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More than 300 Global Regulators and Industry Partners Gather in Columbus for MedCon 2023

April 27, 2023 (Columbus, Ohio) For the first time since 2019, MedCon reunited in-person April 24-27 in Columbus, Ohio for three days of purpose-driven discussions that harmonize different perspectives to inspire collaboration, lead innovation, and make a difference in 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.

“It was so wonderful to come together in-person again to continue the important work and conversations that MedCon has sparked for the past 15 years,” said Gina Brackett, Division 1/East Director, Compliance Branch, Office of Medical Device and Radiological Health Operations (OMDRHO), Office of Regulatory Affairs (ORA), FDA and MedCon 2023 Strategic Committee Co-Chair.

The event welcomed more than 300 attendees from 14 countries across five continents, including 42 FDA participants. This year’s educational program consisted of 50 speakers and 15 moderators—including more than 30 FDA experts—for 26 sessions and 4 tracks focused on trends, issues and collaborations to improve patient care. Some of the speaker highlights included:

- Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH), FDA
- Elizabeth Miller, Assistant Commissioner for Medical Products and Tobacco Operations, FDA-ORA
- Monica Wilkins, Vice President Regulatory and Quality, Abbott
- Sabina Hoekstra-van den Bosch, Global Director Regulatory Strategy, TÜV SÜD Medical Health Services
- Kim Trautman, Managing Director and Vice President, MEDicept Inc.
- Keisha Thomas, Associate Director for Compliance and Quality, CDRH, FDA
- Douglas Kelly, Deputy Center Director for Science Office of the Center Director, CDRH, FDA
- Phil Pontikos, National Expert, OMDRHO – ORA, FDA (Invited)
- Heather Rosencrans, Executive Vice President, Medical Devices & Combination Products, Greenleaf Health and Vice President Regulatory Affairs, MDMA



The program was curated by the MedCon Strategic Committee with key content themes centered on the new EPA EtO rules and the FDA Radiation Sterilization Master File Pilot Program, the recall process from initiation to termination, MDUFA/TAP, investigation trends, and cybersecurity risks. In addition, attendees participated in an interactive Solutions Exchange that explored innovation by design, cybersecurity/digital health and global market strategies.

The event also featured a preconference workshop on Risk Management: Practical Applications of Risk Management Throughout the Device Life Cycle with expert insights from executives at Agilis Consulting Group, KTA Compliance Consulting, MEDIcept, Inc. and STERIS.

“No other event unites global regulators and industry experts for open, candid conversations on the most critical issues like MedCon,” said Timothy Hsu, Chief Collaboration Officer, AFDO/RAPS Healthcare Products Collaborative. “The event is designed to dive below the surface, challenge the status quo, engage attendees in collaborative dialogue, and provide practical information that can be implemented.”

MedCon is the premier medical device conference driving the speed of innovation in a community focused on patient outcomes. Next year’s gathering will tentatively be held April 23-26, 2024. Sign up for information and updates on MedCon 2024 by visiting www.healthcareproducts.org/medcon.

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.

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