MEDICAL DEVICE REGULATIONS CONFERENCE

UNIVERSITY OF GEORGIA

FDA

November 15 – 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	Digital Devices/Software as Medical Device/Software in a Medical Device – what constitutes change to a device for software? Difference between a recall and an enhancement.	**FDA - Invited**
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	**FDA (CDRH) Speaker - Invited**
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**

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2:45 – 3:00 PM	**Afternoon Refreshment Break**	**Pecan Tree Galleria**
International Updates		
3:00 – 3:30 PM	Transitioning into MDR and IVDR	**Notified body - Invited**
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	**FDA – Invited**
11:00 – 11:30 AM	Breakthrough Designations/Step Program	**FDA – Invited**

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11:30 – 12:00 PM	Warning letter trends/enforcement action trends	**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**	**Industry Speaker – Invited**
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)**	**FDA (CDRH) - Invited**
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**	**Industry Speaker – TBD**
2:45 – 3:00 PM	**Closing Remarks – Anna Fallon, Renovo Biomedical and UGA**	

*Solely sponsored by UGA