ComplianceOnline Medical Device summit - 2020

5th Annual ComplianceOnline

Medical Device Summit - 2020

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

April 16-17, 2020

02	20+	25+	MULTIPLE
DAYS	SPEAKERS	KEY AREAS	TRACKS

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SPEAKERS

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**

Cont...

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

SSA Steven T. Sciavolino

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

Cont...

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 eader/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.

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FDA Regulatory Compliance Specialist, JAF Consulting Inc

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AGENDA

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	TRACK B - SESSIONS
2:45 - 3:15 PM	**3D Printing**	**MDR, IVDR** Tony Rizzo, Assistant VP Healthcare Development, **BSI**
3:25 - 3:50 PM	**Wearable Device** Barry Peterson, Independent Consultant, **BTPeterson Consulting**	**EU MDD, MDSAP**
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

AGENDA

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	**NanoEHS Risk Assessment Lessons for Medical Devices -** Keynote Speech Rob MacCuspie, PhD, Industry Consultant, Advisor and Scientific Director, **(Former NIST Researcher)** 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. This session will provide the following insights: ▸ 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	**Emerging Technologies of the Digital Health -** Panel Discussion Jyotsna Mehta and Team, Founder, Keva Health **(Ex-FDA)**
11:15 - 11:40 AM	**Medical Device Enhancements -** Keynote (FDA Invited (CDRH))
11:45 - 12:15 PM	**FDA's New Import/Export Trauma in 2020** Casper E. Uldriks, Former Associate, **Center Director of FDA's CDRH**
12:15 - 1:15 PM	Lunch
1:15 - 1:50 PM	**Quality Challanges and Risk Management (ISO 13485 and ISO 14971) -** Panel Discussion

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

Note: This program may be subject to alterations and additions

Registration Form

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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

Attendee 1 : Name .....Email .....

Attendee 2 : Name .....Email .....

Attendee 3 : Name .....Email .....

Attendee 4 : Name .....Email .....

Attendee 5 : Name .....Email .....

Attendee 6 : Name .....Email .....

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