FDANEWS PRESENTS THE

Featuring in-depth panels and presentations by top FDA and industry experts!

12TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

with Device Supplier Quality Management Training

THE #1 EVENT FOR DEVICE QUALITY AND COMPLIANCE PROFESSIONALS

"MDQC was very good, especially around recalls and MDR's."

– Nicola Martin, Associate Director, Quality & Compliance, Covidien

"Very pleased that most speakers were directly from industry, either FDA or corporations. Good to hear directly from the source."

– Rossellen Miller, Product Development Quality Engineer, Terumo Cardiovascular

"Subject matter was very relevant. Interaction with attendees was great."

– Michael Healy, QA/QC Director, Tryton Medical

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

MARCH 17-19, 2015 | MARRIOTT BETHESDA NORTH HOTEL & CONFERENCE CENTER • BETHESDA, MD

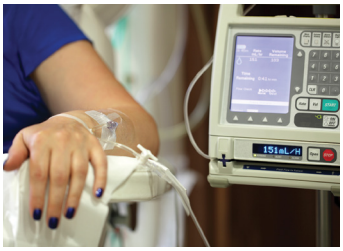
Now in its 12th year, FDAnews' **Medical Device Quality Congress (MDQC)** has become the indisputable must-attend annual quality and compliance event for medical device and diagnostics professionals. **With over 1,700 attendees since 2004, there's simply no other medical device quality event that even comes close.**

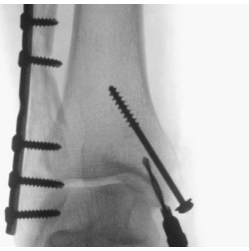
Invited FDA Speakers

- Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA
- Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA
- Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA
- Dr. Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA
- William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA
- Dr. Joni Foy, Deputy Director, Office of Device Evaluation, CDRH, FDA
- Dr. Suzanne Schwartz, Director, Emergency Preparedness/Operations and Medical Countermeasures, OCD, CDRH, FDA
- Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH

Industry Experts

- Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations (MDQC Co-chair)
- Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA (MDQC Co-chair)
- Karl Vahey, Director of Compliance, International RA/QA, Covidien
- Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx
- Patrick Caines, Director, Product Surveillance, GE Healthcare
- Paul Brooks, Vice President and Country Manager, BSI Americas
- Vinny Sastri, President, WINOVIA
- Steven Walfish, President, Statistical Outsourcing Services
- John Avellanet, Managing Director & Principal, Cerulean Associates
- Dan O'Leary, President, Ombu Enterprises
- Deb Kacera, Regulatory and Industry Strategist, Pilgrim Software





PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 17

8:30 a.m. – 9:00 a.m.
REGISTRATION AND CONTINENTAL BREAKFAST

9:00 a.m. – 12:00 p.m.

Integrating Risk Management Into Complaint Management And CAPA Processes

The importance of integrating risk management into your processes can't be overstated, and more and more devicemakers are seeing that its effective application helps them better prioritize and focus on their most important concerns – especially with CAPA and complaint management. With complaints on the rise (thanks to social media) and the FDA's high expectations of your CAPA program, embracing the tenets of risk management to improve your processes is a no-brainer. Attend this in-depth session – taught by a risk management expert who deals with complaint management and CAPA every day – and you'll return to your office filled with newly-acquired knowledge and ready to move into a leadership role in this always difficult area.

Attendees will learn:

- Understanding how to review complaints and CAPAs with a risk management mindset to prioritize valuable time and resources
- Creating and writing SOPs that govern and explain how you integrate risk management to manage complaints and CAPAs — the FDA will expect to see these during an inspection
- Managing emerging sources of complaints and applying risk management tools to determine how best to handle them

Larry Kopyta
Vice President, Quality Assurance & Regulatory Affairs, Omnyx

CONFERENCE AGENDA

Tuesday, March 17

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.

FDA Update On Inspectional Corps Re-Organization — What Does it Mean For Devicemakers?

The FDA unveiled a broad plan that will change the way it inspects devicemakers, handles recalls, issues and reviews enforcement decisions and screens imports, with companies likely to start feeling the impact in 2015. The reorganization will create a distinct inspectorate for just medical devices, eliminating the existing region-based model. In an eight-page document, CDRH outlined the steps it will take to create a new specialized approach to inspections. The plan includes creating specialist investigators who will be extensively trained in specific types of devices. CDRH says it will survey staff to subdivide its inspectorate into subspecialties.

Attendees will learn:

- Why Commissioner Hamburg asked for feedback on how to improve operations
- What's the latest on the specialization and training that investigators are receiving

William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA

2:00 p.m. – 3:30 p.m.

FDA Expectations For Risk Management Files And Their Relationship To ISO 14971 Requirements

Many devicemakers are relying on FMEAs to be the heart of their risk management strategy. But if that's your strategy, you're looking for trouble. For starters, a FMEA is not compliant with ISO 14971, and FDA and international regulators want to see comprehensive risk management that covers and fully documents all the known risks of your product. So, what exactly are the expectations for using risk management files in production and post-production to make smart risk-based decisions? This panel discussion will feature FDA and industry representatives who will explore best practices in using FMEA and ISO 14971 properly — and show you how to avoid the trap of overreacting to every risk that might present itself.

Attendees will learn:

- How FDA views using FMEA, ISO 14971 to remain proactive within your risk management strategy
- What do regulators want to see when they examine risk management files? Is there a sweet spot between too little information and too much?
- Best practices for creating holistic event tracking methods that provide more accurate views of a product's risk profile
- What companies need to do to address the latest in ISO 14971 enforcement — including how devicemakers are struggling with EU compliance

Moderator:
Vinny Sastri, President, WINOVIA

Featured FDA Panelists:

- **William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA**
- **Dr. Joni Foy, Deputy Director, Office of Device Evaluation, CDRH, FDA (invited)**

Panelists:

- **Karl Vahey, Senior Director Global Quality and Compliance, Covidien**
- **Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations**
- **Paul Brooks, Senior Vice President, Healthcare Solutions, BSI Group**

3:30 p.m. – 3:45 p.m. | REFRESHMENT BREAK

3:45 p.m. – 5:00 p.m.

Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms
- Handling data requests, particularly for electronic records — best practices from inspectional veterans
- Being a SME in your job doesn't make you an

inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

Moderator:
Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

Featured FDA Panelists:
- **William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA**
- **Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH (invited)**

Panelist:
- **Larry Kopyta, Vice President, Quality Assurance & Regulatory Affairs, Omnyx**

5:00 p.m. – 6:30 p.m. | NETWORKING RECEPTION

Wednesday, March 18

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, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

9:15 a.m. – 10:00 a.m.

Medical Device Single Audit Program Gaining Steam, Canada To Require Audits in 2016

All signs point to progress with the Medical Device Single Audit Pilot Program, in which a third-party inspector's single audit is considered sufficient to prove compliance in the U.S., Canada, Australia and Brazil. Results to date also suggest that a single audit costs less and takes less time than is required in each separate market. In the meantime, Canada is taking a leadership role, announcing that beginning in 2016, products sold there will require shared audits. Plan to attend this session to learn more about this breakthrough pilot and how it could dramatically affect your business.

Attendees will learn:
- How multiple sites will be audited under the program
- Results from results, including comments from both companies and inspectors
- Could EU nation states join the program in 2015?

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

10:00 a.m. – 10:45 a.m.

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.

Attendees will learn:
- Dos and don'ts when communicating with the District or the Center regarding recalls
- Understanding the 4 points that should be included in recall communications
- Tips for avoiding promotional messages within your recall announcements
- Best practices for following up with those that fail to respond to an initial communication

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

10:45 a.m. – 11:00 a.m. | REFRESHMENT BREAK

11:00 a.m. – 12:00 p.m.

Classification and Conformity Assessment Routes For Obtaining CE Marketing and European Distribution

In order to receive a CE marking, you must travel a tortuous path of compliance with myriad regulations, most notably Directive 93/42/EEC … receive a thorough review of your device and its supporting documentation … pass an assessment of your quality systems and technical documentation … and possibly meet "state-specific" registration requirements relating to the language of the device's accompanying information. This session will start you on the right path if you desire European distribution of your devices.

Attendees will learn:
- How to properly review Directive 93/42/EEC and assure you're classifying your device correctly — failure to do so causes nothing but wasted time and money
- Best practices for working with Notified Bodies and getting their stamp of approval
- Which states have requirements regarding state-level registration and how to effectively comply
- Why some states require additional language requirements before marketing can begin

Paul Brooks, Vice President, BSI Healthcare Solutions

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 1:45 p.m.

FDA's Focus on Risk Management and Cybersecurity for Devices that Contain Software

Software has increasingly become a critical part of medical devices. More and more medical devices have software embedded or interface with another device or healthcare system that has software as an integral part. Given the increased complexity of medical device software, best practices in risk management and cybersecurity is critical and challenging.

Attendees will learn:
- What are FDA's latest initiatives on device software risk management and cybersecurity
- How a device manufacturer overcomes technical as well as regulatory compliance challenges
- What are the resources and tools available
- What are the industry's best practices

Dr. Suzanne Schwartz, Director, Emergency Preparedness/Operations and Medical Countermeasures, OCD, CDRH, FDA

1:45 p.m. – 2:30 p.m.

Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the 21 CFR 820.30 requirements: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. Also, your sample sizes must be appropriate for the type of testing you're doing and the type of product. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA. This presentation will help you select the right statistical methods to make this determination. You'll learn how to get the right sample size to ensure that user requirements are met in the product design. Finally, you'll understand how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

Attendees will learn:
- How to examine the discrete or continuous statistical data you collect. With testing involving discrete data, you'll be doing simple pass/fail tests. With continuous data, you'll measure the output of a device, such as cycle times, voltages or pressures
- Determine how many units you must test to provide sufficient confidence that zero failures in the sample can be interpreted to mean that the product meets the user requirements, including safety factors
- Tips and tricks to look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems
- Best practices for choosing design verification and validation tests, particularly regarding choice of sample size

ice Supplier Quality Management Training

- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process

Steven Walfish, President, Statistical Outsourcing Services

2:30 p.m. – 2:45 p.m. | REFRESHMENT BREAK

2:45 p.m. – 4:15 p.m.

The eMDR Challenge — Test Your Adverse Event Reporting and Implementation Expertise

Pop quiz: eMDR is an incredibly useful tool to help your company more effectively handle complaints…or eMDR is a technical nightmare that will tax your team and leave you vulnerable to new regulatory review? The answer is up to you. Mishandled, eMDR implementation can take too much of your organization's time and resources. But if you've got a smart plan in place, it can be one of your front line defenses against serious complaint system weaknesses. In this session, you'll learn from leading experts how to get it right, what your options are for implementing, and what the FDA is looking for in your MDR reporting system.

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

Moderator:

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations

Panelists:

- **Sharon Kapsch, Chief, MDR Policy Branch, Office of Surveillance and Biometrics, CDRH, FDA (invited)**
- **Dr. Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA (invited)**
- **Patrick Caines, Director, Product Surveillance, GE Healthcare**
- **Deb Kacera, Regulatory and Industry Strategist, Pilgrim Software**

4:15 p.m. – 4:30 p.m.

Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY SESSION!

DEVICE SUPPLIER QUALITY MANAGEMENT TRAINING

Thursday, March 19, 2015

In 2014, supplier management and purchasing controls rose to the #3 position within FDA enforcement statistics. The FDA's Division of International Compliance Operations, within CDRH's Office of Compliance, has been laser focused on reducing international supply chain concerns. Domestic — and overseas — inspections are also ramping up amid mushrooming international component sourcing and overseas contract manufacturing. This special full day training session is a must-attend.

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

8:00 a.m. – 8:30 a.m. | CONTINENTAL BREAKFAST

8:30 a.m. – 5:30 p.m.

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

5:30 p.m. | TRAINING ADJOURNMENT

Expert Instructors:

John Avellanet,
Managing Director & Principal, Cerulean Associates

Dan O'Leary,
President, Ombu Enterprises

FDANEWS PRESENTS THE

12TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

with Device Supplier Quality Management Training

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
- Design Control
- Supply Chain Management
- Risk Management and Product Lifecycle Management
- Post Market Surveillance
- 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 the President of the Medical Device Practice, NSF Health Sciences. 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 U.S. In total, Ms. Messa spent nearly 16 years in management positions within FDA district offices.

12TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

with Device Supplier Quality Management Training

Register Today!

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 **12th 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
5701 Marinelli Road
North Bethesda, MD 20852

Toll free: (800) 859-8003 • Tel: +1 (301) 822-9200

www.bethesdanorthmarriott.com

Room rate: $219 plus 13% tax
Reservation cut-off: Feb. 23, 2015

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.MDQC2015.com

Fax: +1 (703) 538-7676

Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600

Mail: FDAnews, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend **12th Annual Medical Device Quality Congress** on March 17-19, 2015 at Bethesda North Marriott Hotel & Conference Center.

.

FDANEWS

	Early Bird Fee through Feb. 6, 2015	No. of Attendees	Regular Fee After Feb. 6, 2015	No. of Attendees
Preconference Workshop Only	$507		$597	
Device Supplier Quality Training Session Only	$847		$997	
Medical Device Quality Congress (MDQC) Only	$1,357		$1,597	
Preconference Workshop + MDQC	$1,527		$1,797	
Device Supplier Quality Training Session + MDQC	$1,697		$1,997	
Preconference Workshop + MDQC + Device Supplier Quality Training Session	$2,122		$2,497	
TOTAL PAYMENT	$		$	

Attendee 2: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization _____

Address _____

City _____ State _____ Zip _____

Country _____

Phone _____ Fax _____

Payment Options

☐ Check enclosed, payable in U.S. funds to **FDAnews**

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. _____

Expiration date _____

Total amount $ _____

Signature _____

(Signature required on credit card and bill-me orders.)

Print name _____

☐ Bill me/my company $ _____

Purchase order # _____

(Payment is required by the date of the conference.)