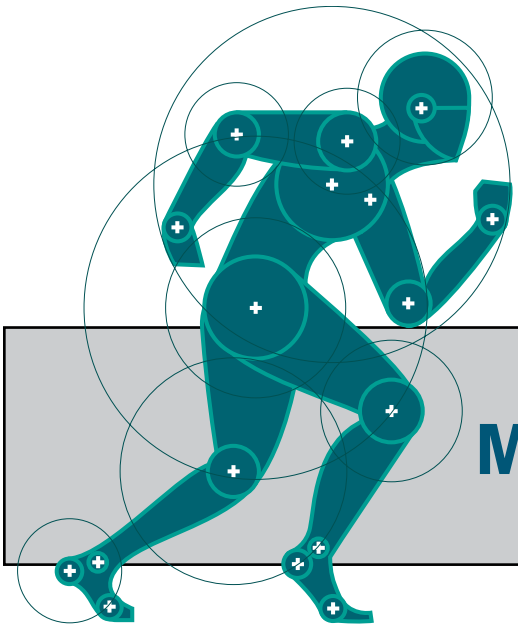

Three-day conference and workshop presented by **FDAnews**

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

Eleventh Annual Medical Device Quality Congress

Managing the "Big Five" Quality Concerns

June 24–26, 2014 • Marriott Bethesda North Hotel & Conference Center • Bethesda, MD

Now in its eleventh year, this year's three-day conference and workshop is the must-attend event of 2014 for medical device quality professionals.

This year's agenda features:

Current FDA Speakers —

Keynote Speaker
Steve Silverman, Director, Office of Compliance, CDRH, FDA

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

Jay Jariwala, Quality System Specialist, Regulatory Compliance Officer, CDRH, FDA

Bill MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA (invited)

Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA (invited)

Sharon Kapsch, Branch Chief, Reporting Systems, Office of Surveillance and Biometrics, CDRH, FDA (invited)

Ann Ferriter, Director, Division of Risk Management Operations, CDRH, FDA (invited)

Jan Welch, Deputy Director for Regulatory Affairs, OC, CRDH, FDA (invited)

Tony Slater, Chief, Field Inspections Support Branch, Division of Analysis Program Operations, OC, CDRH (invited)

Expert Speakers —

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations (Co-chair)

Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA (Co-chair)

Jay Crowley, Vice President and Practice Lead – UDI, USDM Life Sciences; former Senior Advisor for Patient Safety, CDRH, FDA

Vinny Sastri, President, WINOVIA

Dan O'Leary, President, Ombu Enterprises LLC

Karl Vahey, Director of Compliance, International RA/QA, Covidien

Oluwole Edwin, Executive Director, Diagnostic Products, Quest Diagnostics

Patrick Caines, Director, Product Surveillance, GE Healthcare

Pamela Forrest, Partner, King & Spalding

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Heath Rushing, Principal Consultant Adsurgo LLC

Eleventh Annual Medica

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PRE-CONFERENCE WORKSHOP: TUESDAY, JUNE 24, 2014

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

9:00 a.m. – 12:00 p.m.
Harness the Power Text Mining the FDA's Recall Data to Handle Medical Device Recalls

Most pharmaceutical and medical device organizations are analyzing structured numerical (and categorical) data such clinical trials, R&D, process development, process monitoring, sales and marketing, product supply and commercial manufacturing. Structured numerical data is, well, numerous and used throughout most organizations. However, the majority of stored data is not numerical; it is in the form of unstructured text in reports and documents, such as nonconformance reports.

Nonconformance reports are written by different people in different areas of the organization; therefore, these reports often contain different words or phrases to report the same problem. The solution? Develop a document-term (word) matrix for the unstructured data. Use proven statistical tools and methods to "rank" words based on importance and frequency, then "translate" these ranked words and phrases into a "word cloud" that very often displays true root problems for systematic nonconformances. Drug and device companies can also use this information to "cluster" seeming unrelated nonconformance reports, providing a much more thorough analysis of nonconformances as part of a comprehensive CAPA program.

During this workshop, the instructor will use data taken directly from the FDA website to teach attendees how text mining can be used to determine how their products (and other products in their class) are being reported. The example used shows how analysis of recall reports from one medical device company established the words "ventilator," "infusion" and "simulator" as true root causes for one company's medical device recalls. Additionally, the instruction will show how analysis of this unstructured data may provide information on unknown trends and potential problems.

Attendees will:

- Understand how to analyze FDA recall data to narrow root causes down to key words
- Know how to develop and populate a matrix of raw data needed for text mining
- Understand how proven statistical tools and methodologies are used to perform text analytics

Your biggest data can be your best data if analyzed efficiently and correctly.

Heath Rushing, Principal Consultant, Adsurgo LLC

CONFERENCE AGENDA: TUESDAY – THURSDAY, JUNE 24-26, 2014

DAY ONE

12:00 p.m. – 1:00 p.m.
Registration

1:00 p.m. – 1:15 p.m.
Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

1:15 p.m. – 2:00 p.m.
KEYNOTE — FDA's Case for Quality Initiative Update

Reviewing and explaining often-cited 483 violations is not the only way to achieve device quality. Steven Silverman will present FDA device quality-related initiatives that move beyond the inspect-and-cite regulatory model.

Attendees will learn:

- How the Case for Quality Initiative works and how you can benefit from it
- Emerging FDA initiatives that similarly focus on device quality outcomes

Steven Silverman, Director, Office of Compliance, CDRH, FDA

2:00 p.m. – 3:30 p.m.
Panel Discussion: 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, many standards and guidance documents point to ISO 14971:2007 as the standard for medical device risk management. An effective risk management strategy, now more than ever, is 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 latest in ISO 14971:2007 enforcement — including how devicemakers are struggling with EU compliance

Moderator:
Vinny Sastri, President, WINOVIA
Panelists:
Ann Ferriter, Director, Division of Risk Management Operations, CDRH, FDA (invited)
Jan Welch, Deputy Director for Regulatory Affairs, OC, CRDH, FDA (invited)
Bill MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA (invited)
Karl Vahey, Director of Compliance, International RA/QA, Covidien

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

3:45 p.m. – 5:00 p.m.
Panel Discussion: Managing Operations Effectively: Delivering Quality Devices and Always Being Audit Ready

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. In alignment with the recent reorganization of the Office of Compliance, CDRH, the FDA will be prepared to effectively follow up and act on potentially volatile situations to reassure the public that they are providing the public health protection they expect and deserve.

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Attendees will learn:

- 5 key elements to have in place to control your manufacturing processes
- How to create an effective listening system to know how your product is performing and the steps to take when something goes awry
- How to build an effective CAPA system to take corrective action quickly when a problem arises

Moderator:
Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA
Panelists:
Tony Slater, Chief, Field Inspections Support Branch, Division of Analysis Program **Operations,** OC, CDRH (invited)
Oluwole Edwin, Executive Director, Diagnostic Products, Quest Diagnostics

5:00 p.m. – 6:30 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 by Co-chair Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA

9:15 a.m. – 10:00 a.m.
KEYNOTE — Recalls: Communicating With FDA — What are the Regulatory Requirements and Expectations?
Getting devices off the market that pose a risk to patients is always your first priority. But effectively communicating with the FDA about it is a close second. In this presentation, the chief of the Recall Branch of CDRH will guide attendees though current recall policy. Plus, provide best practices for how to effectively communicate with the FDA. This session will give you a first-hand account of what the FDA expects of you.

Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA

10:00 a.m. – 10:45 a.m.
Medical Device Recalls: Unique Challenges and Opportunities
What some devicemakers commonly call "product enhancements" the FDA might consider a recall. Recalls are defined in FDA regulations, a product enhancement is not. The FDA recently issued draft guidance that could impact your Part 806 recall efforts. The FDA was clear… devicemakers are required to file Part 806 forms if a recall, removal, correction or product enhancement was made "to reduce a risk to health posed by" the device. Even if the event was caused by user error.

Attendees will learn:

- What factors to consider to determine if you are effectively initiating a recall
- How to document the process you go through with product enhancements, servicing or removals to prove compliance
- How to create internal systems that assure you are in compliance at all times

Pamela Forrest, Partner, King & Spalding

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

11:00 a.m. – 12:00 p.m.
Design Changes Impact Multiple Parts of Your QSR System — Are You Sure You Know All The Implications?
So your company has a procedure for handling design changes — that's good news. But when you make a design change are you documenting the impact of that change on multiple of parts of your QSR system? The bad news is most likely not. From nuanced requirements found in CFR preambles to 510K requirements to QSIT to UDI one improperly considered and document change can cause a cascade of problems. This session will help you understand how your design changes and controls procedures must always be in line with the other parts of your operations.

Attendees will learn:

- The reasoning behind these requirements
- Commonly confused or unknown considerations of production related to design output and design transfer
- The CDRH evaluation of 510(k) changes, its commitment to Congress, and the implications for design control
- Some side effects of the UDI rule that will impact your implementation strategy
- How evaluation design change impact your Risk Management File

Dan O'Leary, President, Ombu Enterprises LLC

12:00 p.m. – 1:00 p.m.
Lunch

1:00 p.m. – 1:45 p.m.
Closing the Loop on Corrective and Preventive Action (CAPA): A Call to Action
CAPA problems continue to be one of the most cited FDA Form 483 deficiencies, generating the single largest number of warning letter citations. A recent industry report breaks down the FDA's 2012 inspection findings into five categories: CAPA (30 percent), production and process controls (30 percent), design problems (15 percent), management issues (14 percent) and other (11 percent). Getting CAPA right remains incredibly important. This session will discuss the importance, requirements and elements of a best-in-class CAPA program, as well as describing how to use CAPA data to help mitigate risk and drive quality in a holistic manner.

Attendees will learn:

- New and updated regulatory requirements and expectations — and how to interpret the latest warning letter enforcement trends.
- How to implement a repeatable, standardized and complete process that can tackle CAPAs and ensure compliance
- The importance of developing closed-loop systems that detect existing potential quality problems and facilitate rapid problem resolution and closure

Jay Jariwala, Quality System Specialist, Regulatory Compliance Officer, CDRH, FDA

1:45 p.m. – 2:30 p.m.
Five MDR Traps That Doom Devicemaker Inspections
FDA inspectors evaluating the adverse event reporting programs at medical device companies are finding a lot of the same problems over and over again. Additionlly the FDA commonly finds weak or missing SOPs and procedure manuals. This presentation will provide you benchmarking data and intel to determine how your organization stacks up if you're ready to pass your next FDA inspection.

Attendees will learn:

- How the agency wants you to define "likely" when assessing whether a malfunction is likely to cause or contribute to a death or serious injury if it reoccurs.
- How to address FDA inspectors' questions during on-site visits when asked what constitutes a reportable event and what does not.

Five" Quality Concerns

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- Best practices for structuring appropriate time frames and deadlines into your adverse event reporting programs.
- Why training is key to successful MDR management — how all staff should be trained. This includes anyone answering the phone. They should know what to do if it's an adverse event call.

Patrick Caines, Director, Product Surveillance, GE Healthcare

2:30 p.m. – 2:45 p.m.
Refreshment Break

2:45 p.m. – 4:15 p.m.
PANEL DISCUSSION: Understanding UDI's True Impact Throughout Your Organization
It's no exaggeration to say that the FDA's UDI rule impacts every device company and applies to multiple parts of each organization's quality systems. This is not a rule that can be overlooked. Implementation is mandated in stages over the next few years, but truth be told, many companies are nowhere near compliance. If you're like most device manufacturers, you're working your way through the regs and adapting and changing your internal processes.

This panel will discuss:

- Top challenges industry is facing as they begin to implement the regulations —standardized date format, combo product/kit concerns and more
- When to assign new device identifier and when can you re-used existing ones
- How is GUDID coming along and best practices for inputting your data — what's working and what's not
- And much more…

Moderator:
Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations
Panelists:
Jay Crowley, Vice President and Practice Lead – UDI, USDM Life Sciences; former Senior Advisor for Patient Safety, CDRH, FDA
Dan O'Leary, President, Ombu Enterprises

4:15 p.m. – 4:30 p.m.
Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY TRAINING SESSION!

SUPPLIER QUALITY MANAGEMENT TRAINING

THURSDAY, JUNE 26, 2014

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.

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

8:30 a.m. – 5:30 p.m.
Medical Device Supplier Qualification and Management — Practical Approaches to Cost-Effective Implementation
The development of extended supply chains raises major issues in risk management. While regulators are looking more closely at device supplier management issues, companies are recognizing the value of risk management in meeting the regulatory requirements.

In addition, risk management can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare by focusing on these important GHTF guidance documents:

- Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008)
- Risk Management Principles in a QMS (GHTF/SG3/N15R8)
- Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010)

These guidance documents provide the foundation, but lack practical details. This workshop gives you the tools and methods you need for a cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management — product risk, business risk, and recalls & liability risk
- How to conduct an on-site supplier audit applying risk management
- How to qualify suppliers that are virtual companies
- Understanding business issues in the supply chain and their risk challenges
- Medical device corrections & removals (recalls)
- How to select and apply supplier metrics and their role in the QMS
- Dealing with FDA record-keeping issues — sponsor vs. supplier

BONUS: Attendees will receive copies of implementation tools, including a process map, sample questionnaire, reevaluation form, audit checklist and more.

Expert Instructors:

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Dan O'Leary, President, Ombu Enterprises

5:30 p.m.
Training Adjournment

FDANEWS

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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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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **Eleventh 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.

Lodging and Conference Venue:
Bethesda North Marriott Hotel & Conference Center
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North Bethesda, MD 20852
Toll free: (800) 859-8003 • Tel: +1 (301) 822-9200
www.bethesdanorthmarriott.com
Room rate: $179 plus 13% tax
Reservation cut-off: June 2, 2014

TUITION

Complete Congress includes Conference, Training Post-session and Pre-conference workshop, written materials, three breakfasts, three luncheons and daily refreshments.

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.

FOUR EASY WAYS TO REGISTER

Online: www.MDQC2014.com
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☑ **YES!** I want to attend **Eleventh Annual Medical Device Quality Congress: *Managing the "Big Five" Quality Concerns*** on June 24–26, 2014 at Doubletree Bethesda Hotel, Bethesda, MD.

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	Early Bird Fee through May 23, 2014	No. of Attendees	Regular Fee After May 23, 2014	No. of Attendees
Preconference Workshop Only	$497		$597	
Device Supplier Quality Training Session Only	$997		$1197	
Medical Device Quality Congress (MDQC) Only	$1447		$1697	
Preconference Workshop + MDQC	$1697		$1997	
Device Supplier Quality Training Session + MDQC	$2197		$2597	
Preconference Workshop + MDQC + Device Supplier Quality Training Session	$2547		$2997	
TOTAL PAYMENT	$		$	

Attendee 1: Name _____ Title _____ Email _____

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