ComplianceOnline Medical Device summit - 2018

4th Annual ComplianceOnline

Medical Device Summit - 2018

Omni San Francisco Hotel
500 California Street
San Francisco, CA 94104

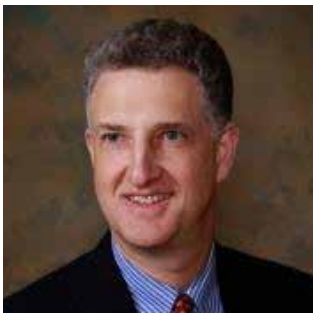
June 7-8, 2018

02	20+	25+	MULTIPLE
DAYS	SPEAKERS	KEY AREAS	TRACKS

SPEAKERS

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

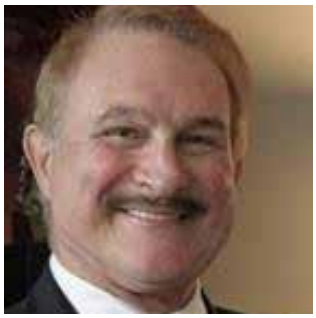
Robin Newman
Director, Office of Compliance, Center for Devices and Radiological Health, FDA



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

Ron Brown
Branch Chief for Medical Device Recalls, 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

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

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

Past Speakers

Pat Baird
Regulatory Head of Global Software Standards, Philips

Roy Wallen
President & CEO, Directional Healthcare Advisors, LLC

Peter Pitts
Chief Regulatory Officer, Adherent Health, LLC.

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

Roni Cohen
Director of the Microbiology & Chemistry Division, HYLabs

Nick Sikorski, CISSP
Senior Consultant, Deloitte Advisory

Stan Mastrangelo
Technical Committee Member of working group on ISO 31000, Center for Applied Health Sciences, Virginia Tech University

Steven Grossman
President, HPS Group, LLC

Virginia A. Lang, PhD
President & Chief Scientist, HirLan, Inc.

Scott Philips
President Starfish Medicals, StarFish Medicals

Cont...

SPEAKERS

Darin Oppenheimer
Director Regulatory, CMC & Combination Products, Merck.

James Edward Ledlum, Jr
Director Corporate Supplier Quality, Hologic, Inc

Nancy Knettell
Principal, Signet Medical Systems

Dan O'Leary
President at Ombu Enterprises, LLC

Nancy Van Schooenderwoert
President, and Managing Partner Development Practice at Lean-Agile PartnersMerck.

Christine Santagate, RAC
Director, Boston Operations

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

Platinum Sponsor

MetricStream

Event Exhibitor

TOXIKON ADVANCING YOUR INNOVATION

VERISAVE

Media Partners

Journal of Medical Device Regulation

TECHNOLOGY NETWORKS

PharmaVOICE

INDUSTRYARC

MM&M

CrowdReviews Buyers Guide Based On Client Reviews

AGENDA

DAY 01 - JUNE 7, 2018

Note: This program may be subject to alterations and additions

08:00 - 08:30 am	Registration and Breakfast
08:30 - 08:45 am	**Welcome Speech with an Introduction of ComplianceOnline & Summit**
08:45 - 09:10 am	**Adequate Directions for Use "in the Age of AI and Watson"**
09:10 - 09:40 am	**FDA Enforcement – Outlook & Implications** - Panel Discussion
09:40 - 10:20 am	**Benefit-Risk: Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions**
10:20 - 10:40 am	**Medical Devices under Trump Administration**
10:40 - 11:10 am	**Change Management - Managing the Cost of Change** It is said that the one Constant in life is Change. Whether it is new features, increased reliability, or cost savings, we are constantly asked to make changes to our products and our processes. However, change comes with a cost, and often this cost is either under-estimated or overshadowed by misperceptions by key stakeholders. **At this session you will learn how to:** ✔ Evaluate the cost of change, including both local and hidden costs ✔ Evaluate the cost of NOT changing ✔ Getting stakeholder buy-in ✔ Propagating success
11:10 - 11:25 am	Networking Break
11:25 - 12:05 pm	**Post-Market Compliance; No Easy Journey** Ineffective or lack of proper Complaint Handing is cited as one of the top violations in a 483 issued at time of inspection by FDA. The number of device companies having their recall classified as a Class 1 (most severe) recall has surged in the past three years. Additionally, product liability and financial risks are staggering when companies fail to properly report and take action when required Ms. Hoffman will explain proper handling of complaints reportable or non-reportable, product complaint handling and documentation, filing for both Medical Device Reports (MDR) and eMDR, effective and appropriate communication with the appropriate regulatory agencies in the event of a recalls and how UDI's factor into reporting. She will provide key factors in implementing and maintaining compliance with the regulations from real life experiences from her career in FDA for a correction and removal actions to avoid a recall crisis, including required recordkeeping, expectation from an FDA perspective on achieving regulatory compliance. In addition, a brief review of the affect that the new FDA Compliance Guidance's issued in 2016 on post-marketing have had on post-marketing.
12:05 - 12:30 pm	**Establishing a Medical Device Security Program** Brief Synopsis of Content: Connected medical devices are playing a transformative and beneficial role in healthcare; however, these devices also pose risks to patient safety and health information security. As innovation continues and the threat landscape evolves, securing medical devices becomes more crucial. Currently, many manufacturers and providers have an ad hoc and device-specific security approach with a lack of a programmatic approach and framework for addressing connected medical device security risks. A mature medical device security program can increase effectiveness and consistency in the execution of security mitigations, including improved collaboration and communication between medical device manufacturers and healthcare providers. This session will focus on industry leading practices related to designing, developing, implementing, and sustaining a mature medical device security program. **Learning Objectives:** Following this session, the audience will have an enhanced understanding of the below topics: ✔ The evolution of connected medical devices ✔ The connected medical device cybersecurity landscape ✔ Recent messaging and action of the FDA around medical device cybersecurity ✔ Industry response to secure connected medical devices ✔ Medical device security program solution for both healthcare providers and medical device manufacturers ✔ The top risks the industry might face over the next five years, as well as some of the potential industry responses
12:30 - 01:30 pm	Lunch & Networking

AGENDA

01:30 - 02:00 pm

Off-label Promotion: Truth or Consequences

FDA inspects many different kinds of firms. If the FDA regulates your product, they can show up at your lobby and say, "I am here to conduct an inspection." What do you do? What have you done to prepare for an inspection? How do you deal with the investigator, including their personality? The scary part is having to explain the error of your ways to the FDA and above all, managing an administrative action, e.g., Warning Letter or Import Alert, or a legal action, e.g., civil money penalties, seizure, injunction or prosecution. This course will explain what you need to know and what you should do to survive an FDA inspection with the least possible pain.

	TRACK A - SESSIONS	TRACK B - SESSIONS
02:00 - 02:25 pm	**Medical Device Single Audit Program (MDSAP) - Can I Really Get Down to Just One Audit?** MDSAP can potentially offer a variety of important advantages. While currently optional for FDA, it will be mandatory for Health Canada in January of 2019. Understand MDSAP inside and out and be sufficiently prepared. Successful first-hand experiences will be shared along with step-by-step practical advice on how to adequately prepare for MDSAP. Real-world case studies provide engaging examples of what to do and how to accomplish it.	**Cleaning, Disinfection and Sterilization of Re-usable Medical Devices** In order for a re-usable medical device to be safe for patient use, a strict and detailed validation for the cleaning and disinfection processes should be performed. A validated cleaning and disinfection instruction for use are the responsibility of the manufacturer that are required to prove their claims for the re-use of the product and the validation should mimic as much as possible the clinically relevant conditions. The testing laboratory encounter many challenges to meet FDA expectation for the right simulation of that cleaning and disinfection process, including – simulated use of the device, artificial contamination with blood, mucus, microorganisms and endotoxins, validated recovery processes of the contaminated devices, devices with different surfaces/materials and complex structures.
02:25 - 02:50 pm	**Documentation for Agile Development - Shared Understanding, Vacation Photos, and Compliance** Working rapidly and flexibly, and demonstrating a working product regularly, are hallmarks of the Agile approach. For medical devices, however, our development also needs to produce documentation - requirements, design, tests, hazard analysis, usability, and traceability. How do we achieve all that and remain Agile? Documenting an Agile process for medical devices needs to serve two almost contradictory challenges: allowing ready sharing, exchange, and revision to build shared understanding on the one hand (see Jeff Patton's book) and satisfying the legal / regulatory demand to prove who, what and when. Take a tour through the documentation landscape and consider with me the primary document deliverables. How can we gather these as development proceeds, while minimizing overhead? How can we assure that inputs are reviewed and approved, without getting mired in the document signoff spiral? How can we address design reviews without bogging down the team in long, droning meetings? How can we capture traceability as a natural outcome of our work? This presentation will focus on concepts rather than tools, but specific tools will be used to provide concrete examples.	**Is Your Medical Device Software Ready for a 510K?**

02:50 - 03:20 pm

Medical Device Risk Management 2017 Updates - Workshop

The last year has been active with changes around the world in Risk Management. Are you familiar with the Compliance Risk requirements of ISO 13485? Is "risk-based thinking" as required by ISO 9001 evident in your organization? Has your organization implemented elements of Enterprise Risk Management based on ISO 31000? And most importantly, the international committee for ISO 14971 is actively working on updating this key standard! Stan will bring you the latest information that will keep you abreast of the recent changes related to managing risk. He will also discuss the vector of future changes. Based on insightful analyses, Stan will present concise key considerations to help you evaluate the currency of your firm's Risk Management program.

03:20 - 03:40 pm — Networking Break

03:40 - 04:10 pm — **Best Practices When Interacting with FDA - Panel Discussion**

04:10 - 04:25 pm — Closing Mark - Next Day Plan

AGENDA

DAY 02 - JUNE 8, 2018

Note: This program may be subject to alterations and additions

08.00 - 08.30 am	Registration and Breakfast	
08:30 - 09:00 am	**Cyber Security Risks and Working with Law Enforcement** - Keynote Speech	
09:00 - 09:30 am	**Medical Devices and the Future of Outcomes Centricity** - Keynote Speech	
09:30 - 10:00 am	**Medical Device Enhancements** - Keynote Speech	
10.00 - 10.25 am	**Effective Internal Auditing for Superior Quality Systems**	
10.25 - 10:55 am	**CDRH Office of Compliance Strategic Priorities and Hot Topics in Compliance** - Keynote Speech	
10:55 - 11:10 am	Networking Break	
11:10 - 11:40 am	**FDA Upcoming Electronic Submission Process**	
11:40 - 12:15 pm	**Is a Quality Agreement Required for All Suppliers?** - Panel Discussion	
12:15 - 12:45 pm	**Global Regulatory Landscape (US, EU and APAC): What's on the Horizon?**	
12:45 - 01:45 pm	Lunch & Networking	
	TRACK A - SESSIONS	**TRACK B - SESSIONS**
01:45 - 02:30 pm	**The EU Regulations - Prepare for Implementation**	**Human Factors Compliance: Just Another "Hoop" or Good Business?**
02:35 - 03:00 pm	**Digital Health & Medical Devices**	**Practical Lessons from 16 years of the Agile Community**
03:00 - 03:15 pm	Networking Break	
03:15 - 03:40 pm	**Learning From FDA Warning Letter - How to Stay Out of Trouble?** - Panel Discussion	
03:40 - 04:00 pm	Vote of Thanks & Participation Certificate Distribution	

Registration Form

Registration Information:

» Register Online. Use your American Express, Visa or MasterCard.
» Get your group to attend the summit at a discounted price call +1-888-717-2436.
» Call +1-888-717-2436 or Fax your PO: +1-650-565-8542
» Pay your check to (payee name) "MetricStream Inc" our parent company and mail the check to: ComplianceOnline (MetricStream, Inc), 2479 East Bayshore Road, Suite 260, Palo Alto, CA 94303
» Please fill this form with attendee details and payment details and fax it to +1-650-565-8542

Terms & Conditions:

Your Registration for the summit is subject to following terms and conditions. If you need any clarification before registering for this summit please call us at +1-888-717-2436 or email us at **customercare@complianceonline.com**

Cancellations and Substitutions:

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund - less a $300 administration fee. No cancellations will be accepted - nor refunds issued - within 10 calendar days from the start date of the event. On request by email or fax (before the summit) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the summit, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Summit: 4th Annual ComplianceOnline Medical Device Summit 2018

Date & Location: San Francisco, CA | June 7-8, 2018

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

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

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

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

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

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

Attendee 7 : Name .....Email .....

Attendee 8 : Name .....Email .....

Company Information

Organization.....

Address.....

City..... State..... Zip.....

Country.....

Phone..... Fax.....

ComplianceOnline
The Largest GRC Advisory Network
MetricStream

Payment Options

☐ Check enclosed, payable in U.S. funds to (Payee Name) (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....Total amount $.....

Signature.....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....Purchase order #.....
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to +1-650-565-8542