

# GRIPS-Mansfield Foundation Joint Seminar

“Insights into Medical Device Regulations in the U.S. and Japan:

Key Resources for Stakeholders”

日米の医療機器規制に関する知見：ステークホルダーのための重要なリソースについて

Friday, December 13, 2024 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 11, 2024.** You will receive an invitation e-mail from the Zoom online system.

[https://grips-ac-jp.zoom.us/webinar/register/WN\\_UZvw\\_XisQAGdQgFV3oliHg](https://grips-ac-jp.zoom.us/webinar/register/WN_UZvw_XisQAGdQgFV3oliHg)



Speaker:	<p><b>Michiko Feehan</b> (Mansfield Fellow)          ミチコ・フィエン(マンスフィールド・フェロー)          Biomedical Engineer Reviewer          Office of Product Evaluation and Quality (OPEQ) Center for Devices and Radiological Health (CDRH) Food and Drug Administration (FDA) U.S. Department of Health and Human Services (HHS)          米国保健福祉省米国食品医薬品局 (FDA)製品評価及び品質室 医療機器審査官</p>
Moderator:	<p><b>Taichi ONO</b>, Professor and Director of Health Policy Course, 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</p>
Description:	<p>From tongue depressors to advanced technologies such as robotic surgery systems, medical devices play a crucial role in patient care across a wide range of applications. This presentation will provide insights into medical device regulations in the U.S. and Japan. It will also introduce practical, publicly available resources to help stakeholders access regulatory information.</p> <p><b>Michiko Feehan</b> is currently a Biomedical Engineer and Total Product Life Cycle (TPLC) Reviewer in the U.S. Food and Drug Administration’s Center for Devices and Radiological Health (CDRH). In this role, she conducts scientific reviews of implantable dental devices for safety and effectiveness, based on clinical and non-clinical data provided by manufacturers before these devices are brought to the U.S. market. Her work includes reviewing dental devices that use additive manufacturing (i.e., 3D printing), as well as patient-specific devices that incorporate computer-aided design/computer-aided manufacturing (CAD/CAM) technology. She applies scientific, technical, and regulatory expertise to integrate premarket, postmarket, and compliance data into medical device reviews, ensuring that patients and providers have timely and continued access to safe and effective devices.</p> <p>As a Mansfield Fellow, Michiko will spend a year in Japan and is currently working at the Pharmaceuticals and Medical Devices Agency. Michiko holds a B.S. in Biomedical Engineering from the University of Rochester in Rochester, NY. She is from Washington, D.C.</p> <p><b>Taichi ONO, Ph.D.</b> (Economics, Osaka City University)          Professor and Director of Health Policy Course, 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.</p>

\*Language: English

\*Admission: Free

\*This seminar will be off the record.

For registration and inquiries, please contact

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(Mr. Asahi/ Ms. Chigiri)

## The National Graduate Institute for Policy Studies

GRIPS was established in October 1997, superseding the Graduate School of Policy Science (GPS) 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.