

5th Annual ComplianceOnline
Medical Device
 Summit - 2020



Omni Parker House Hotel,
 60 School Street,
 Boston, MA, 02108, USA



April 16-17, 2020



02
 DAYS

20+
 SPEAKERS

25+
 KEY AREAS

MULTIPLE
 TRACKS

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2020 SUMMIT SPEAKERS



Darin S. Oppenheimer,
DRSc, FRAPS, RAC, PMP,
Executive Director, Regulatory
Devices & Digital Health Solutions,
Merck



Casper E Uldriks
Former Associate Center Director,
FDA's, CDRH



Haja Sittana El Mubarak
PhD, Former Master IVD Reviewer,
FDA



Archana Reddy
ExRegulatory Advisor/Public
Health Advocate, (FDA)



Oleg Kornienko
External Service & Operations
Quality Head, **Novartis Institutes
for BioMedical Research (NIBR)**



Rob MacCuspie, PhD
(Former NIST Researcher)
Industry Consultant, Advisor and
Scientific Director



Tony Rizzo
Assistant VP Healthcare
Development, **BSI**



Jyotsna Mehta
Founder, Keva Health (Ex-FDA)



Barry Peterson
Independent Consultant,
BTPeterson Consulting



Kwame Ulmer
Principal, **Ulmer Ventures**



Nathan McBride
Vice President, Global IT at
Orchard Therapeutics



Zoe Braiterman
Consultant at **GYMedical Device
Consulting, LLC**



Charlie Schick
Business Development, Healthcare
and Life Sciences, **Owl Cyber
Defense**

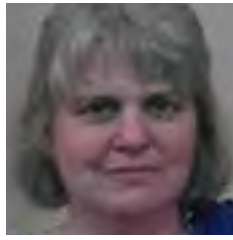
Past Speakers from FDA, FBI and FDA Information Repository (IRAI)



SSA Steven T. Scivolino
 Mission Critical Engagement Unit,
 Cyber Division, FBI



Adam Saltman, MD PhD
 Medical Officer, CDRH/Office of
 Compliance



Ann Ferriter
 Director, Division of Analysis and
 Program Operations, CDRH/OC,
 FDA



Marisa White
 Lead Consumer Safety Officer,
 Division of Bioresearch Monitoring,
 Office of Compliance, CDRH



Bakul Patel
 Associate Director for Digital
 Health, FDA



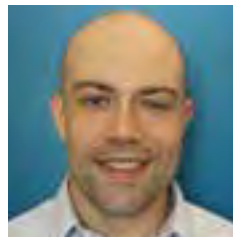
Robin Newman
 Director, Office of Compliance,
 Center for Devices and
 Radiological Health, FDA



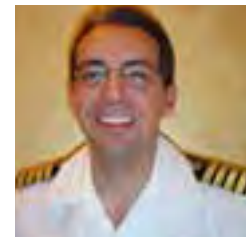
Ronny Brown
 Branch Chief for Medical Device
 Recalls, FDA



Daniel L. Aisen
 Quality Assurance, Regulatory
 Compliance, Proven Leadership,
 Former FDA Field Investigator and
 Former Public Health Inspector
 Naval Chief Hospital



Seth D. Carmody, Ph.D
 Cybersecurity Project Manager,
 CDRH



James Saviola
 Deputy Director of Regulatory
 Affairs (Acting), and Director,
 Division of Biomedical Research,
 Office of Compliance, CDRH



Erin Keith
 Director, Division of
 Anesthesiology, General Hospital,
 Respiratory, Infection Control and
 Dental Devices, CDRH, FDA



Cisco Vicenty
 Acting-Branch Chief, Office of
 Compliance, CDRH/FDA



Stephen Allan Weitzman
 Editor in Chief, FDA Information
 Repository, IRAI



Casper E Uldriks
 Former Associate Center Director,
 FDA, CDRH



Rita Hoffman
 RAC, Managing Partner, Regs &
 Recall Strategies, Former Branch
 Chief, Recalls, CDRH, FDA



**Neil Mafnas, LCDR, USPHS,
 M.S.**
 Assistant Regulator, CDRH/FDA



**Anupama V. Govindarajan,
 Ph.D.**
 Medical Device Recall Branch
 Chief, FDA



Bill MacFarland
 Supervisory Biomedical Engineer,
 FDA



Larry Stevens
 Principal Consultant (Ex FDA),
 One Way Consultants, LLC, FDA
 Regulatory Experts

PAST SUMMIT SPEAKERS

Marisa White
 Lead Consumer Safety Officer,
 Division of Bioresearch
 Monitoring, Office of Compliance,
 CDRH

Robin Newman
 Director, Office of Compliance,
 Center for Devices and
 Radiological Health, FDA

Seth D. Carmody, Ph.D
 Cybersecurity Project Manager,
 CDRH

Bakul Patel
 Associate Center Director for
 Digital Health, FDA

Chrissy Cochran
 Acting Director,
 Division of Enforcement and
 Postmarketing Safety, FDA

Bill MacFarland
 Director, Division of Enforcement
 B, Office of Compliance,
 FDA/CDRH

Erin Keith
 Director, Division of
 Anesthesiology, General Hospital

Cisco Vicenty
 Acting-Branch Chief, Office of
 Compliance, CDRH/FDA

Neil Mafnas, LCDR, USPHS
 Assistant Regulator, CDRH/FDA

Ann Ferriter
 Director, Division of Analysis and
 Program Operations, CDRH/OC,
 FDA

James Saviola
 Deputy Director of Regulatory
 Affairs (Acting), and Director

Rick Williams
 Partner, Newport Board Group
 New England Practice, Chairman
 of Point Care Technology, Board
 member of Amorphex
 Therapeutics

French Caldwell
 Chief Evangelist, MetricStream

Michael Weickert
 Strategic & Entrepreneurial
 Executive, Trail-blazing
 Leadership in Biotech, Medical
 Device & Pharmaceutical
 Business

Minda Wilson
 Founder, Affordable Healthcare
 Review

Fletcher Wilson
 CEO and Founder, InterVene Inc

David Nettleton
 Industry Leader, Author, and
 Teacher for 21 CFR Part 11, Annex
 11, HIPAA, Software Validation,
 and Computer System Validation

Geetha Rao
 CEO, Springborne Lifesciences

Andrew Pfeifer
 Account Executive, REED TECH

Angela Bazigos
 CEO, Touch Stone Technologies
 Silicon Valley

Darin Oppenheimer
 Regulatory Affairs Expert, Global
 Medical Device Regulations &
 Licensure Authority, Strategic &
 Engaging Leader, Baxter
 Healthcare Corporation

Dr. Ron Weissman
 Chairman, Software SIG, Band of
 Angels

Terri Jollymour
 Sr. Director, Operations Readiness
 & Convergence Johnson &
 Johnson Corporate Supply Chain
 Quality & Compliance

Haley Lentz
 GUDID Submission Subject Matter
 Expert, Reed Tech

Mitch Levinson
 Founder, President & CEO,
 Cerebrotech Medical Systems

Mark Mitchell
 SVP Corporate Development,
 MetricStream &
 Business Head ComplianceOnline

Kevin Fleming
 National Healthcare Managing
 Director, Newport Board Group

Peter Pitts
 Chief Regulatory Officer, Adherent
 Health, LLC.

Daphne Walmer
 Thought leader/Expert/Consultant
 in Medical Device Labeling and
 Technical Communications

Rohit Bedi
 Senior Vice President & Executive
 Leadership, MetricStream

Stan Mastrangelo
 Professor, Center for Applied
 Health Sciences, Virginia Tech
 University

Patrick Rousche
 Co-Founder and Chief Scientific
 Officer, Hemotek Medical, Inc

Brian Shoemaker, Ph.D.
 Principal Consultant, ShoeBar
 Associates

Keith Morel, Ph.D.
 VP, Regulatory Compliance,
 Qserve Group US Inc.

Virginia A. Lang, Ph.D.
 President & Chief Scientist,
 HirLan, Inc.

Eduardo Cervantes
 President & CEO, Morf Media Inc

Tom Loker
 Businessman | Author | Speaker,
 Startup Consultant and Advisor
 SYDK.ORG, Contributor to
 California Political Review

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DAY 01 - APRIL 16, 2020

Note: This program may be subject to alterations and additions

🕒 08:00 - 08:30 am	Registrations and Networking Breakfast
🕒 08:30 - 08:45 am	Welcome Speech with an Introduction of ComplianceOnline & Summit
🕒 08:45 - 09:10 am	FDA Enforcement – Outlook & Implications - Keynote (FDA Invited (ORA))
🕒 09:15 - 09:45 am	CDRH Office of Compliance Strategic Priorities and Hot Topics in Compliance - Keynote (FDA Invited (ORA))
🕒 09:45 - 10:35 am	Medical Device Quality Challenges and Risk Management (ISO 13485 and ISO 14971) - Panel Discussion Darin S. Oppenheimer, DRSc, FRAPS, RAC, PMP, Executive Director, Regulatory Devices & Digital Health Solutions, Merck
🕒 10:35 - 10:45 AM	Networking Break
🕒 10:45 - 11:20 AM	Regulations in the U.S. and Globally (GDPR, Brexit, US-China Relationship)
🕒 11:25 - 12:00 PM	Artificial Intelligence in Medical Device - Keynote (FDA Invited (ORA))
🕒 12:00 - 1:00 PM	Lunch
🕒 1:00 - 1:35 PM	FDA Communication Power Tools Kwame Ulmer, Principal, Ulmer Ventures (Ex-FDA) The US Food and Drug Administration offers a range of mechanisms to communicate with premarket review staff. The timing of communication and best practices to ensure both parties understand each other's messages is not well understood. Manufacturers regularly under-estimate the time and preparation required for effective communications for premarket applications and postmarket communications. Kwame Ulmer will highlight effective communication with FDA in a comprehensive manner to include the power tools that can be used immediately when seeking clearance, approval and effective compliance remediation.
🕒 1:40 - 2:30 PM	Cybersecurity, Machine Learning and IoT/IIoT Zoe Braiterman, Consultant at GYMedical Device Consulting, LLC
🕒 2:30 - 2:45 PM	Networking Break
	TRACK A - SESSIONS
🕒 2:45 - 3:15 PM	3D Printing
	TRACK B - SESSIONS
	MDR, IVDR Tony Rizzo, Assistant VP Healthcare Development, BSI
🕒 3:25 - 3:50 PM	Wearable Device Barry Peterson, Independent Consultant, BTPeterson Consulting
🕒 4:00 - 4:40 PM	FDA Electronic Submission Process - Keynote (FDA Invited (ORA))
🕒 4:40 - 4:50 PM	Closing Mark - Next Day Plan

Note: This program may be subject to alterations and additions

DAY 02 - APRIL 17, 2020

Note: This program may be subject to alterations and additions

8:00 - 8:30 AM	Registration and Networking Breakfast
8:30 - 9:00 AM	<p>NanoEHS Risk Assessment Lessons for Medical Devices - Keynote Speech <i>Rob MacCuspie, PhD</i>, Industry Consultant, Advisor and Scientific Director, (Former NIST Researcher)</p> <p>Assessing the nanoEHS risks of nanomaterials can be facilitated by a tiered-approach framework, which can be extended to assessing risks of other new technologies being responsibly commercialized. Example risk mitigation strategies will also be identified, including in context of product development and occupational settings.</p> <p>This session will provide the following insights:</p> <ul style="list-style-type: none"> ▶ Learn the key elements of a tiered-approach framework for nanoEHS risk assessment ▶ Identify example nanoEHS risk mitigation strategies ▶ Applying nanoEHS lessons learned to the context of medical devices
9:05 - 9:35 AM	REACH and RoHS and Environmental Compliance in FDA Regulated Industries
9:40 - 10:20 AM	Medical Device Marketing and Advertisement, Social Media
10:20 - 10:35 AM	Networking Break
10:35 - 11:10 AM	<p>Emerging Technologies of the Digital Health - Panel Discussion <i>Jyotsna Mehta and Team</i>, Founder, Keva Health (Ex-FDA)</p>
11:15 - 11:40 AM	<p>Medical Device Enhancements - Keynote (FDA Invited (CDRH))</p>
11:45 - 12:15 PM	<p>FDA's New Import/Export Trauma in 2020 <i>Casper E. Uldriks</i>, Former Associate, Center Director of FDA's CDRH</p>
12:15 - 1:15 PM	Lunch
1:15 - 1:50 PM	Quality Challenges and Risk Management (ISO 13485 and ISO 14971) - Panel Discussion

TRACK A - SESSIONS

TRACK B - SESSIONS

1:50 - 2:20 PM	<p>Combination Products <i>Archana Reddy</i>, Former Regulatory Advisor/Public Health Advocate, FDA</p>	<p>Cyber Security <i>Charlie Schick</i>, Business Development, Healthcare and Life Sciences, Owl Cyber Defense</p>
2:20 - 2:50 PM	Technical Writing and Documentation	
2:50 - 3:00 PM	Networking Break	
3:00 - 3:30 PM	<p>Robotics and Artificial Intelligence (AI) <i>Nathan McBride</i>, Vice President, Global IT, Orchard Therapeutics</p>	
3:30 - 3:50 PM	<p>FDA Inspection - Keynote (FDA Invited (CDRH))</p>	
3:50 - 4:15 PM	<p>ISO 10993 and Biocompatibility - Workshop <i>Oleg Kornienko</i>, External Service & Operations Quality Head, Novartis Institutes for BioMedical Research (NIBR)</p>	
4:15 - 4:35 PM	Vote of Thanks & Participation Certificate Distribution	

Note: This program may be subject to alterations and additions

Registration Form

Registration Information:

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- » Get your group to attend the summit at a discounted price call +1-888-717-2436.
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Summit: 5th Annual ComplianceOnline Medical Device Summit 2020

Date & Location: Boston, MA | April 16-17, 2020

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Attendee 2 : Name	Email
Attendee 3 : Name	Email
Attendee 4 : Name	Email
Attendee 5 : Name	Email
Attendee 6 : Name	Email
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