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 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
Senior IVD consultant, **Biologics consulting Inc**

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

Coy Murchison
Chief Strategist, Berry Herring Hayes & Associates

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**

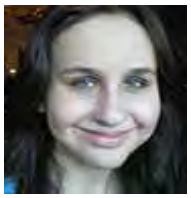
Jyotsna Mehta
Founder, Keva Health **(Ex-FDA)**

Royth v. Hahn
Global head of TUV SUD's Business Unit at **Medical and Health Services**

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

Kwame Ulmer
Principal, **Ulmer Ventures**

Nathan McBride
Vice President, Global IT at **Orchard Therapeutics**



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

Bill Enos
Senior Commercial Operations Director at **BSI Group**

Kelly Eisenhardt
Managing Director & Co-Founder, **BlueCircle Advisors LLC**

L. Stephan Vincze
President & CEO at **Trestle Compliance, LLC**

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.

Eduardo Cervantes
President & CEO, Morf Media Inc

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

Scott Phillips
President Starfish Medicals

Susan W. Neadle
Sr. Director, Janssen Pharmaceuticals

Gunjan Sinha
Executive Chairman, MetricStream

Julia Rasooly
CEO, Puracath

Joe Franchetti
FDA Regulatory Compliance Specialist, JAF Consulting Inc

Jon Speer
Founder and VP of QA/RA, greenlight.guru

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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 (CDRH)
09:45 - 10:15 AM	**Current Healthcare Eco System: Challenges & Opportunities -** Keynote Coy Murchison, Chief Strategist, **Berry Herring Hayes & Associates** Ensuring HIPAA security in today's health IT environment requires HDOs hit a daily trifecta of HIPAA compliance, cyber security, and medical device management to ensure the IT infrastructure and PHI is protected. The FDA's Guidance states there is a shared responsibility among health care facilities, health care providers, patients, and manufacturers. This collaboration of stakeholders demands a comprehensive security plan which must align key departments: (1) Cyber Security; (2) HIPAA Privacy and Security; and (3) HTM. Because IT departments understand the IT infrastructure, HIPAA privacy departments understand OCR rules and HTM understands the functionality of the device – repair and maintenance, there must be an understanding of whom manages specific threats to the IT network and the medical device. Learn the strategies to develop thorough strategies to lessen and alleviate OCR violations should a breach occurs: ▸ Incorporate functionality systems which detect cybersecurity events in devices, in a timely manner; ▸ Develop strategies to contain medical device intrusion; ▸ Contain the impact of a potential cybersecurity incident; ▸ Create contracts which lessen the risk of the health delivery organization; ▸ Learn strategies to ensure proper management of PHI captured within the medical devices.
10:15 - 10:35 AM	**Regulations in the U.S. and Globally (GDPR, Brexit, US-China Relationship)**
10:35 - 10:45 AM	Networking Break
10:45 - 11:20 AM	**GDPR 2020: The evolution of general data protection and the rights of individuals over their own data.** L. Stephan Vincze, President & CEO, **Trestle Compliance, LLC (Former Counsel, U. S. House of Representatives Committee)** Nearly two years after becoming effective, the EU General Data Protection Regulation (GDPR) has had significant effects on companies around the world. This interactive session will have a panel of experts discussing the following key issues: ▸ A quick review of key GDPR principles and requirements ▸ How has GDPR affected the rest of the world and the U.S.? ▸ Where are we/you today nearly 2 years after GDPR went live? ▸ Is it too late to become compliant? ▸ Key steps to become GDPR compliant now.
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**

Cont...

AGENDA

2:30 - 2:45 PM	Networking Break	
	TRACK A - SESSIONS	**TRACK B - SESSIONS**
2:45 - 3:15 PM	**3D Printing**	**MDR Implementation - Status, Next Steps and (revised) Timelines** Bill Enos, Senior Commercial Operations Director, Regulatory Services (Medical Devices) Americas, **BSI Group** ▸ How to prepare for May 26, 2020 for devices using the soft transition ▸ Art 120(3) ▸ Economic Operators ▸ PMS/Vigilance ▸ Market Surveillance ▸ NB audits under MDR ▸ EUDAMED status updat
3:25 - 3:50 PM	**Wearable Device**	**Software as a Medical Device - What to consider?** Royth v. Hahn, Global head of TUV SUD's Business Unit, **Medical and Health Services(MHS)** ▸ Software as a medical device under MDR ▸ Apps as medical devices ▸ Software as part of a medical device ▸ Classification under MDR ▸ App Stores in regards of economic operators: status of the discussion
4:00 - 4:40 PM	**FDA Electronic Submission Process -** Keynote FDA Invited	
4:40 - 4:50 PM	**Closing Mark - Next Day Plan**	

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	**Protecting Company Revenues with Product Compliance -** Keynote Kelly Eisenhardt, Managing Director & Co-Founder, **BlueCircle Advisors** Hazardous material and substance regulations continue to increase across the globe. Preventing lost sales from stop shipments, fines, and fees is crucial. Kelly Eisenhardt will discuss how understanding the web of compliance requirements for customers, governments, suppliers, and products is key to protecting your company's revenues. Learn the ten (10)steps to building better product compliance programs.
9:40 - 10:00 AM	**Medical Device Marketing and Advertisement, Social Media**
10:00 - 10:20 AM	**Effective Medical Device Premarket, Postmarket and Recalls -** Avoiding Costly Errors Haja Sittana El Mubarak, PhD, Former FDA Official, Senior IVD consultant, **Biologics consulting Inc** The vision of the FDA's Center of Devices and Radiological Health (CDRH) includes a commitment to that patients in the US have access to high-quality, safe and effective medical devices of public health importance first in the world. To this end CDRH selected strategic priorities and is implementing several advances in the pre and post market areas to; reduce the time and cost to the U.S. market, and support the devices throughout the product life cycle without compromising reasonable assurance of safety and effectiveness. This session will explore key advances and trends in the FDA's approaches to premarket, post market and Recalls in the medical devices area. The session will discuss premarket, post market and compliance processes with focus on the impact of the following: ▸ Changes in the IDE program, NEST, Parallel review program, Partnering with patients, customer service and quality management ▸ The total product life cycle approach. ▸ The Simplicity approach and Least burdensome approach. ▸ Collaborative communities
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	**Medical Device Outsourcing, Supply Chain Management and new Foreign Trade Problems for Import/ Export Business** Casper E. Uldriks, Former Associate, **Center Director of FDA's CDRH** Global markets create new and costly demands for a device import/export business. Firms must consider and update their short and long-term business plans to assure an effective positioning in the global market. New foreign regulatory requirements, effective quality assurance programs and evolving freight forwarding demands all require well planned in-house regulatory program to avoid expensive surprises and delays. For example, the European Union's (EU) new Medical Device Regulation (MDR) and cybersecurity programs are hot topics for FDA that should be considered as the impact your products.

Cont...

AGENDA

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**	**CHANGE CONTROL - Is Your Change Management System Effective?** Stephanie Harrell, CQA (Former US FDA Investigator) Quality and Compliance Consultant, Auditor and Trainer, **ProPharma Group** Controlling change in a quality system will require key tools and resources alike. In an ever evolving regulatory landscape it invites all involved participants to engage fully and embrace their part in the process. This session will provide the following insights: ▸ How to recognize when change controls are needed ▸ Who should be involved in the change control process ▸ What resources will be needed to effectively manage change controls ▸ Remaining current with change controls as part of cGMP's
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**	

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

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