GRIPS welcomed its first domestic students in April 2000, followed six months later by its first international students. About two-thirds of the student-intake of GRIPS consist of international students coming from over sixty countries in Asia, Africa, and Eastern Europe. Students normally have three to five years working experience for governments, central banks, custom offices or other relevant organizations. The International Programs at GRIPS are conducted solely in English, while Domestic Programs are taught in Japanese.

GRIPS aims to be the center of a consortium, consisting of industry, government, and academia, for the exchange of information, ideas, and personnel among graduate schools, government-related institutes, and private research institutes in Japan. In addition, through its international faculty, student body, and alumni, and by promoting international exchange of policy research and information, GRIPS aims to establish an international network among academics and government officials in the field of policy studies, contributing to the promotion of a better understanding among peoples around the world in an age of globalization.

The Maureen and Mike Mansfield Foundation

The Maureen and Mike Mansfield Foundation was created in 1983 to advance Maureen and Mike Mansfield's life-long efforts to promote understanding and cooperation among the nations and peoples of Asia and the United States. The Foundation sponsors exchanges, dialogues, and publications that create networks among U.S. and Asian leaders, explore the underlying issues influencing public policies, and increase awareness about the nations and peoples of Asia. The Foundation receives support from individuals, corporations, and philanthropic organizations. It also provides support to The Maureen and Mike Mansfield Center at the University of Montana.

The Mansfield Fellowship Program - named after Mike Mansfield, former U.S. ambassador to Japan, U.S. Senate majority leader, and U.S. congressman from Montana - is a first-of-its-kind program for the United States and Japan. The U.S. Congress created the Mansfield Fellowships in 1994 to build a corps of U.S. federal government employees with proficiency in the Japanese language and practical, firsthand knowledge about Japan and its government. During a one-year program in Japan, Fellows develop an in-depth understanding of Japan's government and policymaking process and establish relationships with their counterparts in the government of Japan and the business, professional, and academic communities. The Mansfield Fellowships are administered by the Maureen and Mike Mansfield Foundation, with the United States Department of State's Bureau of Educational and Cultural Affairs as grantor.

The Foundation has offices in Washington, DC, Tokyo, and Missoula, Montana.