

## Media Release



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## Registration Open for Combination Products Summit 2023

York, Pa. August 17, 2023 -- The AFDO/RAPS Healthcare Products Collaborative announced today that registration is open for the Combination Products Summit 2023, taking place November 28-30 at the Omni Fort Worth Hotel.

Regulatory authorities, industry experts, and professionals across the combination products spectrum will convene to tackle the industry's most pressing issues. Attendees will engage in collaborative sessions, hands-on workshops, and purpose-driven discussions aimed at overcoming hurdles and implementing solutions to advance patient care.

Combination Products Summit 2023 is 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.

"We're thrilled to bring this community back together again in Fort Worth to drive meaningful progress," said Timothy Hsu, Chief Collaboration Officer, AFDO/RAPS Healthcare Products Collaborative. "The Combination Products Summit facilitates the open dialogue and cooperation needed to navigate ongoing challenges and seize new opportunities in this dynamic industry."

**The agenda** features interactive sessions, including From the Desk of the Office of Combination Products: Strategic Priorities & Action; Global Harmonization Opportunities In Combination Products; Next-Generation Combination Products; Building Clarity to Address Regulatory Challenges of On-Body Delivery, and more.

The Summit also includes a full-day three-part pre-conference workshop, as well as meals and many opportunities for networking. Registrants can also sign up for FDA Office Hours, a dedicated time to meet with FDA representatives, on a first-come, first-served basis.

A Strategic Committee of industry experts guides the program development. The Strategic Committee includes:

- Tine Albeck, Senior QA – Global Quality Devices, ALK A/S
- Khaudeja Bano, Vice President, Combination Product Quality, Amgen
- James Bertram, Director, Office of Combination Products, FDA- OCP
- Francis Blacha, Global Quality Leader – Drug Delivery System Development, Eli Lilly
- Sandra Boyd, Independent Consultant
- Fran DeGrazio, President, Kymanox
- Ryan Hoshi, Director, Regulatory Policy and Intelligence, AbbVie
- Timothy Hsu, Chief Collaboration Officer, AFDO/RAPS Healthcare Products Collaborative
- Ryan McGowan, Director, Digital Devices and Combination Products, AstraZeneca
- Hemal Mehta, Associate Director, Global CMC-Regulatory Affairs, Medical Devices and Combination Products, Janssen Research & Development
- Susan Neadle, Principal Consultant & President, Combination Products Consulting, LLC
- Thinh Nguyen, Director, Office of Clinical Policy and Programs, FDA- OCP
- Jason Lipman, Senior Director, Global Regulatory Affairs, Device and Combination Products, Sanofi
- David Shore, Senior Quality Director, Indy Device Manufacturing, Eli Lilly
- Chin-Wei Soo, Global Regulatory Head, Combination Products, Devices, Genentech, a member of the Roche Group
- Bradley Thompson, Counsel, Epstein Becker Green
- James Wabby, Global Head – Emerging Technologies, Combination Products, and Devices, AbbVie
- John “Barr” Weiner, Associate Director for Policy, Office of Combination Products, FDA- OCP
- Rich Wolf, Global Head of PV Operations, Global Clinical Safety & Pharmacovigilance (GCSP), CSL Behring
- Jiaying Shen, Distinguished Scientist, Medical Device and Combination Product Development, Regulatory and Quality, Merck
- Rumi Young, Director, Regulatory Policy, BD

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**About the AFDO/RAPS Healthcare Products Collaborative** [www.healthcareproducts.org](http://www.healthcareproducts.org)

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.