UNIVERSITY OF GEORGIA

MEDICAL DEVICE REGULATIONS CONFERENCE

FDA

November 15-17, 2022 **Georgia Center, 1197 South Lumpkin Street**

Medi

Day 1 Agenda: November 15, 2022 Moderated by: TBD		
8:30 - 9:00 AM	**Welcome and Conference Overview**	**Dean Kelly Smith, UGA**
Opening Plenary Session		
9:00 - 9:30 AM	FDA CDRH Update	**FDA – Dr. Shuren (invited)**
9:30 - 10:00 AM	FDA ORA Update	**FDA - Anne Reid**
10:00 - 10:15 AM	**Morning Break**	
Medical Device Innovation		
10:15 - 10:45 AM	AI/Machine learning	**Industry Speaker – TBD**
10:45 - 11:15 AM	Cybersecurity-compliance; challenges of developing product that is compliant and secure. Design considerations	**Industry Speaker – TBD: Bakul Patel pending (Back up speaker Phill Fisk-invited)**
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 – TBD (ORA)**
11:45 - 12:45 PM	**Lunch Break**	
12:45 - 1:15 PM	Digital Devices/Software as Medical Device/Software in a Medical Device – Diagnostics – Patient Data – where does this data reside? Differences between EU and US approval	**Industry Speaker – Frances Cohen**
1:15 - 1:45 PM	Wearables	**FDA (CDRH) Speaker – Lt Steven Browning (invited)**
1:45 - 2:15 PM	3D Printing	**Industry Speaker – TBD**
2:15 - 2:45 PM	Tissue/Stem Cell – Combination product challenges	**Industry Speaker – Melissa O'Connor**

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2:45 – 3:00 PM	**Afternoon Break**	
International Updates		
3:00 - 3:30 PM **3:30 – 4:00 PM?**	Transitioning into MDR and IVDR	**TBD – Notified Bodies:** **TUV - Seppe / Phillipe** **BSI – Tony Rizzo**
3:30 - 4:00 PM	China talk – privacy for digital devices/software	**Industry Speaker – Qianqian Zhu**
4:00 - 4:45 PM	Regulatory of other countries o Indonesia o S. America o Australia Bringing products to market more quickly	**TBD**
4:45 - 5:00 PM	**Wrap-up**	**TBD**

Day 2 Agenda: November 16, 2022 **Moderated by: TBD**		
8:30 - 8:45 AM	**Welcome and Day 2 Overview**	**TBD**
Compliance and Post-market Activities		
8:45 - 9:15 AM	EU UDI / UDI in US; Future link to EUDAMED	**Melissa Michurski – Di vision 2 FDA (Invited)**
9:15 - 9:45 AM	Remote assessments/Inspection	**FDA (ORA) – Shari Shambaugh (Invited)** **(Trang Cox – back-up)**
9:45 - 10:15 AM	13485 harmonization with QSR (QMSR)	**FDA preferred (CDRH) – Karen Masley-Joseph (Invited)** **(Kim Trautman-back-up industry speaker)**
10:15 – 10:30 AM	**Morning Break**	
10:30 – 11:00 AM	Transition from EUA to 510(K) or De novo for IVD diagnostics	**FDA – Angela Krueger (Invited)**
11:00 – 11:30 AM	Breakthrough Designations/Step Program	**FDA (CDRH) – TBD (Invited)**

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		Industry Back-up John Doucet
11:30 – 12:00 PM	Warning letter trends/enforcement action trends (FDA Speaker)	**FDA (ORA) – Melissa Michurski (Invited)**
12:00 – 1:00 PM	**Lunch Break**	
1:00 – 1:45 PM	Integrating ongoing post-market surveillance data (internal/external) into risk management for product life cycle	**Industry Speaker – Kim Trautman**
1:45 - 2:45 PM	**Panel Discussion**	**All Speakers**
2:45 - 3:00 PM	**Closing Remarks**	**TBD**

Day 3 Agenda – Workshop* November 17, 2022 Total Product Life Cycle Management for Medical Devices Containing Software Moderated by: TBD		
9:00 - 9:30 AM	**Overview –** Total Product Lifecycle (TPLC)	**Industry – TBD**
9:30 - 9:45 AM	**Design and Development**	**Industry – Anna**
9:45 - 10:15 AM	**Device Classification and Submission Management**	**Industry – Anna**
10:15 - 10:30 AM	**Morning Break**	
10:30 - 11:30 AM	**Glucose Meter/Insulin Pump Case Study**	**Industry – Seppe**
11:30 - 12:00 PM	**New Device – Breakout** App to monitor food (patient enters food intake) that can interact with glucose meter and insulin pump to modify insulin delivery	**Industry – TBD (Maybe GA Tech?)**
12:00 - 12:45 PM	**Lunch Break**	
12:45 - 1:15 PM	**Classify and Create Mock Submission for New Device**	**Industry – TBD (Anna?)**
1:15 - 1:45 PM	**Changes to Devices by Classification**	**FDA - (CDRH) addresses classification of recalls)**
1:45 - 2:15 PM	**Data collection and storage – cybersecurity**	**FDA - TBD**

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2:15 - 2:45 PM	**Post-market surveillance/maintenance of software-based devices**	**Industry (Anna to reach out)**
2:45 - 3:00 PM	**Closing Remarks**	

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