

DK Kim International Center for Regulatory Science

**SPRING 2024** 

# **MISSION**

to apply regulatory science to regulatory and health solutions globally

The D.K. Kim International Center for Regulatory Science, part of USC Mann School of Pharmacy and Pharmaceutical Sciences, is an academic and research institution focused on educating individuals with a scientific background in international regulatory science. The center aims to meet the growing demand for professionals equipped to navigate global regulatory processes. Through transformative education and research, it seeks to contribute to a healthier and safer world by emphasizing the crucial role of regulatory science in shaping global health outcomes.

## **NEWS**





#### **KOREA: NEW KNOWLEDGE ADVENTURES BEGINS**

The Kim Center and Department of Regulatory and Quality Sciences [DRQS] hosted students from Yonsei and Sungkyunkwan Universities in Seoul, Korea. As part of our commitment to nurturing future leaders in regulatory and quality sciences, these students participated in classes and showcased their work as part of their independent studies fieldwork. We also warmly welcomed Ajou University's President Keecho Choi, Vice President for International Affairs Shin-Goo Kang, Director of International Exchange and Cooperation Joonghwa Kim, and Manager Seung Chul Yoo. They introduced the Ajou Bespoke College Program, promoting joint symposiums and academic exchange with American universities like USC, spanning fields like artificial intelligence, future automobiles, molecular science, energy systems, medicine, and law. We look forward to future collaborative opportunities.

## THE 2023 KIM CENTER ANNUAL REPORT PUBLISHED

The recently published Annual Report outlines the activities, contributors, and goals of the Kim Center. You can access it for free download using this link.

## QUALITY IS AN INVESTMENT WITH GREAT ROI

Discover how researchers from the Kim Center, the US FDA, MIT, and Temple University explored the pivotal role of return-on-investment (ROI) calculations in facilitating necessary upgrades to pharmaceutical manufacturing operations and the prompt resolution of medicinal quality risks. Read the article here: ICH Q9: Attaining a Quality-Business Synergy through Quality Risk Management, ROI Analysis, and Highly Capable Facilities [pharmtech.com]



#### **BRAZIL: GLOBAL HEALTHCARE LEADERSHIP**

Dr. Lawrence Liberti participated in an international workshop in Sao Paulo on "New Ways of Working - Enabling Patient Access through Reliance or Regional Review Models," hosted by the Centre for Innovation in Regulatory Science. He also contributed to the 12th Annual Regulators Forum, which aimed to explore how agencies can collaborate to ensure timely availability of medicines. Additionally, he co-chaired a session titled "Embedding a Unilateral Risk-Based Model in the Modern Agencies Regulatory Toolkit," which drew 53 industry and agency representatives from around the world.



#### FURTHERING OUR RELATIONSHIP WITH THE KOREA REGULATORY SCIENCE CENTER

The Kim Center staff convened virtually with Dr. Misun Park, Planning Director, alongside Mirim Baek, Business Planning Team Leader, and Jungtaek An, Business Planning Team Manager, to further explore collaborative initiatives between the two organizations.



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# **NEWS**





## KIM CENTER SUPPORTS THE AMERICAS RISE FOR HEALTH INITIATIVE

Dr. Lawrence Liberti was invited to join over 100 representatives hailing from regulatory agencies, pharmaceutical companies, civil society, NGOs, and academia at the second convening of the RISE initiative, hosted in Punta Cana, Dominican Republic, The initiative aims to foster resilient, inclusive, sustainable, and equitable health economies and ecosystems across the Americas. The Kim Center stands ready to contribute its expertise to the RISE Network for Regulatory Capacity Building by promoting convergence through adopting international standards, partnering with academia and stakeholders, and organizing capacity-building workshops across the region.

#### UNITING MINDS ACROSS DISCIPLINES FOR GLOBAL HEALTH EXCELLENCE

Dr. Lawrence Liberti, invited speaker at the annual meeting of the Consortium of Universities for Global Health, held at the USC/Keck School of Medicine, gave the oral presentation 'Global Medicine Access: The Impact of US FDA's Agile Regulatory Approaches on Medicine Accessibility Worldwide.' Additionally, he shared insights via a poster presentation, furthering global health initiatives and fostering exchange of ideas at the event.



Dr. Liberti at the poster session

#### KIM CENTER ADVISORY COMMITTEE

The Kim Center's Advisory Committee convened for its inaugural meeting in a virtual setting, with the participation of ten members across Europe, North America, Latin America, and Africa. These members represent a diverse spectrum, including representatives from regulatory agencies, international pharmaceutical and device companies, academia, and NGOs. The discussion centered around two key themes: "How can the Kim Center Contribute to Your Organization?" and "How can your Organization Support and Interact with the Kim Center?" We thank the Committee for their invaluable insights and practical suggestions. Moving forward, the Advisory Committee will convene three times per year.

## **UPCOMING EVENTS**



# WEBINAR

Join us on May 7, 2024, for an enriching webinar experience titled "Product Sameness and Risk Assessment," co-hosted by Drs. Lawrence Liberti and Mario Alanis. This event marks the ninth episode of ongoing series, sponsored by MSD. Stay connected with us here to secure your free registration use this link: https://frpanoramaforum2024may.eventbrite.com



# DIA GLOBAL ANNUAL MEETING

On June 16-19, 2024, the Kim Center will actively participate in the DIA Global Annual Meeting to be held in San Diego, CA.

### KIM CENTER ADVISORY COMMITTEE

On June 17, 2024, the pivotal mid-year meeting of the Kim Center Advisory Committee will be held in conjunction with the DIA Global Annual Meeting in San Diego, CA.