

USP recognized as a leader in medicines quality and supply chain integrity by the Asia Pacific Economic Cooperation

As an APEC Center of Excellence USP will promote the exchange of best practices, tools, and standards to secure the medical product supply chain and protect public health

Rockville, MD – August 31, 2017 -- USP has been designated a Center of Excellence (CoE) in global medical product quality and pharmaceutical supply chain security by the Asia-Pacific Economic Cooperation (APEC), and will regularly convene international regulatory staff, industry and health policy makers to advance quality in the global supply chain for medical products.

APEC, a regional economic forum that encourages economic integration and technical cooperation in the world's largest consumer market, endorsed USP's CoE status during its Life Sciences Innovation Forum Regulatory Harmonization Steering Committee meeting on August 18. This steering committee meeting was the first in a series of meetings on health and the economy by representatives from government, industry and academia in the 21 APEC member economies.

As an APEC CoE, USP will develop capacity through hands-on collaboration, workshops and policy dialogue in support of the APEC Global Supply Chain Integrity Roadmap championed by the U.S. Food and Drug Administration (FDA). These efforts are intended to help improve medicines quality by leveraging communities of practice and enabling knowledge sharing among regulatory agencies and researchers from across the Pacific Rim.

"Regulatory convergence, networking among stakeholders, and sharing of best practices are key steps in promoting global health," said U.S. Department of Health and Human Services Secretary Tom Price, MD, during remarks at the APEC high-level meeting on health and the economy on August 23. Ensuring quality in medical products throughout the global supply chain is a major focus for USP. "Variation in medical product manufacturing, distribution and regulation can present challenges in ensuring medicines quality, and pose threats to patient safety and the public health. As an APEC CoE, USP will facilitate the exchange of best practices, tools, and standards among stakeholders to better ensure quality throughout the medical product supply chain," said USP's Katherine Bond, Vice President of International Public Policy and Regulatory Affairs.

USP is one of two Centers of Excellence focused exclusively on supply chain integrity. "Protecting the integrity of the medical product supply chain is a complex challenge that requires a global, collaborative approach," said Ilisa Bernstein Pharm.D., J.D., Deputy Director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research. "The Centers of Excellence will help bring together global stakeholders and regulators to share best practices designed to better prevent, detect, and respond to unsafe and falsified medical products that threaten the health and safety of patients around the world."

USP's work in medicines quality was featured prominently throughout the APEC meetings, including:

- APEC Life Sciences Innovation Forum named Ronald T. Piervincenzi, Ph.D., USP CEO, to the Executive Board.
- Dr. Piervincenzi addressed public quality standards as a driver from innovation to access during a panel presentation at the High Level Dialogue on Innovation, Regulatory Systems and Regulatory Convergence.

“Public quality standards provide a common benchmark for medicines quality, regardless of who makes a medicine or pharmaceutical ingredient or how that product is manufactured,” said Piervincenzi. “These standards are applicable and useable by everyone, allowing manufacturers to more efficiently develop medicines, encouraging innovation and enabling multiple manufacturers into a market.”

- Katherine Bond, Ph.D., USP VP International Public Policy and Regulatory Affairs, spoke about partnerships that contribute to medicines quality in the face of antimicrobial resistance during the high level meeting on health and the economy.

For more information about the Center of Excellence, please contact USP's APEC CoE Director Phillip Nguyen (ppn@usp.org).

About USP

The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are used worldwide. For more information about USP visit <http://www.usp.org>

About APEC

The Asia-Pacific Economic Cooperation (APEC) is a regional economic forum established in 1989 to leverage the growing interdependence of the Asia-Pacific. [APEC's 21 members](#) aim to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration. The APEC Harmonization Center (AHC) is established under the authority of the APEC Life Sciences Innovation Forum (LSIF). For more information, please visit: <http://www.nifds.go.kr/apec/index.do>

APEC Member Economies

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Canada
Chile
China
Hong Kong, China
Indonesia

Japan
Republic of Korea
Malaysia
Mexico
New Zealand
Papua New Guinea
Peru

The Philippines
Russia
Singapore
Chinese Taipei
Thailand
U.S.A.
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