COMBINATION PRODUCTS SUMMIT
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AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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240 Global Regulators and Industry Partners Gather in Providence for Combination Products Summit 2024

York, Pa., October 11, 2024 — The Combination Products Summit 2024 convened this week in Providence, Rhode Island, welcoming a sold-out attendance of 240 participants from 10 countries and five continents 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.

"If you are in the combination products space, this is the place to be," said Kim Belsky, the strategic facilitator for the Summit at the AFDO/RAPS Healthcare Products Collaborative. "The level of collaboration, the diversity of industry and regulatory backgrounds, and the opportunity to engage with the FDA we have seen here the past three days solidifies that this is the premiere event for anyone working in combination products and looking for insights into today's challenges and opportunities."

This year's educational program consisted of 33 speakers and 14 moderators across 14 sessions, including two representatives from the European Commission and 17 leaders from the FDA. Some of the speakers included:

- **James Bertram,** Director of the Office of Combination Products (OCP), FDA
- **Ashley Boam,** Director Office of Policy for Pharmaceutical Quality, Office of Policy, Center for Drug Evaluation and Research (CDER), FDA
- **Isabelle Clamou,** Policy Officer, European Commission
- **Andrea Gray,** Biomedical Engineering Advisor, Center for Biologics Evaluation and Research (CBER), FDA
- **Tina Kiang,** Director, Division of Regulation and Guidance (DRG), Office of Policy for Pharmaceutical Quality (OPPQ), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), FDA
- **Kristina Lauritsen,** Combination Products Regulator, Center for Drug Evaluation and Research (CDER), FDA
- **Juliane Lessard,** Director, Division of Drug Delivery, General Hospital Devices, and Human Factors, Center for Devices and Radiological Health, (CDRH), FDA
- **Patricia Love,** Deputy Director, Office of Combination Products, FDA
- **Annette Marthaler,** Senior Regulatory Counsel, Office of Combination Products, FDA
- **Sarah Mollo,** Combination Products Analyst, Center for Devices and Radiological Health (CDRH), FDA
- **Stephanie Shapley,** Associate Director for Policy, Office of Combination Products, FDA
- **Olga Tkachenko,** Policy Officer, European Commission

- **Nik Thakur,** Senior Program Manager, Quality and Compliance, Center for Devices and Radiological Health, (CDRH), FDA
- **Andrew Yeatts,** Combination Product Policy Analyst, Center for Devices and Radiological Health (CDRH), FDA

The Combination Products Strategic Committee curated the program with key content themes centered on updates from FDA, on-body delivery systems (OBDS), drug CMC review principles, generic substitutability for DDCs, platform technologies, the EU COMBINE Project, human factors, and more. In addition, attendees participated in an interactive Solutions Exchange Case Study, which explored diabetes and pain management.

The event also featured a preconference workshop on Tuesday, October 8, entitled “Delving Into Combination Product Challenges,” featuring expert presenters from Genetech/Roche, Sanofi, Johnson & Johnson, AstraZeneca, AbbVie, and Combination Products Consulting, LLC. 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 Summit is a great opportunity for industry to hear from and stay in touch with the agency," said James Bertram, director of the Office of Combination Products (OCP) at the FDA. "It’s not only a great way to hear from each other, but also a way to foster important discussions, and the Summit has been an amazing forum for those discussions."

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 2025 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