

24th Annual Meeting

Ritz Carlton Hotel

New Orleans

3rd – 5th May 2017





New Orleans Meeting Agenda

Ritz Carlton Hotel – New Orleans

3rd – 5th May 2017

Wednesday 3rd May

1:30 – 3:30 pm

FDA Refresher Workshop – Workshop Contributors:

Casper Uldriks, Esq.

Jim Goldner

Rob Kerwin, Esq.

Topics include:

- Surviving and Benefiting from an FDA Inspection
- Compliance Management Systems
 - Key elements of successful quality management and why you must adopt
 - Managing Post-Market Cyber Security Vulnerabilities

6:30 pm

Reception and dinner – on the Terrace @ Ritz Carlton



Casper Uldriks, Esq.
Encore Insight, LLC



Jim Goldner
President, First Source
IAMERS Treasurer &
Legislative Chairman



Robert Kerwin, Esq.
IAMERS General Counsel

Thursday 4th May

8 am	Breakfast
9 am	Welcome
9:15 am	<i>Keynote Address</i> – Dr. William Maisel, FDA, Chief Scientist and Deputy Center Dir.
10 am	<i>Medical Device Adverse Event Reporting</i> – Mark Bruley, CCE, ECRI Institute
11 am	<i>Best Practices Protocols / Update on Quality Management Systems</i>
12:15 pm	Lunch
1:15 pm	<i>Legislative & Regulator Developments</i> – Rob Kerwin, Esq. <ul style="list-style-type: none">• 21st Century Cures Act• Medical Device Excise Tax Repeal Possibilities• FDA Docket on Refurbishing and Servicing
2 pm Weber	<i>Straight Forward & Simple Tips on Quality Management Systems</i> – Mark
3 pm	<i>“Maximizing the value of your business: The secrets of private equity.”</i> – David Trogden, Probo Medical
4 pm	Meeting adjourns for the day
7 pm	Reception & Dinner at Broussard’s



Friday 5th May

8:15 am	Breakfast
9:15 am	<i>Cyber Scans Targeting Your Company</i> – FBI/New Orleans Cyber Squad – Special Agent James Ridder
10:15 am	<i>2017 Challenges for Your Business</i> – Casper Uldriks, Esq.
11:15 am	IAMERS Business Meeting including Code of Ethics Changes
12 noon (est.)	Program adjourns

Faculty @ 2017 IAMERS Annual Meeting in New Orleans

William H. Maisel, MD, MPH – FDA



William H. Maisel, MD, MPH is Chief Scientist and Deputy Center Director for Science at FDA's Center for Devices and Radiological Health (CDRH). He is also currently Acting Director of the CDRH Office of Device Evaluation. He is responsible for providing leadership in the development, implementation, execution, management and direction of the Center's broad national and international biomedical science programs.

Prior to joining FDA, Dr. Maisel was Associate Professor of Medicine at Harvard Medical School with more than 15 years of clinical experience as a Board-certified cardiologist.

He is former Chair of the FDA Circulatory System Medical Device Advisory Committee and is a former member of the Center for Medicare and Medicaid Services Coverage Advisory Committee. Dr. Maisel received his undergraduate degree in biology from MIT, his medical degree from Cornell Medical College, and his Masters in Public Health from the Harvard School of Public Health.

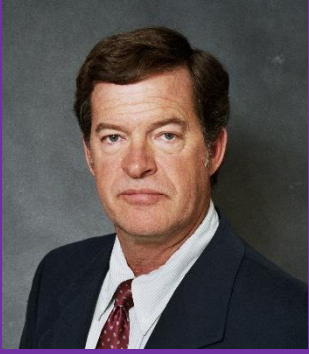
Mark Bruley, VP – ECRI



Mr. Bruley, is a biomedical engineer and Vice President for Accident and Forensic Investigation at ECRI Institute in suburban Philadelphia. Patient safety with medical devices has been the focus of his work for more than 40 years. He frequently lectures and consults on medical device safety and medical device accident investigation. He has lectured or taught on healthcare technology topics at more than 270 domestic and international venues. Publications by Mr. Bruley include more than 160 articles and book chapters. The Joint Commission, state departments of health, the FDA, standards committees, and professional societies have relied on Mr. Bruley for his expertise for decades. He will summarize ECRI's analysis of injuries and deaths related to refurbishing, reconditioning, rebuilding, etc., that was presented at the October 2016 FDA workshop on those activities.

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Mark Weber



Mark Weber offers consulting services to small and medium size organizations that are seeking ISO registration of their quality systems. He has extensive "hands-on" experience in procedure and document development, auditing, employee training, and day to day implementation issues that face companies involved in the registration process. Mark has taken multiple and diverse facilities to ISO 9001, ISO14001, AS 9100 and ISO 13485 registration since 1993.

He is certified by The Institute of Quality Assurance, International Register of Certificated Auditors as a Quality System Lead Auditor, with auditing experience in both manufacturing and service-type industries.

David Trogden, President – Probo Medical



David Trogden is the President of Probo Medical, a refurbished ultrasound equipment and probe repair company. Based in Indianapolis, Probo has gone from startup to over 50 employees in under 3 years. Prior to founding Probo, David spent 10 years in private equity, acquiring and growing small businesses. In 2008, David was part of a private equity group that acquired Ultra Solutions, an ultrasound equipment reseller. David ultimately ran that business through a successful exit in 2013. David will speak on the secrets of private equity and how they evaluate companies in the medical equipment repair, parts, service, and remarketing industry”.

Casper Uldriks, Esq., President, Encore Insight, LLC

Jim Goldner, President, First Source

Rob Kerwin, Esq., IAMERS General Counsel

James Ridder, FBI Cyber Squad



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diana@iamers.org