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FDANEWS PRESENTS THE
13TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

with Managing & Auditing to Assure Medical Device Supplier Quality

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

MARCH 15-17, 2016 | HILTON WASHINGTON DC/ROCKVILLE HOTEL & EXECUTIVE MEETING CENTER • ROCKVILLE, MD

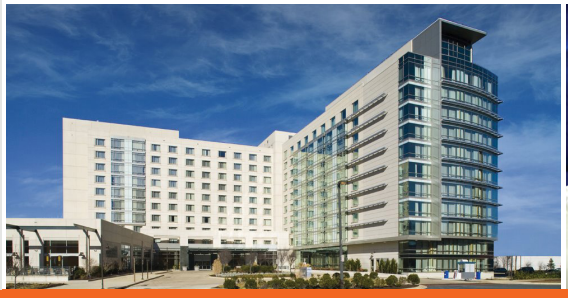
Now in its 13th year, FDAnews' **Medical Device Quality Congress (MDQC)** has become the indisputable must-attend annual quality and compliance event for medical device and diagnostics professionals. **With over 1,700 attendees since 2004, there's simply no other medical device quality event that even comes close.**

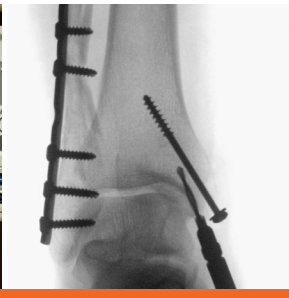
Invited FDA Speakers

- William MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA
- Jan Welch, Medical Products Program Director, ORA, FDA
- Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA
- Capt. Sean Boyd, Acting Director, Office of Compliance, CDRH, FDA
- Dr. Seth Carmody, Staff Fellow, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA
- Erin Keith, Director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices, ODE, CDRH, FDA

Industry Experts

- Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding; former FDA Deputy Associate Commissioner for Regulatory Operations (Co-chair)
- Elaine Messa is President of the Medical Device Consulting at NSF Health Sciences former Director of the Los Angeles District, FDA (Co-chair)
- Karl Vahey, Senior Director Manufacturing Quality, Europe and Asia, Medtronic
- John Avellanet, Managing Director & Principal, Cerulean Associates LLC
- Dan O'Leary, President, Ombu Enterprises
- Joe Pinto, Executive Vice President & Chief Operating Officer, Performance Review Institute
- Paul Brooks, Senior Vice President, Healthcare Solutions, BSI Healthcare Solutions





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PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 15

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

9:00 a.m. – 12:00 p.m.

Designing Your Defensible Data Integrity Program

Regulators around the world are shining the spotlight on data integrity issues. Device makers have watched pharma firm after pharma firm get hit with FDA-483s, warning letters and costly import bans. The FDA is now expanding its data integrity focus to medical devices as investigators get trained on data integrity inspectional techniques.

To protect yourself, you can start to prepare with important data integrity guidance documents from other regulators: MHRA's GMP Data Integrity Definitions and Guidance for Industry and the World Health Organization's draft Guidance on Good Data and Record Management Practices. And yet, these guidance documents don't provide practical design and implementation techniques.

Based upon Mr. Avellanet's world-class two-day corporate workshops, this 3-hour pre-conference session lays out the basics of what you need to know in order to design and implement your own defensible data integrity program to avoid FDA-483s and public embarrassment.

Attendees will learn:

- What the FDA really requires for data integrity and the data lifecycle
- How to quickly and consistently parse regulations, guidance documents and warning letters to find specifics that apply to your firm
- Typical FDA inspection tactics to uncover data integrity issues
- Building your core team – who to have, their roles and how to get started now
- Key policies and SOPs to put in place – the FDA's view versus practical reality
- Tips on incorporating data integrity into your internal quality audits
- What to look for when looking at audit trails and why – and how to avoid overkill
- Internal quality audit points for assessing data recordkeeping and long-term data archival controls to avoid easy FDA-483 observations.

BONUS: Attendees will receive a sample good data integrity practices policy, a quick guide to implementing a compliant data integrity program, a checklist on detecting electronic data fraud during an internal quality audit and several regulatory guidance documents.

John Avellanet, Principal, Cerulean Associates LLC

TUESDAY, MARCH 15

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 LLP; former FDA Deputy Associate Commissioner for Regulatory Operations

1:15 p.m. – 2:00 p.m.

FDA Program Alignment Plans: An Update from the Field Perspective — What Does it Mean For Devicemakers?

After two years of planning, the FDA is moving forward with implementation of the program alignment plan to better coordinate field inspections with product reviews from FDA research centers. This initiative, announced in September 2013 and clarified in February 2015, is dissolving ORA's five regional offices and establishing commodity-based and vertically integrated inspection programs for medical devices that will operate out of ORA's 20 district offices. The aim of the plan is to create clear, coherent enforcement strategies to reduce layers of review and involve closer collaboration between center staff and field inspectors. Come listen to an update of where the program is today and how it will affect you.

Jan Welch, Medical Products Program Director, ORA, FDA (invited)

2:00 p.m. – 2:45 p.m.

Update from the Office of Compliance at CDRH: The Year of Leveraging "Big Data"

The Regulatory Science Subcommittee (RSS) of CDRH has identified 10 areas of focus for fiscal 2016. This session will update you on progress so far and what is still left to do. Some key areas of interest include:

- Leveraging "Big Data" for regulatory decisionmaking
- Improving the quality and effectiveness of reprocessing reusable medical devices
- Enhancing performance of digital health and medical device cybersecurity
- Incorporating human factors engineering principles into device design

Capt. Sean Boyd, Acting Director, Office of Compliance, CDRH, FDA (invited)

2:45 p.m. – 3:00 p.m. | BREAK

3:00 p.m. – 3:45 p.m.

Getting to Root Cause During Your CAPA Investigation

Under the FDA's risk-based requirements, every company doing business in the medical products industry, including suppliers, must have a corrective and preventive action (CAPA) program. The most essential component of a CAPA program is a documented system for discovering the root cause of system failures, nonconformances, product complaints and inspection findings.

Attendees will receive step-by-step guidance on conducting an effective root cause analysis, from recognizing problems that need to be investigated to documenting the investigation so regulators can see you are on top of the situation

Karl Vahey, Senior Director Manufacturing Quality, Europe and Asia, Medtronic

3:45 p.m. – 4:30 p.m.

Reprocessing Reusable Medical Devices

Reducing the risk of exposure to improperly reprocessed medical devices is a shared responsibility. It is the manufacturer's responsibility for providing adequate reprocessing instructions that are user-friendly and proven to work. Come learn how to implement the agency's current thinking on one of CDRH's top 10 priorities for 2016.

Bill MacFarland, Director, Manufacturing and Quality, Office of Compliance, CDRH, FDA (invited)

4:30 p.m. – 5:15 p.m.

Quality Metrics for Devices: Update on the Device Quality Measures Project

As we continue to see increasingly complex devices and use environments, the case for quality only gets stronger. In this session, we will report on the Device Quality Measures Project, who's involved and what is being measured. A culture of quality enhances process stability, which drives productivity and performance, increases cross-functional skills and collaboration, reduces compliance risks and costs, and results in fewer complaints and investigations.

Pat Baird, Technical Director, Baxter Healthcare (invited)

5:15 p.m. – 6:30 p.m. | NETWORKING RECEPTION

WEDNESDAY, MARCH 16

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

8:30 a.m. – 8:45 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

8:45 a.m. – 9:30 a.m.

Medical Device Single Audit Program Pilot (MDSAP) in Full Swing

Attendees will hear first-hand about progress on the program from the FDA's Kim Trautman, who will share lessons learned from the pilot program. Devicemakers will learn what to expect from an audit and how multiple sites should be audited.

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

9:30 a.m. – 10:15 a.m.

ISO13485: What's New and How It Affects You

It's been 12 years since ISO 13485 was last updated, so there's a lot of ground to cover in the standard's upcoming revision. The main benefit of the revision will be greater transparency of the requirements and alignment between the regulators, auditing bodies and manufacturers of medical devices. This session will clarify everything you need to know about the changes.

Paul Brooks, Senior Vice President, Healthcare Solutions, BSI Healthcare Solutions

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 11:45 p.m.

Panel Discussion: How to Effectively Prepare for an Audit of Your Complaint Management and MDR Systems

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 implementation options are what the FDA is looking for in your MDR reporting system.

Attendees will learn:

- Requirements for MDRs on events occurring outside the U.S.
- 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:

- **Patrick Caines, Director, Quality & Global Post Market Surveillance, Baxter (invited)**
- **Dick Roy, Product Surveillance Director, GE Healthcare (invited)**

11:45 a.m. – 12:30 p.m.

MedAccred Update: Devicemakers Driving Quality Standards for Their Suppliers

What Rx-360 has done for drugmakers, MedAccred is trying to do for devicemakers. The goal of the program is to qualify each of the critical processes in the supply chain. To get there, devicemakers are working together to set standards via consensus for those processes and to devise auditing checklists for their suppliers. This session will give you an overview of the work done so far and how you can get involved.

Joe Pinto, Executive Vice President & Chief Operating Officer, Performance Review Institute

12:30 p.m. – 1:30 p.m. | LUNCH

1:30 p.m. – 2:45 p.m.

Panel Discussion: FDA Expectations for Risk Management Files and Their Relationship to ISO 14971 Requirements

Devicemakers that rely on FMEA to drive their risk management strategy may not be looking for trouble, but they are sure to find it. Why? For starters, FMEA is not compliant with ISO 14971, and the 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 the FDA views using FMEA, ISO 14971 and how to remain proactive within your risk management strategy
- What 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: **Pat Baird, Technical Director, Baxter Healthcare (invited)**

Panelists:

- **Bill MacFarland, Director, Manufacturing and Quality, Office of Compliance, CDRH, FDA (invited)**
- **Karl Vahey, Senior Director Manufacturing Quality, Europe and Asia, Medtronic**
- **Erin Keith, Director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices, ODE, CDRH, FDA (invited)**
- **Julius Aviza, Director, Quality Engineering, Allergan (invited)**
- **Dan O'Leary, President, Ombu Enterprises LLC**

2:45 p.m. – 3:00 p.m. | BREAK

3:00 p.m. – 3:45 p.m.

How to Deal with Difficult Inspections

Co-Chair's Steve Niedelman and Elaine Messa will provide real-world scenarios for dealing with tense inspections. Through open discussion and feedback, the audience will work together to come to the correct conclusion for each scenario.

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

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

3:45 p.m. – 4:30 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 are critical and challenging.

Attendees will learn:

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

Seth Carmody, Staff Fellow, CDRH, FDA (invited)

4:30 p.m.

Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

"I really liked the examples, scenarios and practical examples. The 'real life' examples were a great way to drive home the points and examples."

– Tanya Taft, Sr. Manager, Post Market Clinical, Fresenius Medical

* SPECIAL FULL DAY SESSION ON THURSDAY, MARCH 17 *

MANAGING & AUDITING TO ASSURE MEDICAL DEVICE SUPPLIER QUALITY

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

8:30 a.m. – 5:30 p.m.

Managing & Auditing to Assure Medical Device Supplier Quality

The development of extended supply chains raises major issues for device manufacturers. While regulators are looking more closely at device supplier management issues, companies are recognizing the issues of supply chain complexity in meeting the regulatory requirements. There are powerful tools that can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare with 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) and Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010). These guidance documents provide the foundation, but lack implementation details. This workshop provides the practical means and methods you need for a compliant and 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, supplier-caused recalls and liability risk
- When and how to conduct an on-site supplier audit applying a rapid risk management technique
- How to qualify and monitor suppliers that are virtual companies
- Business issues in the supply chain and their risk challenges
- How to select and apply supplier metrics and their role in the QMS
- How to deal with FDA recordkeeping and data integrity issues with suppliers

5:30 p.m. | ADJOURN

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

Dan O'Leary, President, Ombu Enterprises

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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 that you're with the 13th Annual Medical Device Quality Congress conference 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 / SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund or credit — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from 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 three 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 +1 (703) 538-7600 for details.

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☑ **YES!** I want to attend **13th Annual Medical Device Quality Congress** on March 15-17, 2016 at the Hilton Washington DC/Rockville Hotel and Executive Meeting Center.

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	Early Bird Fee through Feb. 5, 2016	No. of Attendees	Regular Fee After Feb. 5, 2016	No. of Attendees
Preconference Workshop Only	$497		$597	
Device Supplier Quality Session Only	$997		$1,197	
Medical Device Quality Congress (MDQC) Only	$1,447		$1,697	
Preconference Workshop + MDQC	$1,697		$1,997	
Device Supplier Quality Session + MDQC	$2,197		$2,597	
Preconference Workshop + MDQC + Device Supplier Quality Session	$2,547		$2,997	
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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 ComplianceManager, 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.