COMBINATION PRODUCTS SUMMIT
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AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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220 Global Regulators and Industry Partners Gather in Ft. Worth for Combination Products Summit 2023

The Combination Products Summit 2023 convened this week at the Omni Ft. Worth in Ft. Worth, Texas, welcoming 220 attendees from 11 countries and four continents — including 19 FDA participants — for two days of purpose-driven discussions inspiring collaboration, leading innovation, and making a difference in combination products and overall patient care. The event was hosted by the AFDO/RAPS Healthcare Products Collaborative and co-sponsored by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services.

"Collaborating with so many visionaries and creative minds for in-depth discussions, exchanges, and collaboration is simply powerful," said Timothy Hsu, Chief Collaboration Officer, AFDO/RAPS Healthcare Products Collaborative. "This forum distinctly allows industry partners to connect directly with FDA to explore and solve tough issues and challenges through the right balance of intellectual exchange, ultimately creating better pathways for world health. It's inspiring to see the community come together with such enthusiasm and commitment."

This year's educational program consisted of 39 speakers and 21 moderators across 16 sessions, including more than 15 FDA expert presenters. Some of the speaker highlights included:

- James Bertram, Director of the Office of Combination Products (OCP), U.S. Food and Drug Administration (FDA)
- Kate Gillespie, Sr. Director, Global Product Vigilance and Post Market Reporting, Johnson & Johnson
- Sujith Kallur, Regulatory Affairs Lead, Wearable Injectors, BD Medical Pharmaceutical Systems
- Joo Hee Kim, Regulatory Strategy Center for Combination Products (RSCP), Ajou University
- Thinh Nguyen, Director of the Office of Clinical Policy & Program, U.S. Food and Drug Administration (FDA)
- Steven Oh, Deputy Office Director, Office of Cellular Therapy and Human Tissue, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA)
- Aftin Ross, Acting Deputy Director – Division of All Hazards Response, Science & Strategic Partnership, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA)
- John (Barr) Weiner, Associate Director for Policy in FDA's Office of Combination Products (OCP), U.S. Food and Drug Administration (FDA)

The Combination Products Strategic Committee curated the program with key content themes centered on updates from FDA, industry experiences, global harmonization, platform drug-delivery devices, essential performance requirements, emerging digital health technologies, next-generation products, and cybersecurity. In addition, attendees participated in an interactive Solutions Exchange Case Study, which explored human factors and connected health considerations for a new drug delivery system.

The event also featured a preconference workshop on Tuesday, November 28, entitled “Notified Body Opinion Workshop — Experiences and Lessons for Combination Products in EU,” featuring expert presenters from BSI Group, AstraZeneca, AbbVie, and Pfizer. Tuesday also offered Combination Products Summit event attendees the opportunity to meet with FDA officials during office hours to ask questions, discuss challenges, and exchange perspectives.

“The ultimate goal is to take a consistent, efficient, and risk-based approach to ensure safe and effective combined uses of different types of medical products,” remarked John “Barr” Weiner, Associate Director for Policy, Office of Combination Products, FDA-OCP, during a session he co-hosted with James Bertram, Director, Office of Combination Products, FDA- OCP. “There are significant challenges and opportunities from innovations in technologies, products, and manufacturing techniques and controls. Varying experience and capabilities of regulators and regulated entities, and differences in regulatory authorities and structures make efforts towards convergence and harmonization more complex. A focus on what questions need to be addressed to effectively address risk of the combined use is key. Having a robust community like this is critical in maintaining and leveraging trust needer for substantial engagement to inform alignment efforts.”

Since 2015, the Combination Products Summit has united the healthcare products industry to work for a better tomorrow. The community continues to be led by top regulatory officials and worldwide industry leaders who built the framework for the regulatory landscape of combination products. This global community drives innovation and navigates the complexities specific to the world of combination products, resulting in the delivery of safe, effective, and high-quality products to the patients who need them.

Sign up for information and updates on Combination Products 2024 by visiting https://www.healthcareproducts.org/combination.

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About the AFDO/RAPS Healthcare Products Collaborative

The AFDO/RAPS Healthcare Products Collaborative is a joint venture established in 2022 between the Association of Food and Drug Officials (AFDO) and the Regulatory Affairs Professionals Society (RAPS).

Continuing and expanding upon Xavier Health's legacy, the Collaborative supports idea sharing, innovation, and action across the global healthcare products community by fostering purpose-driven discussions between regulators, industry, academia, and thought leaders about the most pressing issues facing the industry.

The Collaborative's distinct events portfolio — which includes the MedCon Conference, AI Summit, Combination Products Summit, and PharmaLink Conference — highlights just one of the ways the partnership inspires collaboration. This unique blend of mission and values guides purpose-driven community building and innovative solutions to make a difference in patients’ lives. www.healthcareproducts.org