



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



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MEDIA PARTNERS



Speakers from FDA



Ron Brown
 Branch Chief for
 Medical Device Recalls,
FDA



Marisa White
 Deputy Director, Division of
 Bioresearch Monitoring,
 Office of Compliance,
CDRH



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



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



Bakul Patel
 Associate Center Director for
 Digital Health at,
FDA

Experts from Industry



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



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



French Caldwell
 Chief Evangelist, **MetricStream**



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



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



Rohit Bedi
 Senior Vice President of Partnerships, **MetricStream**



Minda Wilson
 Founder, **Affordable Healthcare Review**



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



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



Patrick Rousche
 Co-Founder and Chief Scientific Officer, **Hemotek Medical, Inc**



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



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



Geetha Rao
 CEO, **Springborne Lifesciences**



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



Scott Phillips
 President, **Starfish Medicals**



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



Andrew Pfeifer,
 Account Executive, **REED TECH**



Bahaa Moukadam
 CEO, **SeeMetrics Partners**



Angela Bazigos,
 CEO, **TouchStone Technologies Silicon valley**

DAY 01 - SEPTEMBER 15, 2016

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| 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 Rohit Bedi , Senior Vice President of Partnerships, 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 Rick Williams (Moderator) Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics Marisa White , Deputy Director, Division of Bioresearch Monitoring, Office of Compliance, CDRH Virginia A. Lang, PhD , President & Chief Scientist, HirLan, Inc. Angela Bazigos , CEO, TouchStone Technologies Silicon valley |
| 09:40 - 10:20 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 |
| 10:20 - 10:40 am | UDI Granular Interpretation & Road Ahead Andrew Pfeifer , Account Executive, REED TECH (Gold Sponsor) |
| 10:40 - 11:10 am | Digital Health and Medical Devices Scott Phillips , President, Starfish Medical |
| 11:10 - 11:25 am | Networking Coffee/Tea Break |
| 11:25 - 12:05 pm | Medical Device Recall and Complaint Management Ron Brown , Branch Chief for Medical Device Recalls, FDA |
| 12:05 - 12:30 pm | Medical Device Cyber Security (Remote) Seth D. Carmody, Ph.D. , Cybersecurity Project Manager, CDRH |
| 12:30 - 01:30 pm | Lunch Break |

TRACK A - SESSIONS

TRACK B - SESSIONS

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| 01:30 - 02:00 pm | Getting Non-dilutive Funding via SBIR Government Grants for Medical Device Development Patrick Rousche , Co-Founder and Chief Scientific Officer, Hemotek Medical, Inc | Interoperable Medical Devices and Connected Medical Networks Geetha Rao , CEO, Springborne Lifesciences |
| 02:00 - 02:40 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 |
| 02:40 - 03:00 pm | Networking Coffee/Tea Break | |
| 03:00 - 03:30 pm | Wearable Devices (Remote) Bakul Patel , Associate Center Director for Digital Health at FDA | |
| 03:30 - 04:10 pm | Risk Management for Medical Devices - Workshop Stan Mastrangelo , Professor, Center for Applied Health Sciences, Virginia Tech University | |
| 04:10 - 04:30 pm | Closing Remark - Next Day Plan | |

DAY 02 - SEPTEMBER 16, 2016

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| 08:00 - 08:30 am | Registration and Breakfast |
| 08:30 - 09:00 am | FDA Data Integrity Program Marisa White , Deputy Director, Division of Bioresearch Monitoring, Office of Compliance, CDRH |
| 09:00 - 09:30 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 French Caldwell , Chief Evangelist, MetricStream Angela Bazigos (Moderator) , CEO, TouchStone Technologies Silicon valley Bahaa Moukadam , CEO, SeeMetrics Partners |
| 09:30 - 10:00 am | FDA Upcoming Electronic Submission Process Ron Brown , Branch Chief for Medical Device Recalls, FDA |
| 10:00 - 10:30 am | Medical Device Recall and Complaint Management Ron Brown , Branch Chief for Medical Device Recalls, FDA |
| 10:30 - 10:55 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 |
| 10:55 - 11:10 am | Networking Coffee/Tea Break |
| 11:10 - 11:40 am | How Patent and Regulatory Exclusivity can Protect Your Business Michael Weickert , Strategic & Entrepreneurial Executive, Trail-blazing Leadership in Biotech, Medical Device & Pharmaceutical Business |
| 11:40 - 12:15 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 French Caldwell , Chief Evangelist, MetricStream Michael Weickert Strategic & Entrepreneurial Executive, Trail-blazing Leadership in Biotech, Medical Device & Pharmaceutical Business |
| 12:15 - 12:45 pm | Future Trends in Healthcare and How You Can Profit From Them Minda Wilson , Founder, Affordable Healthcare Review |
| 12:45 - 01:45 pm | Lunch Break |

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 | The New Off-Label Peter Pitts , Chief Regulatory Officer, Adherent Health, LLC | FDA Quality Metrics Update Angela Bazigos CEO, TouchStone Technologies Silicon valley |
| 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 Coffee/Tea Break | |
| 03:25 - 04:00 pm | Vendors/Suppliers - Are You Choosing them Right? - Panel Discussion Angela Bazigos (Moderator) CEO, Touch Stone Technologies Silicon valley Peter Pitts , Chief Regulatory Officer, Adherent Health, LLC. Daphne Walmer , Thought Leader/Expert/Consultant in Medical Device Labeling and Technical Communications | |
| 04:00 - 04:15 pm | Closing Remarks & Certificates | |

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Summit: 2nd Annual ComplianceOnline Medical Device Summit 2016

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

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