UGA-FDA Medical Device Regulations Conference

November 28-29, 2023 (Conference)

University of Georgia Center for Continuing Education

1197 South Lumpkin Street

Athens, GA 30602

Conference Day 1 Agenda: November 28, 2023		
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	**FDA invited**
9:30 – 10:00 AM	FDA ORA Update - Current topics of interest and looking forward to FY24	**Blake Bevill**
10:00 – 10:30 AM	**Morning Refreshment Break**	
Pre-Market Medical Device		
10:30 – 11;00 AM	Translate research to development of devices	**Mark Prausnitz, Georgia Tech**
11:00 – 11:30 AM	Current regulatory agency expectation for testing	**Industry invited**
11:30 – 12:00 PM	Use of RWD data for supporting applications	**FDA invited**
12:00– 1:00 PM	**Lunch Break**	
1:00 – 1:30 PM	AI/Digital devices	**FDA invited**
1:30 – 2:00 PM	Breakthrough technology/ Step program	**John Doucet, MCRA**
2:00 – 2:30 PM	Software validation and mobile applications – Focus on cybersecurity risk	**FDA invited**
2:30 – 3:15 PM	EUA's and strategies for keeping the product in the market	**FDA invited**
3:15 – 3:30 PM	**Afternoon Refreshment Break**	
International Updates		
3:30 – 4:00 PM	MDR/IVDR rollout: A status update	**Johnathon Bis, BSI**

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4:00 – 4:30 PM	Exemption of clinical trials with RWD in China	**Qianqian Zhu, Intuitive Surgical**
4:30 – 5:00 PM	Recent Changes in Brazil, Mexico, and other countries in Latin America: Towards Global Regulatory Alignment	**Evangeline Loh, Emergo by UL**
5:00 PM	**Wrap-up**	**Anna Fallon, UGA**
6:00 – 7:30 PM	**Reception**	

Conference Day 2 Agenda: November 29, 2023		
7:30 – 8:30 AM	**Breakfast**	
8:30 – 8:45 AM	**Welcome and Day 2 Overview**	**Michael Bartlett, UGA**
Post-market Activities		
8:45 – 9:15 AM	Investigator Insights from Inspections and Strategies for Managing Inspections	**FDA invited**
9:15 – 9:45 AM	Citizen petitions and Court decisions or Two way communication with the agency and the role of the Ombudsman in facilitating the process	**TBD** Request has to be submitted
9:45 – 10:15 AM	Strategies and best practices for communicating recalls w/ FDA	**FDA invited**
10:15 – 10:30 AM	**Morning Refreshment Break**	
10:30 – 11:00 AM	Risk Management - FDA Transition to ISO 13485	**Kimberly Trautman, Medicept**
11:00 – 11:30 AM	CDRH Portal and ESTAR Program for Streamlining submissions	**FDA invited**
11:30 – 12:00 PM	Supplier Controls and strategies for sustainability in Post-Pandemic world	**FDA invited**
12:00 – 1:00 PM	**Lunch Break**	

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1:00 – 1:45 PM	Current compliance trends and Responding to Issues found by FDA	**FDA invited**
1:45 – 2:45 PM	**Open Forum- Panel Discussion**	**All speakers invited**
2:45 – 3:00 PM	**Closing Remarks**	**Grace Gowda, UGA**

*Workshop solely sponsored by UGA