ComplianceOnline Medical Device summit - 2017

3rd Annual ComplianceOnline

Medical Device Summit - 2017

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June 8-9, 2017

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DAYS	SPEAKERS	KEY AREAS	TRACKS

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SPEAKERS

2017 Summit Speakers

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

Pat Baird
Regulatory Head of Global Software Standards,
Philips

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

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

Nick Sikorski, CISSP
Senior Consultant,
Deloitte Advisory

Stan Mastrangelo
Technical Committee Member of working group on ISO 31000, ISO 14971, and ICH Q9 Standards, Professor, Center for Applied Health Sciences,
Virginia Tech University

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

Roy Wallen
President & CEO,
Directional Healthcare Advisors, LLC

Rohit Bedi
Senior Vice President & Executive Leadership,
MetricStream

Peter Pitts
Chief Regulatory Officer,
Adherent Health, LLC.

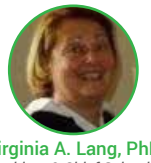
Steven Grossman
Public Policy & FDA Regulatory Consultant,
HPS Group

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

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

Daniel L. Aisen
Quality Assurance. Regulatory Compliance,
Proven Leadership

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



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

Martyn Gross
CEO,
Skylit Medical

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

Fletcher Wilson
CEO,
InterVene, Inc

Roni Cohen
Director of the Microbiology & Chemistry Division,
HYLabs

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

Cont...

SPEAKERS

Past Summit Speakers from FDA

Ron Brown
Branch Chief for Medical Device Recalls,
FDA

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

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

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

Bakul Patel
Associate Center Director for Digital Health at ,
FDA

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

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

Erin Keith
Director, Division of Anesthesiology, General Hospital

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

Neil Mafnas
Assistant Regulator
CDRH/FDA

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

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

Past Summit Speakers

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 Nettelton
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,
TouchStone 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 at ***MetricStream*** *& Business head* ***ComplianceOnline***

Kevin Fleming
National Healthcare Managing Director at,
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
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Stan Mastrangelo
Technical Committee Member of working group on ISO 31000, ISO 14971, and ICH Q9 Standards, 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, PhD
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,
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AGENDA

DAY 01 - JUNE 8, 2017

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** Rohit Bedi, *Senior Vice President & Executive Leadership,* ***MetricStream***
08:45 - 09:10 am	**Adequate Directions for Use" in the Age of AI and Watson -** Keynote Speech Stephen Allan Weitzman, *Editor in Chief at FDA Information Repository,* ***IRAI***
09:10 - 09:40 am	**FDA Enforcement – Outlook & Implications -** Panel Discussion Casper E Uldriks, *Former Associate Center Director of FDA's CDRH* Rita Hoffman, *RAC, Managing Partner, Regs & Recall Strategies, Former Branch Chief, Recalls, CDRH,* ***FDA*** FDA Invited
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** Steven Grossman, *Public Policy & FDA Regulatory Consultant,* ***HPS Group***
10:40 - 11:10 am	**Change Management - Managing the Cost of Change** Pat Baird, *Regulatory Head of Global Software Standards,* ***Philips*** 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** Rita Hoffman, *RAC, Managing Partner,* ***Regs & Recall Strategies, Former Branch Chief, Recalls, CDRH, FDA*** 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** Nick Sikorski, CISSP, *Senior Consultant,* ***Deloitte Advisory*** 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

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01:30 - 02:00 pm	**Off-label Promotion: Truth or Consequences** Casper E Uldriks, *Former Associate Center Director of,* ***FDA's CDRH*** 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	**Sterilization Validation & Biocompatibility for MedTech**	**Cleaning, Disinfection and Sterilization of Re-usable Medical Devices** Roni Cohen, *Director of the Microbiology & Chemistry Division,* ***HYLabs***
02:25 - 02:50 pm	**Onward to Approval: Documenting Development for Regulatory Compliance** Brian Shoemaker, Ph.D., *Principal Consultant,* ***ShoeBar Associates***	**Clinical Evaluation in the EU for Medical Devices - Changing Expectations** Keith Morel, Ph.D., *VP, Regulatory Compliance,* ***Qserve Group US Inc***
02:50 - 03:20 pm	**Medical Device Risk Management 2017 Updates -** Workshop Stan Mastrangelo, *Technical Committee Member of working group on ISO 31000, ISO 14971, and ICH Q9 Standards, Professor, Center for Applied Health Sciences,* ***Virginia Tech University*** 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 FDA Invited	
04:10 - 04:25 pm	Closing Mark - Next Day Plan	

AGENDA

DAY 02 - JUNE 9, 2017

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 FBI Presenting
09:00 - 09:30 am	**Learning From FDA Warning Letter - How to Stay Out of Trouble?** - Panel Discussion Scot Philips, *President,* ***Starfish Medicals***
09:30 - 10:00 am	**FDA Upcoming Electronic Submission Process** - Keynote Speech
10.00 - 10.25 am	**Effective Internal Auditing for Superior Quality Systems** Daniel L. Aisen, *Quality Assurance. Regulatory Compliance,* ***Proven Leadership***
10.25 - 10:55 am	**CDRH Office of Compliance Strategic Priorities and Hot Topics in Compliance** - Keynote Speech FDA Invited
10:55 - 11:10 am	Networking Break
11:10 - 11:40 am	**Global Regulatory Landscape (US, EU and APAC): What's on the Horizon?** Darin Oppenheimer, *Director regulatory, CMC, & Combination Products,* ***Merck***
11:40 - 12:15 pm	**Is a Quality Agreement Required for All Suppliers?** - Panel Discussion James Edward Ledlum, Jr., *Director Corporate Supplier Quality,* ***Hologic, Inc.*** Casper E Uldriks, *Former Associate Center Director of,* ***FDA's CDRH***
12:15 - 12:45 pm	**Medical Devices and the Future of Outcomes Centricity** Peter Pitts, *Chief Regulatory Officer,* ***Adherent Health, LLC.***
12:45 - 01:45 pm	Lunch & Networking

	TRACK A - SESSIONS	TRACK B - SESSIONS
01:45 - 02:25 pm	**FDA Compliance for SaaS/Cloud Environments** David Nettelton, ***Industry Leader, Author, and Teacher*** *for 21 CFR Part 11, Annex 11, HIPAA, Software Validation, and Computer System Validation*	**Human Factors Compliance: Just Another "Hoop" or Good Business?** Virginia A. Lang, PhD., *President & Chief Scientist,* ***HirLan, Inc.***
02:25 - 02:50 pm	**Digital Health & Medical Devices** Roy Wallen, *President & CEO,* ***Directional Healthcare Advisors, LLC*** This presentation addresses the challenges of bringing new medical device technologies to market in the context of market trends that seem to circumvent regulatory requirements. There is a need to balance market opportunity – such as wearable devices that provide useful diagnostic data – with the need to assure safe and effective adoption of those devices. Specific examples of new technologies are presented that appear to avoid standard compliance requirements under the disclaimer that they are "not a medical device". The presentation addresses the issue of how users (i.e., patients) can adopt these devices, how clinicians can use the data in patient treatment, and how regulatory oversight could address the gap between device use and safety.	**FDA Quality Metrics Update**
02:50 - 03:10 pm	**Developing a Global Strategy for Labelling** Daphne Walmer, *Thought Leader/Expert/Consultant in Medical Device Labeling and Technical Communications*	**Early R&D Best Practices from Concept to First in Human Studies** Fletcher Wilson, *CEO,* ***InterVene, Inc.***
03:10 - 03:25 pm	Networking Break	
03:25 - 04:00 pm	**Compliance as an Element of M&A Strategy** Michael Weickert, *Strategic & Entrepreneurial Executive, Trail-blazing Leadership in Biotech,* ***Medical Device & Pharmaceutical Business***	
04:00 - 04:15 pm	Vote of Thanks & Participation Certificate Distribution	

Registration Form

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Summit: 3rd Annual ComplianceOnline Medical Device Summit 2017

Date & Location: Boston, MA | June 8-9, 2017

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

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

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

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

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

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