

4th Annual ComplianceOnline  
**Medical Device**  
Summit - 2018



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



June 7-8, 2018



02  
DAYS

20+  
SPEAKERS

25+  
KEY AREAS

MULTIPLE  
TRACKS

## 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



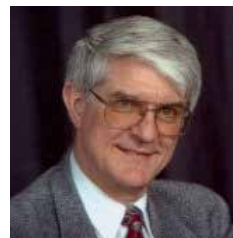
**Roy Wallen**

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 Health Sciences



**Steven Grossman**

President, HPS Group, LLC



**Virginia A. Lang, PhD**

President & Chief Scientist, HirLan, Inc.



**Scott Philips**

President Starfish Medicals, StarFish Medicals



**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 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

**Scott Phillips**  
 President Starfish Medicals

**Susan W. Needle**  
 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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## 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	<b>Welcome Speech with an Introduction of ComplianceOnline &amp; Summit</b>
🕒 08:45 - 09:10 am	<b>Adequate Directions for Use "in the Age of AI and Watson"</b>
🕒 09:10 - 09:40 am	<b>FDA Enforcement – Outlook &amp; Implications - Panel Discussion</b>
🕒 09:40 - 10:20 am	<b>Benefit-Risk: Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions</b>
🕒 10:20 - 10:40 am	<b>Medical Devices under Trump Administration</b>
🕒 10:40 - 11:10 am	<p><b>Change Management - Managing the Cost of Change</b></p> <p>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.</p> <p><b>At this session you will learn how to:</b></p> <ul style="list-style-type: none"> <li>✓ Evaluate the cost of change, including both local and hidden costs</li> <li>✓ Evaluate the cost of NOT changing</li> <li>✓ Getting stakeholder buy-in</li> <li>✓ Propagating success</li> </ul>
🕒 11:10 - 11:25 am	Networking Break
🕒 11:25 - 12:05 pm	<p><b>Post-Market Compliance; No Easy Journey</b></p> <p>Ineffective or lack of proper Complaint Handling 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.</p>
🕒 12:05 - 12:30 pm	<p><b>Establishing a Medical Device Security Program</b></p> <p>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.</p> <p><b>Learning Objectives:</b> Following this session, the audience will have an enhanced understanding of the below topics:</p> <ul style="list-style-type: none"> <li>✓ The evolution of connected medical devices</li> <li>✓ The connected medical device cybersecurity landscape</li> <li>✓ Recent messaging and action of the FDA around medical device cybersecurity</li> <li>✓ Industry response to secure connected medical devices</li> <li>✓ Medical device security program solution for both healthcare providers and medical device manufacturers</li> <li>✓ The top risks the industry might face over the next five years, as well as some of the potential industry responses</li> </ul>
🕒 12:30 - 01:30 pm	Lunch & Networking



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

## 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	<b>Cyber Security Risks and Working with Law Enforcement - Keynote Speech</b>
09:00 - 09:30 am	<b>Medical Devices and the Future of Outcomes Centricity - Keynote Speech</b>
09:30 - 10:00 am	<b>Medical Device Enhancements - Keynote Speech</b>
10:00 - 10:25 am	<b>Effective Internal Auditing for Superior Quality Systems</b>
10:25 - 10:55 am	<b>CDRH Office of Compliance Strategic Priorities and Hot Topics in Compliance - Keynote Speech</b>
10:55 - 11:10 am	Networking Break
11:10 - 11:40 am	<b>FDA Upcoming Electronic Submission Process</b>
11:40 - 12:15 pm	<b>Is a Quality Agreement Required for All Suppliers? - Panel Discussion</b>
12:15 - 12:45 pm	<b>Global Regulatory Landscape (US, EU and APAC): What's on the Horizon?</b>
12:45 - 01:45 pm	Lunch & Networking

### TRACK A - SESSIONS

### TRACK B - SESSIONS

01:45 - 02:30 pm	<b>The EU Regulations - Prepare for Implementation</b>	<b>Human Factors Compliance: Just Another "Hoop" or Good Business?</b>
02:35 - 03:00 pm	<b>Digital Health &amp; Medical Devices</b>	<b>Practical Lessons from 16 years of the Agile Community</b>
03:00 - 03:15 pm	Networking Break	
03:15 - 03:40 pm	<b>Learning From FDA Warning Letter - How to Stay Out of Trouble? - Panel Discussion</b>	
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.
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- » Please fill this form with attendee details and payment details and fax it to +1-650-565-8542

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