“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

“MDQC was very good, especially around recalls and MDR’s.”
– Nicola Martin, Associate Director, Quality & Compliance, Covidien

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, Executive Vice President, NSF Health Sciences, Medical Device International Services, Former 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

Register by February 12 and save $200!
Incorporating human factors engineering principles into device design

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

3:00 p.m. – 3:45 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.

Marc-Henri Winter, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA

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.

Kimberly Trautman, Executive Vice President, NSF Health Sciences, Medical Device International Services, Former Associate Director, International Affairs, Medical Device

International Quality Systems Expert, Office of the Center Director, CDRH, FDA

10:15 a.m. – 10:30 a.m.  | BREAK

10:30 a.m. – 11:15 a.m.
European Medical Device Regulations: What To Expect
This session will discuss the proposal to replace the European Medical Device Directives for CE Marking with new EU regulations. There has been significant discussion and debate within the EU legislative process and progress towards finalized regulations. Hear the latest on how the proposals, as amended by the European Council, are progress towards confirmation as European Regulations and what to expect in 2016, what’s changed and what remains the same, industry concerns, consider how to start preparing for and implementing the new requirements, the timetable/process for transition from the current directives to achieve full compliance with the new European Medical Device Regulation and continue placing devices in Europe.

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

11:15 a.m. – 12:00 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

12:00 p.m. – 12:45 p.m.
Medical Device Complaint Management

Bo Kim, VP, Global Regulatory and Compliance, Iluminage Beauty

Esther Sur, Senior Manager, Global Regulatory and Compliance, Iluminage Beauty

12:45 p.m. – 1:45 p.m.  | LUNCH

1:45 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:
- Erin Keith, Director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices, ODE, CDRH, FDA
- Lorie Erikson, Consumer Safety Officer, CDRH, FDA
- Karl Vahey, Senior Director Manufacturing Quality, Europe and Asia, Medtronic
- Julius Aviza, NSF Health Sciences; formal Global VP, Quality Engineering, Allergan
- Dan O’Leary, President, Ombu Enterprises LLC

2:45 p.m. – 3:00 p.m.  | BREAK
MANAGING & AUDITING TO ASSURE MEDICAL DEVICE SUPPLIER QUALITY

3:00 p.m. – 3:45 p.m.

How to Deal with Difficult Inspections

Co-Chairs 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

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
LOCATIONS AND HOTEL ACCOMMODATIONS
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.

Lodging and Conference Venue:
Hilton Washington DC/Rockville Hotel and Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852
Toll free: (800) HILTONS • Tel: +1 (301) 468-1100
www.RockvilleHotel.com
Room rate: $219 single or double (plus 13% tax)
Reservation cut-off date: Feb. 22, 2016

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

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.

FOUR EASY WAYS TO REGISTER
Please mention priority code BROCHURE when ordering.
Online: www.MDQC2016.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

LOCATION AND HOTEL ACCOMMODATIONS
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.

Lodging and Conference Venue:
Hilton Washington DC/Rockville Hotel and Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852
Toll free: (800) HILTONS • Tel: +1 (301) 468-1100
www.RockvilleHotel.com
Room rate: $219 single or double (plus 13% tax)
Reservation cut-off date: Feb. 22, 2016

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

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.

FOUR EASY WAYS TO REGISTER
Please mention priority code BROCHURE when ordering.
Online: www.MDQC2016.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

Early Bird Fee through Feb. 12, 2016
No. of Attendees
Device Supplier Quality Session Only $997 $1,197
No. of Attendees
Preconference Workshop + MDQC $1,697 $1,997
No. of Attendees
Medical Device Quality Congress (MDQC) Only $1,447 $1,697
No. of Attendees
Preconference Workshop Only $497 $597
No. of Attendees
Device Supplier Quality Session + MDQC $2,197 $2,597
No. of Attendees
Preconference Workshop + MDQC + Device Supplier Quality Session $2,547 $2,997
No. of Attendees
TOTAL PAYMENT

$ $

Attendee 1: Name______________ Title______________ Email______________
Attendee 2: Name______________ Title______________ Email______________

Company Information
Organization ________________________________
Address ____________________________________
City ________ State ________ Zip ____________
Country ____________________
Phone ______________ Fax ______________

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

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.)

REGISTER EARLY - SPACE IS LIMITED!
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.

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

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