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EVENTS LIST

4th Annual ComplianceOnline Medical Device Summit 2018 (COM)

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Organizer : NYMT

Venue :

Location :	Omni San Francisco Hotel500 California StreetSan Francisco, CA 94104United States, San Francisco, CA, US, ZIP: 0001

4th Annual ComplianceOnline Medical Device Summit 2018

***** LIMITED TIME OFFER: FREE $100 AMAZON GIFT CARD! *****
REGISTER TODAY!

Key Attraction

Innovate novel ideas for advancements in medical device technologies without compromising their safety and effectiveness. This summit brings together some of the renowned R&D experts and technology innovators to share information regarding opportunities, obstacles, best practices and challenges in the development of the new devices. Attendees will get insight into device innovation trends and upcoming changes in the medical device regulations.

Plan for successfully executing regulatory inspections by providing industry best practices. Panel discussions led by the former FDA office bearers and industry experts will provide a set of comprehensive strategies on how to prepare for and manage an FDA inspection, including how to follow-up and closing out 483s or Warning Letters. Attending this summit will enable you to improve and better prepare for your next inspections.

Build FDA compliant quality management systems. Attend this summit to learn how to develop and implement effective, consistent and reliable quality management systems. Ex-FDA officials and senior company executives will share thoughts and ideas to improve the performance of your current system.

Interact with leading minds in the industry. Attendees will get to network with the prominent decision makers in the industry to exchange ideas, offer thoughts and know-how, and share experiences. Joining this summit will offer a unique opportunity to the attendees to market their offerings and identify new business opportunities.

Deliberate the current state of medical device laws and technology and government oversight. Panel comprising of some of leading medical device experts and veterans will discuss the recent changes to the regulatory environment for the medical device industry and how these changes will impact the approval of new devices. Attendees will gain insight into the current issues and future challenges in the industry. Join this summit to hear from the experts who have extensive experience in all aspects of medical device including R&D, manufacturing quality assurance, approval and commercialization process.

Scale factors for successful medical device commercialization. Discussions with industry veterans through real case studies will help medical researchers, healthcare professionals, industrialists and entrepreneurs better understand the criterias for successful commercialization of medical devices. This summit also offers numerous opportunities for medical device companies and suppliers to showcase their products and services to potential customers, generating leads and growing their businesses.

Enhance risk management strategies for the safe, effective and efficient use of medical devices. Medical device professionals will join together to share their knowledge and best practices for implementing good risk management principles within the industry. Attending this summit will help you to develop a robust and integrated risk management plan to improve quality management system.

Why you should attend this summit

- Future Trends of Medical Device Regulation, Risk Management, UDI, Recall Complaint Management etc.
- Listen from FDA/CDRH Directors:
    - What is Critical to Quality
    - Get Update on FDA compliance
- Listen from FBI:
    - Cyber Security Risks
- Learn More about Medical Device Global Regulatory Landscape and Off-label Promotion

- Explore Upcoming Changes in Medical Devices under Trump Administration
- Change Management
- Criteria for Supplier Quality Agreement
- Establishing a Medical Device Security Program
- Panel Discussion
    - FDA Warning Letter
    - FDA Enforcement
    - FDA Interaction

Find out who had attended the Medical Device Summit 2015 and 2016 by completing the short form below.

Who Will Benefit?

- Quality Assurance/Quality Control
- Manufacturing and Contracting
- Supply Chain Management
- Import/Export
- Sales, Marketing and Business Development
- IT and Software
- Risk Management and Product Lifecycle Management
- Executive Management
- Regulatory Affairs
- Research and Development
- Engineers
- Scientists
- Documentation
- Compliance Officers
- Clinical/Lab
- Consultants/Service Providers/Suppliers

AGENDA

DAY 01 JUNE 07, 2018

8:00 - 8:30 am
Registration and Breakfast

8:30 - 8:45 am
Welcome Speech with an Introduction of ComplianceOnline & Summit

8:45 - 9:10 am
Adequate Directions for Use "in the Age of AI and Watson"

Stephen Allan Weitzman, Editor in Chief at FDA Information Repository, IRAI
9:10 - 9:40 am
FDA Enforcement – Outlook & Implications - Panel Discussion

9:40 - 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

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

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 - 1:30 pm
Lunch

1:35 - 2:05 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

2:10 - 2:35 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.

2:40 - 3:05 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.

2:10 - 2:35 pm
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.

2:40 - 3:05 pm
Is Your Medical Device Software Ready for a 510K?

3:10 - 3:40 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.
3:40 - 3:55 pm
Networking Break

3:55 - 4:25 pm
Best Practices When Interacting with FDA - Panel Discussion

4:25 - 4:35 pm
Closing Mark - Next Day Plan
DAY 02 JUNE 08, 2018

8:00 - 8:30 am

Registration and Breakfast

8:30 - 9:00 am

Cyber Security Risks and Working with Law Enforcement - Keynote Speech

9:00 - 9:30 am

Medical Devices and the Future of Outcomes Centricity - Keynote Speech

9:30 - 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 - 1:45 pm

Lunch

Track A - Sessions

1:50 - 2:30 pm
The EU Regulations - Prepare for Implementation

2:35 - 3:00 pm
Digital Health & Medical Devices

Track B - Sessions

1:50 - 2:30 pm

Human Factors Compliance: Just Another “Hoop” or Good Business?

2:35 - 3:00 pm

Practical Lessons from 16 years of the Agile Community

3:00 - 3:15 pm

Networking Break

3:15 - 3:40 pm

Learning From FDA Warning Letter - How to Stay Out of Trouble? - Keynote Speech

3:40 - 4:00 pm

Vote of Thanks & Participation Certificate Distribution

PAST SPEAKERS

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

Robin Newman is the Director for the Office of Compliance at FDAâ€™s Center for Devices and Radiological Health. Dr. Newman has 25+ years of senior level clinical/regulatory and compliance management experience in new product research and development. Sheâ€™s served as a senior level executive and consultant for regulatory strategy, clinical trial design and execution, standards and SOP development, quality system management and compliance, medical and technical writing, customer/patient interface and education, and management of Data Safety Monitoring Boards. Prior to joining FDA, Dr. Newman served as the Vice President of Quality Management for Siemens Healthcare Diagnostics, where she managed a

multidisciplinary quality management and regulatory team and functioned as the primary representative for AdvaMedDx and the Diagnostic Tests Working Group. She holds a B.S. and M.S. in Nursing from the University of Texas, an Ed.D. from The George Washington Universityâ€™s Executive Leadership Program, and holds certifications as a Pediatric Nurse Practitioner, in regulatory affairs (RAPS), and as a CCRA (ACRP).

Adam Saltman, MD PhDMedical Officer, CDRH/Office of Compliance

Adam E Saltman MD PhD is a Medical Officer in the Office of Compliance, Center for Devices and Radiological Health, at the Food and Drug Administration. He has worked with the FDA in both the premarket and postmarket arenas as a clinical reviewer since 2008. His primary responsibilities there now focus on the compliance medical device removal and correction process, as well as incorporating clinical benefit risk evaluations in recall and potential recall situations. Dr. Saltman consults regularly on clinical risk evaluations, device recall classifications, and public-facing FDA and manufacturer communications. Dr. Saltman left his clinical practice in cardiothoracic surgery in 2016, during which he held a special interest and key opinion leadership in the surgical treatment of atrial fibrillation. He has published more than 100 peer-reviewed articles, served on several journal editorial boards, and conducted competitively funded research projects. Dr. Saltman also holds an appointment of Clinical Associate Professor of Surgery at the Ohio University Heritage College of Osteopathic Medicine, where he teaches residents and medical students. He received his MD and his PhD degrees from Columbia University, his MS in health informatics from the University of Illinois at Chicago, and is certified as a Quality Improvement Associate by the American Society for Quality.

Ronny BrownBranch Chief for Medical Device Recalls, FDA

Stephen Allan WeitzmanEditor in Chief, FDA Information Repository, IRAI

Stephen Weitzman has been involved in healthcare matters for the past 45 years as a practicing lawyer and science consultant in the pharmaceutical, medical device, and food industries. He is a pioneer of the use of computers in legal and science research and litigations support systems from mainframe to personal computers. In the early 70's he set up complex litigations support systems for fortune 100 corporations and their associations in the FTC nutrition advertising proceeding. Those systems blended data from exhibits, attorney files, science literature, surveys, and court decisions, including text and image files. He worked with Brower Murphy who created the first CD-ROM for data on a Toshiba music disc player, the Library of Congress Catalog as Library Corporation. Steve created the first CD-ROM on a government agency (FDA) in 1984, including internal FDA documents and manuals relating to training drug reviewers to enforcement manuals. He also built the FDA's original website section on regulation enforcement.

In recent years he has also been involved in prosecuting major civil fraud litigation and patent infringement. The fraud litigation involved drug diversion and potential counterfeiting. The patent matters relate to information technology systems.

Currently focuses on the Medical Informatics for healthcare issues related to establishing a functional national health information infrastructure for sharing medical records for research, safety surveillance, and personalized medicine.

Casper E UldriksFormer Associate Center Director, FDA, CDRH

Casper (Cap) Uldriks, through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He specialized in the FDA's medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health. He developed enforcement actions and participated in the implementation of new statutory requirements. His comments are candid, straightforward and of practical value. He understands how FDA thinks, how it operates and where it is headed. Based on his exceptionally broad experience and knowledge, he can synthesize FDA's domestic and international operational programs, institutional policy and thicket of legal variables into a coherent picture.

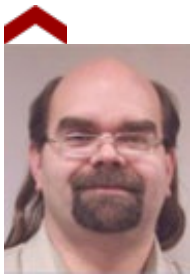
Rita HoffmanRAC, Managing Partner, Regs & Recall Strategies, Former Branch Chief, Recalls, CDRH, FDA

Rita Hoffman, RAC. Managing Partner Regs & Recall Strategies, LLC .Ms. Hoffman has more

than 36 years of FDA experience across the device, drug and veterinary industries. She has an intimate understanding of FDA regulatory and compliance issues from the perspective of both FDA and regulated industry. As an FDA compliance consultant, she provides clients with regulatory insight, advises on critical compliance deficiencies, performs compliance and new product audits, provides insight and guidance on recall strategies to the medical device industry, and advises on jurisdiction determinations for combination products.

Ms. Hoffman retired from the FDA in January 2011 as the Recall Branch Chief for the Center for Devices and Radiological Health (CDRH), where she was responsible for oversight and review for all medical device recalls. Ms. Hoffman held several positions including the Center for Drug Evaluation and Research (CDER) Jurisdiction Review Officer (providing guidance on drug/device product designation, combination products and co-packaging), Acting Associate Ombudsman, Small Business Liaison, and was a Policy Analyst for eight years in the Office of the Commissioner. She served as co-chair of RAPS' Baltimore/Washington Metropolitan Area Chapter for 2-terms, and in 2008 was presented with the Special Recognition Award by RAPS.

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



Pat BairdRegulatory Head of Global Software Standards, Philips

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