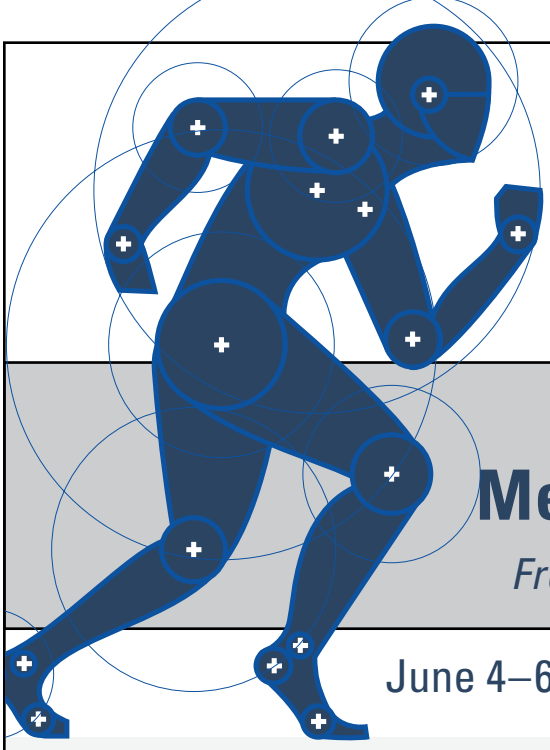

Three-day conference and workshop presented by **FDAnews**

Featuring more than 12 in-depth sessions headed up by leading quality experts, including sessions led by 5 FDA officials

Tenth Annual Medical Device Quality Congress

From Risk Management to Postmarket Surveillance

June 4–6, 2013 • Doubletree Bethesda Hotel • Bethesda, MD

Now in its tenth year, this year's three-day conference and workshop is the must-attend event of 2013 for medical device quality professionals.

This year's agenda features:

Current FDA confirmed speakers —

Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA

Jay Crowley, Senior Advisor for Patient Safety, CDRH, FDA

Ron Brown, Chief, Recall Branch, Division of Risk Management Operations, Office of Compliance, CDRH, FDA

Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA

Victoria Schmid, Consumer Safety Officer, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA

Former FDA confirmed speakers —

- **Elaine Messa**, Executive Vice President, Becker & Associates; former Director of the Los Angeles District, FDA (Co-Chair)
- **Steve Niedelman**, Lead Quality Systems and Compliance Consultant, FDA & Life Sciences Practice, King & Spalding; former Deputy Associate Commissioner for Regulatory Affairs and Chief Operating Officer of the ORA, FDA (Co-Chair)
- **Phil Phillips**, President, Phillips Consulting Group; Former Deputy Director, Office of Device Evaluation, CDRH, FDA
- **Heather Rosecrans**, Senior Regulatory Advisor, Greenleaf Health; Former Director of the 510(k) Pre-Market Notification Program, CDRH, FDA
- **Martin Browning**, President and Co-Founder, EduQuest; Former local, national, and international expert investigator, Special Assistant to the Associate Commissioner for Regulatory Affairs, Vice Chair of the Electronic Record and Signature Working Group, which drafted the 21 CFR Part 11 regulations
- **Janis Olson**, Vice President of Quality and Regulatory Services, EduQuest; Formerly supervisor in the FDA Atlanta District

Three in-depth panel discussions focusing on the hottest aspects of medical device quality. This year's panels include:

- **UDI Rule** — What Does It Mean for You? Featuring Jay Crowley, Senior Advisor for Patient Safety, CDRH — FDA's point person on UDI
- **FDASIA Shakes Up 510(k) Landscape**; Featuring former deputy director of ODE and former director of Office of 510(k) Pre-Market Notification
- **Overcome the Pitfalls of Design Control**; Led by internationally renowned device expert Dan O'Leary

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PRE-CONFERENCE WORKSHOP: TUESDAY, JUNE 4, 2013

8:30 a.m. – 9:00 a.m.
Registration and Continental Breakfast

9:00 a.m. – 12:00 p.m. Writing for Compliance: Approaches and Methods for Writing High-Impact, Persuasive Compliance-Related Documentation within FDA-Regulated Companies

Despite being one of the most regulated industry sectors in the world, attention to and development of even basic writing practices within most FDA-regulated organizations is almost nonexistent. With extensive requirements for bulletproof communication of complex technical and scientific concepts, and documentation required for almost every operational activity, highly technical personnel struggle to write to the appropriate audiences, and to choose the proper writing styles and techniques to effectively support their day-to-day business objectives.

Even more striking is that many documents are never written with the anticipation and knowledge that an FDA inspector will likely read them in the future and use these documents as part of the overall determination of the organization's compliance profile.

Now, John C. (Jack) Garvey, Esq., Founder and Principal of Compliance Architects®, has developed an introductory workshop to help participants apply a collection of writing tools to achieve improved compliance outcomes within FDA-regulated companies. Based on his experiences of more than 25 years in the industry, Mr. Garvey will apply long-established writing principles to common writing challenges within FDA-regulated companies and help participants understand:

- The first question you must ask and answer before you engage in a writing activity
- How to analyze your audience(s) to obtain the proper tone and voice for the writing
- What one basic writing structure should be applied to all CAPA investigations
- Which styles are necessary for different document types, including which should be the dominant style and how and where to include other styles
- What one principle lawyers apply to create powerful persuasive writing regardless of the soundness of their case
- The role of technical information within a document, and how this information should be presented

In addition, given the importance the FDA places on CAPA, Jack will spend considerable time on techniques and approaches for improving the documentation of CAPAs, nonconformances, and other investigation and product analysis events.

John (Jack) Garvey, Esq., Founder and Principal, Compliance Architects®

12:00 p.m. – 1:00 p.m. Lunch

CONFERENCE AGENDA: TUESDAY – THURSDAY, JUNE 4-6, 2013

DAY ONE

1:00 p.m. – 1:15 p.m.
Welcome and Introduction — Co-chair Steven Niedelman, King & Spalding

1:15 p.m. – 2:00 p.m.
Update on International Medical Device Regulators Forum's Medical Device Single-Audit Program (MDSAP)

The FDA's head of an important new working group will give you a fresh insider's take on the standard requirements it will demand of auditors of medical device manufacturers' quality management systems. The group's final document will help establish a single audit program. So far, so good. But the devil will be in the details. How will these changes impact the way you do business? Where and when should you weigh in to make certain your concerns are heard? A single-audit program can go in a lot of directions. In this session, you'll hear the latest developments and get a better understanding of how to make this work for you.

Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA

2:00 p.m. – 3:30 p.m.
Panel Discussion: UDI Rule— What Does It Mean for You?

The Office of Management and Budget (OMB) released the FDA's proposed rule on unique device identification (UDI) system in 2012 ending a nearly year-long delay in finalizing the much-anticipated safety mechanism. The UDI itself will have two components: the device identifier, which is analogous to a National Drug Code and differentiates between packaging; and the production identifier, which primarily uses serial numbers and lot numbers as control mechanisms. This panel will discuss:

- What the FDA expects from devicemakers
- Deadlines for implementation by product class
- How to integrate UDI into your existing supply chain operations
- Unexpected implications of UDI for small/mid-sized device companies

Moderator: Elaine Messa, Executive Vice President, Becker & Associates

Panelists:
Jay Crowley, Senior Advisor for Patient Safety, CDRH, FDA
Dan O'Leary, President, Ombu Enterprises
Jackie Rae Elkin, Global Process Owner, Medtronic
Rosalind Parkinson, Chief Supply Chain Officer, The Ohio State University Wexner Medical Center

3:30 p.m. – 3:45 p.m. Refreshment Break

3:45 p.m. – 4:30 p.m.
Survival Guide for Quality System Remediation

Managing quality system improvements and remediation related to 483s, warning letters, or consent decrees can be a daunting task for any company. There are many aspects of your approach that need to be carefully managed and the decisions that you make will affect the validity and quality of outcomes. There are a number of things that companies struggle with such as: whether or not to use their CAPA system; how and when to do look backs; how do you or should you involve third party experts from outside your company. This presentation will walk you through considerations and approach using practical examples.

What will attendees learn:

- Things to consider when determining approach for use of the CAPA system, managing look backs, determining when interim mitigation or controls are needed
- Things to consider when determining use of internal versus external resources

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- How do you communicate with the FDA and handle the legal aspects
- How to manage implementation of quality system solutions
- Managing preparation for the inevitable FDA re-inspection

Julie Larsen, Director Inspection Readiness Services, BioTeknica

4:30 p.m. - 6:00 p.m.
Panel Discussion: FDASIA Shakes Up 510(k) Landscape

The sweeping FDASIA is rewriting the 510(k) rule book — again. You'll like some of the changes; others not so much. This panel of experts will show you how to leverage new ways to secure supervisory review of adverse decisions, why the de novo application process modification will help manufacturers of low-to-moderate risk devices, and where FDASIA actually makes it much easier to reclassify a device — minus the pile of paperwork it once required.

Moderator: Steve Niedelman, Lead Quality Systems and Compliance Consultant, FDA & Life Sciences Practice, King & Spalding

Panelists:
Phil Phillips, President, Phillips Consulting Group; Former Deputy Director, Office of Device Evaluation, CDRH, FDA
Heather Rosecrans, Senior Regulatory Advisor, Greenleaf Health; Former Director of the 510(k) Pre-Market Notification Program, CDRH, FDA
Laurie Clarke, Partner, King & Spalding

6:00 p.m. – 7:00 p.m. Networking Reception

DAY TWO

8:30 a.m. – 9:00 a.m. Continental Breakfast

9:00 a.m. – 9:15 a.m.
Welcome and Introduction — Co-chair Elaine Messa, Becker & Associates

9:15 a.m. – 10:00 a.m.
FDA's Tips on Preventing Recall Disasters

The prospect of a recall keeps most medical device manufacturers up at night. The costs…the public relations black eye…the angry board…The plummeting stock price. In this session, you'll get proven tips and tactics to help you better understand FDA's postmarketing requirements for medical device reports (MDRs), what the agency considers an effective change control program, and how to balance risk with FDA expectations in mind.

Ron Brown, Chief, Recall Branch, Division of Risk Management Operations, Office of Compliance, CDRH, FDA

10:00 a.m. – 10:45 a.m.
Best Practices in Implementing an Effective Risk Management System

As technologies and innovation push the boundaries for new medical devices, there is an increased emphasis and expectation that such devices shall be free from unacceptable risk to the patient and end-user. In addition, several recent standards and guidance documents point to ISO 14971:2007 as the standard for medical device risk management. An effective risk management strategy has thus become a necessity for medical device manufacturers.

Attendees will learn:
- Organizational factors that lead to an effective risk management system
- How companies integrate their product life-cycle processes with risk management
- What constitutes an effective risk management file
- Methods companies use to review, validate and improve their risk management systems
- What companies need to do to address the 2012 changes to ISO 14971:2007

Vinny Sastri, President, Winovia LLC

10:45 a.m. – 11:00 a.m. Refreshment Break

11:00 a.m. – 12:30 p.m.
The MDR Challenge — Test Your Adverse Event Reporting Expertise

The audience will be challenged with an interactive session on the reporting requirements of 21CFR Part 803, Medical Device Reporting. Three case studies will be used to engage the audience in a debate on proper reporting requirements. Each exercise will conclude with a summary of expert opinions.

Attendees will learn:
- Requirements for MDRs on events occurring outside the US
- Reporting requirements when no injury has occurred
- Number of reports to file when there are multiple occurrences
- What to do in "User Error" situations

Michael Crader, President, Matrix Resource Solutions, LLC1

Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA

Victoria Schmid, Consumer Safety Officer, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA

12:30 p.m. – 1:30 p.m. Lunch

1:30 p.m. – 2:15 p.m.
How to Effectively Present Your Complaint and Adverse Event Files to the FDA and Reduce Your Risk of a 483

FDA inspections for any class device will always review complaints and adverse event files. It is critical to have well-documented files and the ability to present these to the investigator in a manner that is clear and concise. This presentation will review contents for your files (including what not to include in your files!) and discuss how to present this information to the FDA in a truthful and effective manner.

Attendees will learn:
- The importance of the truth — how to present files that provide an accurate picture of your product
- What to include — and NOT include — in your complaint files and adverse event files
- Understanding when too much information becomes dangerous
- The importance of trending — and why the FDA is focusing on your ability to properly trend complaints and AERs
- Top 10 complaint file red flags

Connie Hoy, Vice President, RA/QA, Cutera (invited)

2:15 p.m. – 3:00 p.m.
Mobile Health Revolution: Emerging Regulation, Risks, and Rewards

A growing network of federal and state authorities — such as FDA, FTC, FCC, and California — are regulating and taking enforcement action in the mobile health arena. This presentation will explore key developments in mobile health technology, provide insights into the complex web of regulation, guidance, and enforcement that is shaping mobile health, and provide recommendations for moving forward in this rapidly changing environment.

Marian Lee, Partner, King & Spalding

3:00 p.m. – 3:15 p.m. Refreshment Break

3:15 p.m. – 5:15 p.m.
Panel Discussion: Overcome the Pitfalls of Design Control

Design control is required for most medical devices sold in the U.S. In addition, other regulatory venues, such as the EU and Canada, require design control for all devices. As postmarket surveillance demonstrates, many device problems result from design control deficiencies. Discover how to overcome one of the biggest obstacles device manufacturers face — how the FDA expects you to develop and implement design controls, then transfer product design to manufacturing operations.

Moderator: Dan O'Leary, President, Ombu Enterprises
Panelists to Be Announced

5:15 p.m. – 5:30 p.m.
Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

o Postmarket Surveillance

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NEW FOR 2013!

FDA EXPECTATIONS FOR MANAGING AND AUDITING SUPPLIER QUALITY
FULL DAY TRAINING SESSION: THURSDAY, JUNE 6, 2013

In December 2012, the FDA proposed the creation of a new Division of International Compliance Operations within CDRH's Office of Compliance as part of the center's increased international supply chain focus. Domestic — and overseas — inspections are also ramping up amid mushrooming international component sourcing and overseas contract manufacturing.

In light of these new changes, FDAnews and EduQuest have joined forces to present, FDA Expectations for Managing and Auditing Supplier Quality. This full-day, in-depth training session will significantly improve your supplier management program and avoid 483s, warning letters and potential patient injuries.

Expert Instructors:

Martin Browning, President and Co-Founder, EduQuest

Janis Olson, Vice President of Quality and Regulatory Services, EduQuest

8:00 a.m. – 8:30 a.m. Continental Breakfast

8:30 a.m. – 10:30 a.m.
The Big Picture: FDA and ISO Requirements for Managing Suppliers

- Why supplier management is a high priority at FDA
- FDA's regulatory authority and enforcement tools
- Interrelationship of ISO and FDA requirements
- Introduction to FDA's 7 subsystems of a compliant Quality System

Role of a Quality System in Managing Suppliers

- Crucial elements your Quality System must include
- Quality management principles under ISO
- Definitions of key terms and concepts
- Incorporating suppliers into your CAPA program

10:30 a.m. – 10:45 a.m. Coffee/Refreshment Break

10:45 a.m. – 12:30 p.m.
Integrated Auditing Techniques

- Differences between auditing and monitoring – know which is appropriate when
- Setting realistic goals and strategies for supplier quality audits
- Linking the mindset of FDA inspectors with your auditing SOPs and techniques
- Objective Evidence: recognizing the gold standard of auditing and compliance

Tips and Requirements for Auditing Management Control

- Management responsibility and reviews: the core of FDA expectations
- What to include in your quality policies and procedures
- Role of internal audits…and the critical importance of audit follow-up
- Examples of FDA warning letters citing management control failure

12:30 p.m. – 1:30 p.m. Lunch Break

1:30 p.m. – 3:00 p.m.
Tips and Requirements for Auditing CAPAs and Nonconformances

- What the FDA looks for in your CAPA system
- Potential sources of CAPA information
- Auditing nonconforming materials, complaints and MDRs
- Examples of FDA Warning Letters citing CAPA and root cause investigation failures

Tips and Requirements for Auditing Production and Process Control

- Importance of Device Master Records and Device History Records for effective design transfer
- FDA expectations for process control and validation
- How responsible are you for ensuring adequate training at your suppliers?
- Examples of FDA Warning Letters citing Process Control failures

3:00 p.m. – 3:15 p.m. Snacks/Refreshment Break

3:15 p.m. – 5:30 p.m.
Tips and Requirements for Auditing Records, Documents and Change Control

- FDA rules for electronic records and signatures
- Expectations for validating computerized systems
- Critical importance of audit trails
- Examples of FDA Warning Letters citing documentation and change control failures

Tips and Requirements for Auditing Materials Control

- Documenting supplier status and establishing purchasing SOPs
- Acceptance activities: ensuring incoming products meet specifications
- Traceability: documenting units, lots and batches
- FDA expectations for materials shipping, labeling, handling and storage
- Examples of FDA warning letters citing Materials Control failures

Regulatory Enforcement: The Consequences of Noncompliance

- Helping your suppliers prepare for an inspection or audit
- Can you shield your audit reports from the FDA?
- Responding to 483s and warning letters
- Latest FDA enforcement priorities and targets

5:30 p.m. Conference Adjournment

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WHAT YOUR COLLEAGUES HAVE TO SAY

"The speakers, topics and content continue to make this conference one of the best for medical device industry professionals. This is the one conference you'll want to keep in your budget."

PAUL ARRENDELL, Vice President, Global Quality Systems,
Wright Medical Technology, Inc.

"I believe that attending this conference was well worth the time expenditure. Great participation, knowledgeable and articulate speakers. I will make this annual offering a must!"

KAREN KIRBY, Compliance Manager,
Baxter Healthcare

"It was great to have such knowledgeable personnel available for three days to ask questions and have discussions."

DIANE ADINOLFO, QA Project Compliance Manager,
DEKA Research and Development

WHO SHOULD ATTEND

- Quality Assurance/Quality Control
- Manufacturing and Contracting
- Supply Chain Management
- Risk Management and Product Lifecycle Management
- Executive Management
- Regulatory Affairs
- Research and Development
- Compliance Officers
- Consultants/Service Providers

ABOUT THE CONFERENCE CO-CHAIRS

STEVEN NIEDELMAN serves as lead quality systems and compliance consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters involving industries regulated by the FDA. Mr. Niedelman retired from the Food and Drug Administration in 2006 after a 34-year distinguished career, where he served as the Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs.

ELAINE MESSA is Executive Vice President at Becker & Associates Consulting, Inc. She has more than 30 years of experience in FDA regulation of medical devices, having focused on the development and implementation of compliant Quality Systems for medical devices in the United States. Her most recent position was as the FDA's Director of the Los Angeles District, which is the district responsible for the largest import operations and medical device workload in the US. In total, Ms. Messa spent nearly 16 years in management positions within FDA district offices.

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To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **Tenth Annual Medical Device Quality Congress** to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rate, and space is limited. The hotel may run out of rooms before the reservation cutoff date. The discounted rate is also available one night before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 24 hours of the date of arrival or "no-shows" will be charged for the first night's room rate plus tax.

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TUITION

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CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 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 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews 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.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call (888) 838-5578 for details.

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☑ **YES!** I want to attend **Tenth Annual Medical Device Quality Congress: *From Risk Management to Postmarket Surveillance*** on June 4–6, 2013 at Doubletree Bethesda Hotel, Bethesda, MD.

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	Early Bird Fee through April 26, 2013	No. of Attendees	Regular Fee April 27 – June 6, 2013	No. of Attendees
Preconference Workshop Only	$497		$597	
FDA Expectations for Managing and Auditing Supplier Quality Full Day Training Session	$997		$1197	
Medical Device Quality Congress (MDQC) Only	$1447		$1697	
Preconference Workshop + MDQC	$1697		$1997	
MDQC + FDA Expectations for Managing and Auditing Supplier Quality Full Day Training Session	$2197		$2597	
Preconference Workshop + MDQC + FDA Expectations for Managing and Auditing Supplier Quality Full Day Training Session	$2547		$2997	
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