



MEDICAL DEVICE REGULATIONS CONFERENCE



November 15, 16 & 17*, 2022
 University of Georgia Center for Continuing Education
 Masters Hall
 1197 South Lumpkin Street
 Athens, GA 30602

Day 1 Agenda: November 15, 2022 Moderated by: Anna Fallon		
7:30 – 8:30 AM	Registration/Check-In	Conference Registration Desk
8:30 – 9:00 AM	Welcome and Conference Overview	Dean Kelly Smith, UGA
Opening Plenary Session		
9:00 – 9:30 AM	FDA CDRH Update	Michael Ryan, FDA
9:30 – 10:00 AM	FDA ORA Update	Anne Reid, FDA
10:00 – 10:15 AM	Morning Refreshment Break	Pecan Tree Galleria
Medical Device Innovation		
10:15 – 10:45 AM	AI/Machine learning	Yarmela Pavlovic & Cassie Scherer, Medtronic
10:45 – 11:15 AM	Cybersecurity-compliance; challenges of developing product that is compliant and secure. Design considerations	Linda Westfall, The Westfall Team
11:15 – 11:45 AM	The Line Between Medical Device Recalls and Enhancements	Meredith Address, FDA
11:45 – 12:45 PM	Lunch Break	Magnolia Ballroom
12:45 – 1:15 PM	Medical Device Software: Rules for handling Patient Data in the EU and US	Frances Cohen, Promenade Software
1:15 – 1:45 PM	Wearables	Anindita Saha, FDA
1:45 – 2:15 PM	Impact of 3D Printed Patient-Specific Surgical Rehearsal Models on Patient Outcomes	Smriti Zaneveld, Lazarus3D
2:15 – 2:45 PM	Innovating the Human Body: Allograft Tissue-based Medical Devices	Melissa O'Connor, StimLabs
2:45 – 3:00 PM	Afternoon Refreshment Break	Pecan Tree Galleria



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International Updates		
3:00 – 3:30 PM	Transitioning into MDR and IVDR	Alireza Hemmati, TÜV SÜD
3:30 – 4:00 PM	China talk – privacy for digital devices/software	Qianqian Zhu, Immucor
4:00 – 4:45 PM	Global Pre-Market Medical Device Regulatory Strategy for ASEAN, Australia	Jenny Lin, PharmaLex Pty Ltd
4:45 – 5:00 PM	Wrap-up	Al Jacks, Axogen and UGA
6:00 – 7:30 PM	Reception	Pecan Tree Galleria

Day 2 Agenda: November 16, 2022
 Moderated by: **Anna Fallon**

7:30 – 8:30 AM	Breakfast	Pecan Tree Galleria
8:30 – 8:45 AM	Welcome and Day 2 Overview	Michael Bartlett, UGA

Compliance and Post-market Activities

8:45 – 9:15 AM	Understanding and Managing Global UDI Compliance	Jay Crowley, Medical Device Solutions and Services
9:15 – 9:45 AM	Remote Regulatory Assessment	Brittani Franklin, FDA
9:45 – 10:15 AM	13485 harmonization with QSR (QMSR)	Karen Masley-Joseph, FDA
10:15 – 10:30 AM	Morning Refreshment Break	Pecan Tree Galleria
10:30 – 11:00 AM	Transition from EUA to 510(K) or De novo for IVD diagnostics	Toby Lowe, FDA
11:00 – 11:30 AM	Introduction to the Breakthrough Devices & Safer Technologies Programs	Ouided Rouabhi, FDA



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11:30 – 12:00 PM	Current Compliance Trends in Office of Medical Device and Radiological Health Operations	Salvatore Randazzo, FDA
12:00 – 1:00 PM	Lunch Break	Magnolia Ballroom
1:00 – 1:45 PM	Integrating ongoing post-market surveillance data (internal/external) into risk management for product life cycle	Kim Trautman, MEDIcept Inc.
1:45 – 2:45 PM	Panel Discussion	All Speakers
2:45 – 3:00 PM	Closing Remarks	Grace Gowda, UGA

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Day 3 Agenda – Workshop* November 17, 2022 Total Product Life Cycle Management for Medical Devices Containing Software Moderated by: Anna Fallon		
7:30 – 8:30 AM	Breakfast	Pecan Tree Galleria
8:30 – 8:45 AM	Welcome and Day 3 Overview	Seppe de Galas, UGA
8:45 – 9:15 AM	Overview – Total Product Lifecycle (TPLC)	Philippe Etter, Medidee
9:15 – 9:45 AM	Design and Development	Chris Rolfes, GCMi
9:45 – 10:15 AM	Device Classification and Submission Management	Andy Meadows, Meadows Design
10:15 – 10:30 AM	Morning Refreshment Break	Pecan Tree Galleria
10:30 – 11:15 AM	Glucose Meter/Insulin Pump Case Study	Seppe de Gelas, UGA
Start at 11:15 AM	Breakout New Device – App to monitor food (patient enters food intake) that can interact with glucose meter and insulin pump to modify insulin delivery	Anna Fallon, Renovo Biomedical and UGA
11:30 – 12:30 PM	Lunch Break	Magnolia Ballroom
End at 1:15 PM	Breakout (contd.) Classify and Create Mock Submission for New Device	Anna Fallon, Renovo Biomedical and UGA
1:15 – 1:45 PM	Changes to Devices by Classification (Addresses classification of recalls)	Nick Walker, FDA
1:45 – 2:15 PM	Data collection and storage – cybersecurity	Linda Ricci, FDA
2:15 – 2:45 PM	Post-market surveillance/maintenance of software-based devices	Alex Smith, Hogan Lowells
2:45 – 3:00 PM	Closing Remarks – Anna Fallon, Renovo Biomedical and UGA	

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