MEDICAL DEVICE REGULATIONS CONFERENCE

UNIVERSITY OF GEORGIA

FDA

November 15, 16 & 17*, 2022

University of Georgia Center for Continuing Education

Conference: Room K – Workshop: Room T&U

1197 South Lumpkin Street

Athens, GA 30602

Conference Day 1 Agenda: November 15, 2022 - Room K **Moderated by: Grace Gowda & 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 J. Ryan, FDA**
9:30 – 10:00 AM	FDA ORA Update	**Blake Bevill, FDA**
10:00 – 10:15 AM	**Morning Refreshment Break**	**Kellogg Concourse**
Medical Device Innovation		
10:15 – 10:45 AM	Medical Device Software: Rules for handling Patient Data in the EU and US	**Frances Cohen, Promenade Software**
10:45 – 11:15 AM	Cybersecurity by Design	**Linda Westfall, The Westfall Team**
11:15 – 11:45 AM	The Line Between Medical Device Recalls and Enhancements	**Meredith Andress, FDA**
11:45 – 12:45 PM	**Lunch Break**	**Magnolia Ballroom**
12:45 – 1:15 PM	AI/Machine learning	**Yarmela Pavlovic & Cassie Scherer, Medtronic**
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**	**Kellogg Concourse**
International Updates		

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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**

Conference Day 2 Agenda: November 16, 2022 - Room K Moderated by: Seppe de Galas		
7:30 – 8:30 AM	**Breakfast**	**Magnolia Ballroom**
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	Understanding Remote Regulatory Assessment (RRA) for Medical Device Facilities	**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**	**Kellogg Concourse**
10:30 – 11:00 AM	Transition from EUA to Marketing Authorization for COVID-19 In Vitro Diagnostics	**Toby Lowe, FDA**
11:00 – 11:30 AM	Introduction to the Breakthrough Devices & Safer Technologies Programs	**Ouided Rouabhi, FDA**
11:30 – 12:00 PM	Current Compliance Trends in FDA's Office of Medical Device and Radiological Health Operations (OMDRHO)	**Salvatore Randazzo, FDA**

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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** **Moderated by: Grace Gowda**	**All Speakers**
2:45 – 3:00 PM	**Closing Remarks**	**Grace Gowda, UGA**

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Workshop Day 3 Agenda: November 17, 2022 - Room T&U Total Product Life Cycle Management for Medical Devices Containing Software Moderated by: Anna Fallon		
7:30 – 8:30 AM	**Breakfast**	**Magnolia Ballroom**
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**	**Kellogg Concourse**
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	**Overview of Medical Device Cybersecurity**	**Linda Ricci, FDA**
2:15 – 2:45 PM	**Algorithm Change Protocols and Predetermined Change Control Plans submitted to FDA for Software as a Medical Device (SaMD) products**	**Alex Smith, Hogan Lowells**
2:45 – 3:00 PM	**Closing Remarks – Anna Fallon, Renovo Biomedical and UGA**	

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