ComplianceOnline Medical Device summit - 2015

Hilton San Diego Bayfront, 1 Park Boulevard,
San Diego, CA | September 17-18, 2015

Announcement:
9 FDA & Ex-FDA Professionals Confirmed to Speak at Medical Device Summit

- 2 Days
- Multiple Tracks
- 4 Keynote Sessions
- 10 FDA & Ex-FDA Professionals
- 20+ Key Areas of Medical Device Industry
- 30+ Elite Industry Experts

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 criteria's 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 Attend This Event?

Why you should attend this summit (some key pointers):

- Future trends of Medical Device Regulation, Risk Management, UDI, recall, complaint Management etc.
- Listen from FDA/CHRH Directors:
  - What is critical to Quality
  - Get update on FDA compliance
- Learn more about Medical Device Single Audit Program (MDSAP) and Other Third Party Programs
- Explore upcoming changes in global regulation
- Supply Chain Optimization
- Criteria for Medical Device commercialization success
- Panel Discussion
  - Advanced Technology
  - How to choose Vendors/Suppliers

And more...

Get Learning from talks by

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

Peter Pitts
(President, Center for Medicine in the Public Interest Former Associate Commissioner, US Food and Drug Administration)

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)

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

Neil Mafnas
(Regulatory Officer)

And more...

Speakers

Speakers from FDA

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

Neil Mafnas
(Assistant Regulator CDRH/FDA)

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

Ronny Brown

James Saviola
(Deputy Director of Regulatory Affairs (Acting), and Director, Division of Biomedical Research, Office of Compliance, CDRH)

James Saviola
(FDA Regulatory Compliance Specialist, JAF Consulting Inc)

Get Learning from Ex-FDA Professionals

Peter Pitts
(President, Center for Medicine in the Public Interest Former Associate Commissioner, US Food and Drug Administration)

Larry Spears
(Ex-FDA Professional, Principal Consultant, Regulatory Affairs & Quality Systems at Certified Compliance Solutions, Inc.)

Experts from Industry

Darin Oppenheimer
(Director Global Regulatory Affairs ,Baxter Healthcare)

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

Ronald Weissman
(Chairman, Software SIG, Band of Angels)

Scott Phillips
(President Starfish Medicals)

Terri Jollymour
(Sr. Director, Operations Readiness & Convergence Johnson & Johnson Corporate Supply Chain Quality & Compliance)

Susan W. Neadle
(Head, Combination Products Center of Excellence Sr. Director, Design to Value and Quality Engineering Janssen Supply Group)

Gary Saner
(Sr. Manager, Information Solutions-Life Sciences at Reed Tech)

Rick Williams
(Partner, Newport Board Group New England Practice, Chairman of Point Care Technology)

Mitch Levinson
(Founder, President & CEO, Cerebrotech Medical Systems)

Angela Bazigos
(President, Touchstone Technologies)

Kevin Fleming
(National Healthcare Managing Director at Newport Board Group)

Dr. Jessica Grossman
(CEO, Sense4Baby, Inc.)

Julia Rasooly
(CEO, Puracath)

Stan Mastrangelo
(Professor, Center for Applied Health Sciences, Virginia Tech University)

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

Agenda

Day One

8.00AM - 9.00AM	60 Mins	Registration
9.00AM - 9.10AM	10 Mins	**Welcome Speech with an Introduction of ComplianceOnline & Summit** - Introduction **By Shellye Archambeau, Chief Executive Officer (CEO), MetricStream**
9.10AM - 9.40AM	30 Mins	**Growth & Opportunities 2020: Vision 2020 & Beyond** - Inspirational Keynote **Tom Loker** *Businessman | Author | Speaker, Startup Consultant & Advisor SYDK.ORG, Contributor to California Political Review*
9.40AM - 10:30AM	50 Mins	**Role & Market Evolution of USA** - Panel Discussion
10.30AM - 11.00AM	30 Mins	**"The 21st Century FDA: Help or Hindrance to Innovation?"** **Peter Pitts** *President, Center for Medicine in the Public Interest, Former Associate Commissioner, US Food and Drug Administration*
11.00AM - 11.20AM	20 Mins	Networking Coffee/Tea Break
11.20AM - 12.00PM	40 Mins	Sponsors Speaking Opportunity – 2 nos (20 mins each)
12.00PM - 12.40PM	40 Mins	**All Medical Device Start-Ups Have One Thing in Common: They are All Unique** **Mitch Levinson** *Founder, President & CEO, Cerebrotech Medical Systems*
12.40AM - 01.00PM	20 Mins	Sponsors Speaking Opportunity – 2 nos (10 mins each)
01.00AM - 02.00PM	60 Mins	Lunch Break

Track A - Sessions

2.00PM - 2.40PM	40 Mins

FDA Compliance and Quality Update

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

2.40PM - 3.10PM	30 Mins

Critical to Quality - What's Under the Hood

Bill MacFarland
Director, Division of Enforcement B, Office of Compliance, FDA/CDRH
Cisco Vicenty
Acting-Branch Chief, Office of Compliance CDRH/FDA

3.10PM - 3.25PM	15 Mins	Networking Coffee/Tea Break

3.25PM - 4.05PM	40 Mins

Future Trends of Medical Device Regulation – Upcoming Changes in Global Regulation

Darin Oppenheimer
Baxter Healthcare Corporation

4.05PM - 4.25PM	20 Mins

Sponsors Speaking Opportunity

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

4.25PM - 5.00PM	35 Mins

QBD & Design Controls

Susan Neadle
Sr. Director Janssen Pharmaceuticals

Track B - Sessions

2.00PM - 2.40PM	40 Mins

Medical Device Recall and Compliant Management

Ronny Brown

2.40PM - 3.10PM	30 Mins

Risk Management for Medical Devices

Erin Keith
Director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices, CDRH, FDA

3.10PM - 3.25PM	15 Mins	Networking Coffee/Tea Break

3.25PM - 4.05PM	40 Mins

Implementation of Combination Product cGMP final Rule

Terri Jollymour
Sr. Director, Operations Readiness & Convergence Johnson & Johnson
Susan Neadle
Sr. Director Janssen Pharmaceuticals

4.05PM - 4.25PM	20 Mins

Sponsors Speaking Opportunity

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

4.25PM - 5.00PM	35 Mins

Be FDA Inspection Ready

Larry Spears
Ex-FDA Professional, Principal Consultant, Regulatory Affairs & Quality S ystems at Certified Compliance Solutions, Inc.

Agenda

Day Two

8.00AM - 8.30AM	30 Mins	**Registration/Sponsored Breakfast**
8:30AM - 9.00AM	30 Mins	**Medical Device an Inside State Perspective**
9:00AM - 9.30AM	30 Mins	**FDA's New Import Program Concerning International Consequences**
9.30AM - 10.00AM	30 Mins	**Advanced Technology - An Essential Resource -** Panel Discussion **Rick Williams** *Partner, Newport Board Group New England Practice, Chairman of Point Care Technology*
10.00AM - 10.40AM	40 Mins	**Medical Device Single Audit Program (MDSAP) and Other Third Party Programs** **Neil Mafnas (Remote)** *Assistant Regulator CDRH/FDA*
10.40AM - 11.00AM	20 Mins	Networking Coffee/Tea Break
11.00AM - 11.20AM	20 Mins	Sponsors Speaking Opportunity – 2 nos (10 mins each)
11.20AM - 11.50AM	30 Mins	**Mergers & Acquisitions: Keynote** **Rick Williams** *Partner, Newport Board Group New England Practice, Chairman of Point Care Technology*
11.50PM - 12.20PM	30 Mins	**Venture Investing** **Ronald Weissman** *Chairman, Software SIG, Band of Angels*
12.20AM - 01.00PM	40 Mins	**Mergers & Acquisitions Panel Discussion** **Rick Williams** *Partner, Newport Board Group New England Practice, Chairman of Point Care Technology* **Kevin Fleming** *National Healthcare Managing Director at Newport Board Group* **Dr. Ron Weissman** *Chairman, Software SIG, Band of Angels*
01.00AM - 02.00AM	60 Mins	Lunch Break

Track A - Sessions

2.00PM - 2.40PM	40 Mins

FDA Data Developed to Improve Product Quality

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

2.40PM - 3.20PM	40 Mins

7 Criteria for Medical Device Commercialization Success

Scott Phillips
President Starfish Medicals

3.20PM - 3.40PM	20 Mins	Sponsors Speaking Opportunity

3.40PM - 4.20PM	40 Mins

Vendors/Suppliers -Are You choosing them Right? - Panel Discussion

Angela Bazigos
President Touchstone Technologies

Larry Spears
Ex-FDA Professional, Principal Consultant, Regulatory Affairs & Quality Systems at Certified Compliance Solutions, Inc.

Julia Rasooly *CEO, Puracath*
Joe Franchetti
Dr. Jessica Grossman *CEO, Sense4Baby, Inc.*

Track B - Sessions

2.00PM - 2.40PM	40 Mins

UDI Granular Interpretation & Road Ahead

Gary Saner
Sr. Manager, Information Solutions - Life Sciences, Reed Tech

2.40PM - 3.20PM	40 Mins

Medical Device Risk Management

Stan Mastrangelo
Professor, Center for Applied Health Sciences, Virginia Tech University

3.20PM - 3.40PM	20 Mins	Sponsors Speaking Opportunity

3.40PM - 4.20PM	40 Mins

Supply Chain Optimization - Enhancing Controls & Controlling Risk

4.20PM to 4.40PM	20 Mins	Networking Coffee/Tea Break
4.40PM to 5.30PM	50 Mins	Prize, Sponsor Prize & Certificate Distribution, Summary & Closure

Supporters

Sponsors

Platinum Sponsor: MetricStream

Gold Partner: Reed Tech

Knowledge Partner: Touchstone Technologies Silicon Valley

Media Partner: Morf Media

Associate Sponsor: Greenlight.Guru

Why San Diego?

San Diego is a major hub for scientific research and development. The city is an important center for medical device innovation – leading companies such as NuVasive, Care Fusion, Medipacs and SpectraScience are headquartered here while companies such as Boston Scientific, Stryker and DePuy are located in nearby San Jose. The spirit of entrepreneurship not in just San Diego but the whole of Southern California has made it the ideal environment for start-ups.

As one of California's legendary coastal cities, visitors come to San Diego to enjoy its wonderful climate, natural attractions and rich history. Some of the city's most popular destinations include:

- ✓ The San Diego Zoo is one of the world's most famous zoological treasures, with a huge botanical plant and orchid garden as well.
- ✓ The San Diego Air and Space Museum preserves the rich past of the aviation industry as well as space technology. It aims to encourage study in science, engineering and technology.
- ✓ La Jolla Shores is one of the must-see and must-experience destinations for scuba divers, snorkelers and kayaks. Nature lovers also go to La Jolla to experience the underwater park – around 6,000 acres of tide lands and artificial reefs with an abundance of marine life.

The strong culture of technological innovation, ground-breaking scientific discovery and spectacular urban and natural heritage makes San Diego the ideal venue for an important industry event like the ComplianceOnline Medical Device Summit.

Venue/Hotel

Hilton San Diego Bayfront,
1 Park Boulevard, San Diego,
CA, 92101, USA
Tel: +1-619-564-3333

Special Offer for the attendees of this Summit:

Rooms available at only $289 per night in Hilton San Diego Bayfront.

Call Central Reservations number at 1-800-445-8667 to make their reservations and referencing group code **"COMPLI"** .Additionally, You may book through this Link

https://resweb.passkey.com/go/ComplianceOnline2015

Please note: Hotel rooms are limited and based on availability

ComplianceOnline Medical Device summit - 2015

September 17-18, 2015
San Diego, CA

Delegate Registration Details

$699.00

One Registration

(For Medical Device/Pharma/Biotech attendee)

(For Registrations till August 5, 2015 - $699
For Registrations till August 20, 2015 - $799
For Registrations after August 20, 2015 - $999)

$3,019.00

~~$4,194.00~~
You Save:
$1,175.00 (28%)*

Special Group Discount for Six Attendees

(For Medical Device/Pharma/Biotech companies)

Hurry! This option is limited and based on availability.
Great Savings with Group Ticket!!! Only 12 left

$3,500.00

One Registration

(For Vendor/CRO/Service Provider)

2600 E. Bayshore Road, Palo Alto, CA 94303

Phone Number: +1-650-284-1695
Email: summit@complianceonline.com

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: 650-963-2556.
» Pay your check to (payee name) "MetricStream Inc" our parent company and mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
» Please fill this form with attendee details and payment details and fax it to 650-963-2556

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 **editor@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 $200 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 ($200) 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.

Seminar: ComplianceOnline Medical Device Summit - 2015

Date & Location: San Diego, CA | Sep 17-18, 2015

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 ComplianceOnline (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 650-963-2556