



**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 and Conference Overview	Dean Kelly Smith, UGA
Opening Plenary Session		
9:00 - 9:30 AM	FDA CDRH Update	Jeffrey Shuren, FDA
9:30 - 10:00 AM	FDA ORA Update	Judith McMeekin, FDA
10:00 - 10:15 AM	Morning Break	
Emergency Use Authorizations		
10:15 - 10:45 AM	Transitioning from EUAs to Traditional Submission Pathways – FDA Perspective	Angela Krueger, FDA
10:45 - 11:15 AM	An Industry Perspective on Converting EUA's to De Novo's and 510(k)'s	Kim Walker, Global Regulatory, Quality & Clinical Consultant
11:15 - 11:45 AM	OPEQ COVID Lessons Learned	Michael Hoffmann, FDA
11:45 - 12:45 PM	Lunch Break	
Compliance		
12:45 - 1:15 PM	Remote Regulatory Assessment	Trang Cox, FDA
1:15 - 1:45 PM	Uncovering and Maximizing the Value of FDA Inspections	Lt. Colin Tack, FDA
1:45 - 2:15 PM	FDA Harmonizing with ISO or MDSAP Implementation	Kim Trautman, Medical Device, IVD and Combination Product Regulatory & Quality Expert
2:15 - 2:30 PM	Afternoon Break	



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International Updates		
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 Notified Body Update – BSI's Tales from the Trenches	Anthony Rizzo, BSI
4:00 - 4:30 PM	Impact of Pandemic on Imports/Exports	Dan Solis, FDA
4:30 - 4:45 PM	Wrap-up	AI Jacks, UGA

Day 2 Agenda: September 22, 2021 Moderated by: Kavita Aulakh		
8:30 - 8:45 AM	Welcome and Day 2 Overview	Michael Bartlett, UGA
Medical Device Innovation		
8:45 - 9:15 AM	The Breakthrough Device Program – Key Considerations and Lessons Learned	John Doucet, MCRA
9:15 - 9:45 AM	Bringing Additive Manufactured Medical Devices to Market: Challenges Faced by Industry	Ayishwariya Menon, Medical Device & Healthcare Consultant
9:45 - 10:15 AM	Digital Health, AI Medical Devices and Software as Medical Device: A Regulatory Update	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	Wound Care Product Landscape: From Human Tissue to Honey	James Bertram, FDA
11:30 - 12:00 PM	FDA Recruitment Talk	Kathleen Sinniger, FDA



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12:00 - 12:30 PM	Lunch Break	
12:30 - 1:45 PM	Panel Discussion	All Speakers
1:45 - 2:00 PM	Closing Remarks	Seppe de Gelas, UGA