



**MEDICAL DEVICE
REGULATIONS CONFERENCE**



September 21-23, 2021

Virtual

UGA Athens

Day 1 Agenda: September 21, 2021 Moderated by: Kavita Aulakh		
8:30-9:00 AM	Welcome/Conference Overview	Dean Kelly Smith, UGA
9:00-9:30 AM	FDA CDRH update	Jeff Shuren, FDA
9:30-10:00 AM	FDA ORA Update	Judy McMeekin, FDA
10:00-10:15 AM	Morning Break	
10:15-10:45 AM	Converting EUA's to De Novo's and 510(k)s – FDA perspective	Timothy Stenzel, FDA
10:45-11:15 PM	Converting EUA's to De Novo's and 510(k)s – Industry	Kim Walker
11:15-11:45 PM	EUA's Lessons learned from the Pandemic	TBD, FDA speaker
11:45-12:45 PM	Lunch Break	
12:45-1:15 PM	Remote Regulatory Assessment	Trang Cox, FDA
1:15-1:45 PM	Uncovering and Maximizing the Value of FDA Inspection	Lt. Colin Tack, FDA
1:45 – 2:15 PM	MQSR: FDA harmonizing with ISO or MDSAP Implementation	Kim Trautman
2:15-2:30 PM	Afternoon Break	
2:30 – 3:00 PM	China's Revised Regulations on Medical Devices and IVD: implications for Industry	QianQian Zhu, Immucor
3:00-3:30 PM	Whirlwind of Change: How New Standards, MDR, and Brexit are Impacting Biocompatibility	Thor Rollins, Nelson Labs
3:30-4:00 PM	Notified bodies update	Anthony Rizzo, BSI
4:00-4:30 PM	Impact of Pandemic on Imports/Exports	Dan Solis (LA) FDA
4:30-4:45 PM	Wrap-up	AI jacks



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Day 2 Agenda: September 22, 2021 Moderated by: Kavita Aulakh		
8:30-8:45 AM	Welcome and Day 2 Overview	Michael Bartlett, UGA
8:45-9:15 AM	Life-Cycle Approach for Breakthrough Designation FDA vs. Industry?	John Doucet
9:15-9:45 AM	3D Printing (Pre and post challenges)	Nelson labs & Namsa
9:45-10:15 AM	Digital/AI medical devices or Software as medical device	Bakul Patel, FDA
10:15-10:30 AM	Morning Break	
10:30--11:00 AM	Transforming Tissue into Treatment: An Overview and Update of Human Tissue Product Regulation	Melissa O'Connor, Stimlabs
11:00-11:30 AM	Tissue based devices: Wound Care – Device vs. Transplant	James Bertram or Andrew Yeatts, FDA
11:30-12:00 PM	FDA recruitment talk	Kathleen Sinninger, FDA
12:00-12:30 PM	Lunch Break	
12:30-1:45 AM	Panel Discussion – All Speakers	JoAnn Pittman
1:45 AM-2:00 PM	Closing Remarks	Sepe de Gelas, UGA