UNIVERSITY OF GEORGIA

MEDICAL DEVICE REGULATIONS CONFERENCE

FDA

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	**Anthony Rizzo, BSI**
4:00 - 4:30 PM	Impact of Pandemic on Imports/Exports	**Dan Solis, FDA**
4:30 - 4:45 PM	**Wrap-up**	**Al 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 Sinninger, 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**