COMBINATION PRODUCTS SUMMIT
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CO-SPONSORED BY THE FDA

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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Media Contacts:

Jason Brill
Association of Food and Drug Officials (AFDO)
jbrill@afdo.org
(216) 571-1767

Ryan Connors
Regulatory Affairs Professionals Society (RAPS)
rconnors@raps.org
(301) 770-2920, ext. 234

240 Global Regulators and Industry Partners Gather in Providence for Combination Products Summit 2026

Baltimore, Maryland, November 18, 2026 — The Combination Products Summit 2026 convened this week at the Hyatt Regency Baltimore Inner Harbor in Baltimore, Maryland, welcoming attendance of 240 participants from 12 countries and four 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).

"Each year I look forward to this event," says James Bertram, Director of the Office of Combination Products (OCP), FDA. "The Summit has been and continues to be a great opportunity to see new and familiar faces in the combination product field. Each day is unique and provides attendees with the chance to engage with colleagues and learn from leaders in the field."

"The AFDO/RAPS Combination Products Summit brings FDA/EMA and leaders across regulatory, quality, and development together for candid, engaging dialogue on the latest policies and regulatory review practices," says Rumi Young, interim Head Global R&D, Regulatory Policy & Advocacy, Novo Nordisk. "These discussions build shared understanding and generate practical solutions that organizations can apply to strengthen development strategies and deliver best-in-class combination products that meet patients' needs."

This year's educational program consisted of more than 60 speakers and moderators across 13 sessions, including a representative from the Austrian Agency for Health and Food Safety (AGES MEA), a representative from the European Commission, and 14 leaders from the FDA. Some of the speaker highlights included:

- **ChiaYee Ang,** Global Regulatory Affairs, Delivery Device & Digital Health Advisor, Lilly
- **Jara Benke,** Senior Product Specialist, TUV SUD (Virtual)
- **Christelle Bouygues,** Senior Regulatory Affairs Officer, EMA (Virtual)
- **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
- **Jacqueline Corrigan-Curay,** Head of Global Regulatory Strategy, Pfizer
- **Carolyn Dorgan,** Vice President, Solution Engineering, Suttons Creek
- **Andrea Gray,** Biomedical Engineering Advisor, Center for Biologics Evaluation and Research (CBER), FDA
- **Steven Hertz,** Consumer Safety Officer, Center for Drug Evaluation and Research (CDER), FDA
- **Amanda Matthews,** Executive Director, Head of GRS Combination Products and Medical Devices, Pfizer

- **Karen Masley-Joseph,** Senior Advisor, Office of Medical Device and Radiological Health Inspectorate (OMDRHI), Medical Products Inspectorate (MPI), Office of Inspections and Investigations (OII), FDA
- **Shruti Mistry,** Assistant Director, Injection Devices Team, Center for Devices and Radiological Health (CDRH), FDA
- **Benedicte Nuyttens,** Head of Clinical Investigation Entity, Federal Agency for Medicines and Health Products (FAMHP / FAGG) (Virtual)
- **Hannah Rosenfeld,** Digital Health Policy Team Lead, Digital Health Center of Excellence, Center for Devices and Radiological Health (CDRH), FDA
- **Stephanie Shapley,** Associate Director for Policy, Office of Combination Products, FDA
- **Alan Stevens,** Global Head of Complex Devices and Drug Delivery Systems, RA CMC Devices, AbbVie, Inc.
- **Keisha Thomas**, Associate Director for Compliance & Quality, Office of Product Evaluation and Quality (OPEQ), 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, evolving European Union legislation, clinical investigations for combined use systems, global updates for drug delivery, final guidance on Prescription Drug Use-Related Software (PDURS), and more. In addition, attendees participated in an interactive Solutions Exchange to build a combination product model and discuss the development, quality, and regulatory strategies used to create the final design. The session enabled participants to share insights from real-world combination product experience, expand their professional network, and uncover new perspectives on early-stage development.

The event also featured a preconference workshop on Monday, November 16, entitled “Navigating Industry Trends: Hot Topics, Regulatory Best Practices, and Drug Delivery Strategies,” featuring expert presenters from FDA, EMA, Genetech/Roche, Sanofi, Johnson & Johnson, AstraZeneca, Eli Lilly, Novo Nordisk, and more. Monday also offered Combination Products Summit event attendees the opportunity to meet with FDA officials face-to-face during office hours to ask questions, discuss challenges, and exchange perspectives.

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 2027 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 and Combination Products Summit — 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