



02
Days



Inspiring Keynote



Case Studies



Multiple
Tracks



20+
Speakers



FDA Presentation



25+
Key Areas



Expert Panel Discussions

2nd Annual ComplianceOnline Medical Device Summit 2016

Manchester Grand Hyatt San Diego, 1 Market Place,
San Diego, CA | September 15-16, 2016



Speakers from FDA



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



Robin Newman
 Director, Office of Compliance,
 Food & Drug Administration, CDRH



James Saviola
 Director, Division of Bioresearch Monitoring,
 FDA/CDRH/ Office of Compliance

Experts from Industry



Shannon Hoste
 RAC, Sr. Staff Fellow



Scott Phillips
 President, **Starfish Medicals**



Susan W. Neadle
 Sr. Director, **Janssen Pharmaceuticals**



Rick Williams
 Partner, Newport Board Group New England Practice,
 Chairman of Point Care Technology,
 Board member of Amorphex Therapeutics



Brian Prom
 Director Design Assurance, **Boston Scientific**



Mitch Levinson
 Founder, President & CEO, **Cerebrotech Medical Systems**



Kevin Fleming
 National Healthcare Managing Director, **Newport Board Group**



Julia Rasooly
 Founder and CEO, **PuraCath Medical Inc**



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



Gunjan Sinha
 Executive Chairman, **MetricStream**



Mark Faupel
 CEO, **Guided Therapeutics Inc.**



Pamela Weagraff
 Director and Medical Device & Diagnostics Regulatory Team Lead,
Quintiles Advisory Services



Peter Pitts
 Chief Regulatory Officer, **Adherent Health, LLC.**



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



Angela Bazigos
 CCO, **Morf Media**



Eduardo Cervantes
 President & CEO, **Morf Media**



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



Geetha Rao
 CEO, **Springborne Lifesciences**



Martyn Gross
 CEO, **Skylit Medical**



Fletcher Wilson
 CEO and Founder, **InterVene Inc**

DAY 01 - SEPTEMBER 15, 2016

Note: This program may be subject to alterations and additions.

08:00 - 09:00 am	Registration and Breakfast
09:00 - 09:05 am	Opening Ceremony and Introduction
09:05 - 09:15 am	Welcome Speech with an Introduction of ComplianceOnline & Summit Gunjan Sinha Executive Chairman, MetricStream
09:15 - 09:40 am	Growth & Opportunities 2020: Vision 2020 & Beyond - Inspirational Keynote Tom Loker Businessman Author Speaker, Startup Consultant and Advisor SYDK.ORG, Contributor to California Political Review
09:40 - 10:10 am	FDA Enforcement – Outlook & Implications - Panel Discussion Darin Oppenheimer Director Global Regulatory Affairs, Baxter Healthcare Virginia A. Lang, PhD , President & Chief Scientist, HirLan, Inc. Angela Bazigos , CCO, Morf Media Inc Rick Williams(Moderator) Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics Bill MacFarland Director, Division of Enforcement B, Office of Compliance, FDA/CDRH
10:10 - 10:40 am	CDRH 2016-2017 Priorities
10:40 - 11:10 am	Onward to Approval: Documenting Development for Regulatory Compliance Brian Shoemaker, Ph.D Principal Consultant, ShoeBar Associates
11:10 - 11:30 am	Networking Coffee/Tea Break
11:30 - 11:50 am	All Medical Device Start-Ups Have One Thing in Common: They are All Unique Mitch Levinson Founder, President & CEO, Cerebrotech Medical Systems
11:50 - 12:10 pm	3-D Printed Medical Devices - Next?
12:10 - 12:30 pm	Sponsorship & Speaking Opportunities
12:30 - 01:40 pm	Lunch Break

TRACK A - SESSIONS

TRACK B - SESSIONS

01:40 - 02:55 pm	FDA Compliance and Quality Update Bill MacFarland Director, Division of Enforcement B, Office of Compliance, FDA/CDRH (Invited) Critical to Quality - What's Under the Hood Cisco Vicenty Acting-Branch Chief, Office of Compliance CDRH/FDA (Invited)	01:40 - 02:10 pm	Interoperable Medical Devices and Connected Medical Networks Geetha Rao , CEO, Springborne Lifesciences
02:55 - 03:15 pm	Networking Tea/Coffee Break	02:10 - 02:55 pm	Risk Management for Medical Devices - Workshop Erin Keith Director Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental at FDA (Invited)
03:15 - 03:55 pm	Data Integrity Program - Panel Discussion Darin Oppenheimer Director global regulatory affairs at Baxter healthcare	03:15 - 03:55 pm	Implementation of Combination Product cGMP Final Rule Terri Jollymour Sr. Director, Operations Readiness & Convergence Johnson & Johnson Susan Neadle , Sr. Director, Janssen Pharmaceuticals
03:55 - 04:35 pm	Human Factors Compliance: Just Another "Hoop" or Good Business? Virginia A. Lang, PhD , President & Chief Scientist, HirLan, Inc.	03:55 - 04:35 pm	QbD & Design Controls Susan Neadle , Sr. Director, Janssen Pharmaceuticals

DAY 02 - SEPTEMBER 16, 2016

Note: This program may be subject to alterations and additions.

08.00 - 08.30 am	Registration and Breakfast	
08.30 - 08.50 am	FDA Data Integrity Program James Saviola Deputy Director of Regulatory Affairs (Acting), and Director, Division of Biomedical Research, Office of Compliance, CDRH (Invited)	
08.50 - 09.20 am	Bringing Compliance to the Boardroom - Panel Discussion Rick Williams Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics Eduardo Cervantes , President & CEO, Morf Media Inc Angela Bazigos (Moderator) CCO, Morf Media Inc Dr. Ron Weissman , Chairman, Software SIG, Band of Angels	
09.20 - 09.40 am	FDA New Import/ Export Program FDA Professional Invited	
09.40 - 10.00 am	What Investors are Looking for In Medical Devices Rick Williams Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics	
10.00 - 10.25 am	Medical Devices and the Future of Outcomes Centricity Peter Pitts , Chief Regulatory Officer, Adherent Health, LLC.	
10.25 - 10.45 am	Networking and Coffee/Tea Break	
10.45 - 11.05 am	Sponsorship & Speaking Opportunities	
11.05 - 11.25 am	Venture Capital in Transition: Current Venture Trends Dr. Ron Weissman , Chairman, Software SIG, Band of Angels	
11.25 - 12.00 pm	Compliance as an Element of M&A Strategy - Panel Discussion Rick Williams (Moderator) Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics Kevin Fleming National Healthcare Managing Director, Newport Board Group Eduardo Cervantes , President & CEO, Morf Media Inc	
12.00 - 12.30 pm	Important issues for Medical Wearables	
12.30 - 01.30 pm	Lunch Break	
	TRACK A - SESSIONS	TRACK B - SESSIONS
01.30 - 02.00 pm	FDA Data Developed to Improve Product Quality	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
02.00 - 02.20 pm	New Methods of Driving Compliance through Innovation Martyn Gross CEO, Skylit Medical	FDA Quality Metrics Update Angela Bazigos CCO, Morf Media Inc.
02.20 - 02.50 pm	How To Prepare a Medical Device CE Marking Submission Larry Spears President, L.Spears Consulting LLC	Medical Device Patents and your strategy Mark Faupel CEO, Guided Therapeutics inc.
02.50 - 03.05 pm	Networking Tea/Coffee Break	
03.05 - 03.45 pm	Vendors/Suppliers - Are You Choosing them Right? - Panel Discussion Angela Bazigos (Moderator) CCO, Morf Media Inc Julia Rasooly Founder and CEO, PuraCath Medical Inc Joe Franchetti FDA Regulatory Compliance Specialist, JAF Consulting Inc	
03.45 - 04.00 pm	Closing Remarks & Certificates	

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 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 \$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.

Summit: 2nd Annual ComplianceOnline Medical Device Summit 2016

Date & Location: San Diego, CA | September 15-16, 2016

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.....

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 650-963-2556



ComplianceOnline Summit Experience



Manchester Grand Hyatt San Diego,
1 Market Place,
San Diego, California, USA, 92101

September 15-16, 2016

