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

ComplianceOnline
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SPEAKERS

Speakers from FDA

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

Linda Godfrey
Deputy Director, Division of Bioresearch Monitoring,
Office of Compliance, CDRH

Marisa White
CSO, Center for Devices and Radiological Health,
FDA

Experts from Industry

Larry Spears,
President, ***L.Spears Consulting LLC, Ex-FDA Official***

Terri Jollymour
Senior Director, Corporate Q&C Strategy, Operations Readiness & Convergence,
Johnson & Johnson

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

Darin Oppenheimer
Regulatory Affairs Expert, Global Medical Device Regulations & Licensure Authority, Strategic & Engaging Leader, ***Baxter Healthcare Corporation***

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

Dr. Ron Weissman
Chairman, ***Software SIG, Band of Angels***

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***

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

Gunjan Sinha
Executive Chairman, ***MetricStream***

Scott Phillips
President, ***Starfish Medicals***

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

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*

Geetha Rao
CEO, ***Springborne Lifesciences***

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

Martyn Gross
CEO, ***Skylit Medical***

Orlando Padilla
President & CEO, ***Pathway Medical Device International***

Joe Franchetti
FDA Regulatory Compliance Specialist, ***JAF Consulting Inc***

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

Angela Bazigos
CCO, ***Morf Media***

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

AGENDA

ComplianceOnline Medical Device summit - 2016

DAY 01 - SEPTEMBER 15, 2016

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

08:00 - 08:30 am	Registration and Breakfast	
08.30 - 08.35 am	**Opening Ceremony and Introduction**	
08.35 - 08.45 am	**Welcome Speech with an Introduction of ComplianceOnline & Summit** **Gunjan Sinha,** Executive Chairman, MetricStream	
08.45 - 09.10 am	**Medical Devices and the Future of Outcomes Centricity** **Peter Pitts,** Chief Regulatory Officer, Adherent Health, LLC.	
09.10 - 09.40 am	**FDA Enforcement – Outlook & Implications -** Panel Discussion **Darin Oppenheimer** Director Global Regulatory Affairs, Baxter Healthcare **Rick Williams (Moderator)** Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics **Virginia A. Lang, PhD,** President & Chief Scientist, HirLan, Inc. **Angela Bazigos,** CCO, Morf Media Inc	
09.40 - 10.10 am	**Benefit-Risk: Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions** **Robin Newman,** Director, Office of Compliance, Center for Devices and Radiological Health, FDA	
10.10 - 10.30 am	**Sponsorship & Speaking Opportunities**	
10.30 - 10.50 am	**Digital Health and Medical Devices** **Scott Phillips,** President, Starfish Medical	
10.50 - 11.05 am	Networking Coffee/Tea Break	
11.05 - 11.20 am	**Sponsorship & Speaking Opportunities**	
11.20 - 11.50 am	**CDRH 2016-2017 Priorities**	
11.50 - 12.10 pm	**Medical Device Cyber Security (Remote)**	
12:10 - 12:30 pm	**Sponsorship & Speaking Opportunities**	
12:30 - 01:30 pm	Lunch Break	
	TRACK A - SESSIONS	**TRACK B - SESSIONS**
01:30 - 01:50 pm	**3-D Printed Medical Devices - Next?** **FDA Professional Invited**	**Interoperable Medical Devices and Connected Medical Networks** **Geetha Rao,** CEO, Springborne Lifesciences
01:50 - 02:20 pm	**Critical to Quality - What's Under the Hood**	**Risk Management for Medical Devices - Workshop** **Stan Mastrangelo** Professor, Center for Applied Health Sciences, Virginia Tech University
02:20 - 02:30 pm	**Incorporating Lessons Learned from Recalls and Audits** **Darin Oppenheimer** Director Global Regulatory Affairs, Baxter Healthcare	**Implementation of Combination Product cGMP Final Rule** **Terri Jollymour** Sr. Director, Operations Readiness & Convergence Johnson & Johnson
02:30 - 02:50 pm	**Onward to Approval: Documenting Development for Regulatory Compliance** **Brian Shoemaker, Ph.D.** Principal Consultant, ShoeBar Associates	**QbD & Design Controls** **Susan Neadle,** Sr. Director, Janssen Pharmaceuticals
02: 50 - 03:05 pm	Networking Tea/Coffee Break	
03:05 - 03:25 pm	**Sponsorship & Speaking Opportunities**	
03:25 - 04:00 pm	**Panel Discussion with FDA Speakers**	
04:00 - 04:15 pm	Closing Mark - Next Day Plan	

AGENDA

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 - 08:55 am	**FDA Data Integrity Program** **Linda Godfrey,** Deputy Director, Division of Bioresearch Monitoring, Office of Compliance, CDRH
08:55 - 09:25 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
09:25 - 09:45 am	**Sponsorship & Speaking Opportunities**
09.45 - 10.05 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
10.05 - 10.25 am	**Implementing the New Usability Engineering Standard**
10.25 - 10:35 am	Networking and Coffee/Tea Break
10:35 - 10:50 am	**Sponsorship & Speaking Opportunities**
10:50 - 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	**The End of Clinical Equivalency in the EU!** **Orlando Padilla,** President & CEO, Pathway Medical Device International
12:30 - 01:30 pm	Lunch Break

	TRACK A - SESSIONS	TRACK B - SESSIONS
01:30 - 01:50 pm	**FDA Data Developed to Improve Product Quality** **FDA Professional Invited**	**Early R&D best practices from concept to first in human studies.** **Fletcher Wilson,** CEO InterVene, Inc
01:50 - 02:10 pm	**New Methods of Driving Compliance Through Innovation** **Martyn Gross,** CEO, Skylit Medical	**FDA Quality Metrics Update** **Angela Bazigos** CCO, Morf Media Inc.
02:10 - 02.30 pm	**How To Prepare a Medical Device CE Marking Submission- Workshop** **Larry Spears,** President, L.Spears Consulting LLC, Ex-FDA Official	**Medical Device Patents and Your Strategy** **Mark Faupel** CEO, Guided Therapeutics inc.
02:30 - 02:50 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.
02:50 - 03:05 pm	Networking Coffee/Tea Break	
03:05 - 03:25 pm	**Sponsorship & Speaking Opportunities**	
03:25 - 04:00 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	
04:00 - 04:10 pm	Closing Remarks & Certifiactes	

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

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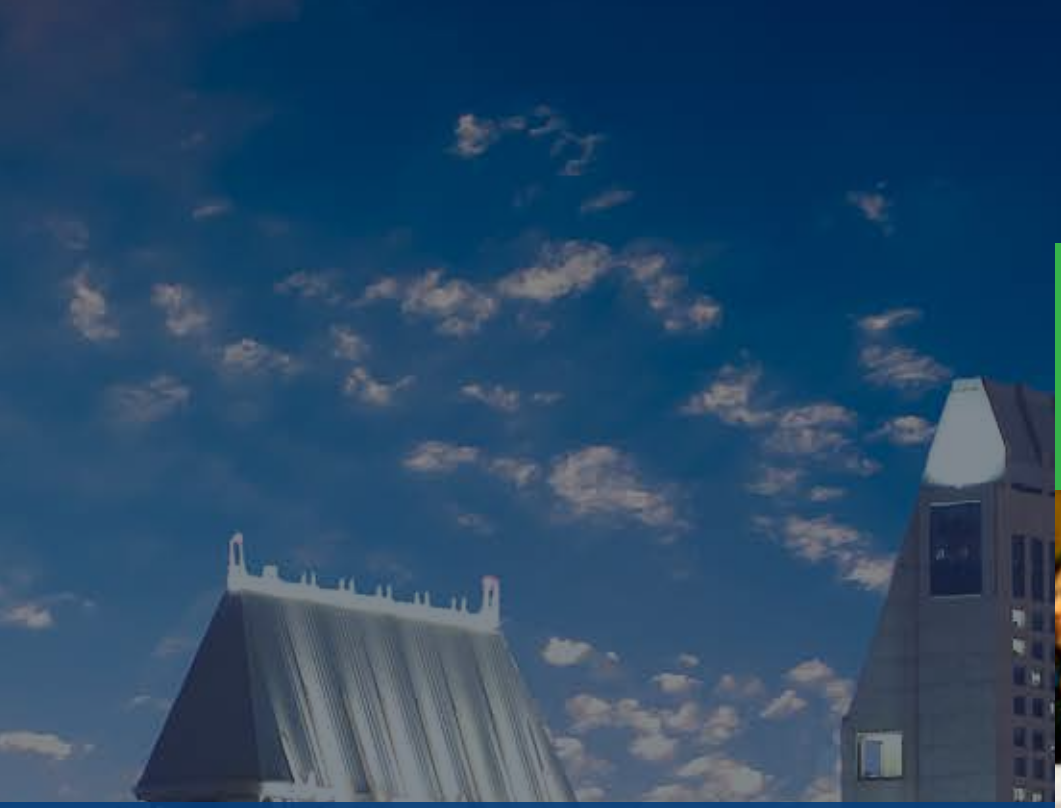

ComplianceOnline Summit Experience

VENUE

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

September 15-16, 2016