International Devices & Diagnostics Monitor

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IN THIS ISSUE

FDA Ordered to Create A New Regulatory Task Force

The FDA will have to create a task force to identify regulations to repeal or modify under an executive order signed by President Trump last week.

Within the next two months, the agency will appoint a new regulatory review officer, who will chair a task force of members of the agency's central policy office and other senior agency officials.

The task force will also seek input from other agencies, state and local governments, trade associations and industry stakeholders.

Trump has already issued an executive order requiring two regulations to be identified for elimination for each major new one proposed. The OMB said that order affects economically significant regulations with impacts over $100 million per year, and affects new guidance documents on a case-by-case basis.

The Trump administration is currently being sued over the "one in, two out" executive order, by Public Citizen, the Natural Resources Defense Council and the Communication Workers of America (AFL-CIO). The suit contends that the order simply focuses on offsetting costs for regulated industry, while disregarding the benefits of existing and proposed polices.

White House Planning to Cut Non-Defense Spending by $54 Billion

An early OMB blueprint for the president's fiscal 2018 budget request looks to transfer $54 billion from non-defense programs and agencies, including the FDA, to the military.

The plan — which focuses on totals for federal discretionary spending, without agency-by-agency details — was made public this week.

White House officials said the full budget proposal will be published in May. Presidential budget requests are considered by Congress in the appropriations process, and are usually submitted in February or March.

Australia's TGA Issues New Guidance on Clinical Evidence

Final guidance from the TGA covers clinical evidence requirements for medical devices and in vitro diagnostics, including how the evidence should be obtained and what it needs to show.

Evidence must obtain clinical data from investigations, literature reviews, or post-market studies, and ensure the data are evaluated by competent experts in the relevant fields, according to the TGA.

The Feb. 28 guidance was developed to supplement existing guidance on medical device regulatory requirements and align with guidance published by the International Medical Device Regulators Forum and the European Commission.

Compliance with recognized standards published by an Australian or international standards agency may be used to satisfy the clinical evidence requirements for devices based on technologies with well-established safety and performance characteristics. Conformity with standards like ISO 13485:2016 (Quality Management Systems) is not mandatory, but using lesser-known standards must produce an acceptable result, TGA said.

The guidance also discusses how to compile clinical evaluation reports, including format and content. In addition, to goes over how to demonstrate substantial equivalence, including when the use of clinical evidence for a predicate or similar marketed device is considered inappropriate.

In addition to general information covering all devices, the guidance discusses clinical evidence requirements for specific types, including joint prostheses, cardiovascular devices, implantable pulse generators, heart value prostheses — and support devices such as meshes, patches, and tissue adhesives.

Read the full guidance here: www.fdanews.com/02-28-17-TGAclinicalevidenceguidance.pdf.

Cooperation, Not Confrontation, Key to Internal Audits

The most common error companies make when conducting internal audits is to take a confrontational approach when fixing them, according to one compliance expert.

Internal audits should be used as a learning tool and teaching mechanism, advised Susan Schniepp of Regulatory Compliance Associates, in a webinar hosted by FDAnews. "Remember that the goal is to find any deficiencies before the government does and fix them," she said.

Internal audit programs should focus on several elements, including communication, objectives, documents, interviews, scope, follow-up, procedures, and management. It is important for internal audits to be team-oriented, instructive, informative, honest, and forward-thinking. They also should be announced in advanced so the people involved have time to prepare.

Results should be reported to management routinely and without fear of recrimination. Audit reports should use clear, straightforward language, and managers should accept that auditors know what they are talking about, without overreacting.

An internal audit process should have an approved schedule and should cover critical areas. These will depend on the company but typically include quality systems, packaging and labeling, suppliers, facilities and equipment, training, and complaints. Letting someone from the functional area partner with the auditor can help uncover hidden issues.

It is also critical to properly track audits and document the results. Reports should be issued according to a pre-established timeline and include the relevant regulation for each observation, along with possible solutions. Confirm that the findings were received and understood, and establish a deadline for responses.

When responding to an audit, follow standard operating procedures and confirm receipt of the audit report. Provide an appropriate rationale and documentation for the response, look for systemic rather than short-term improvements, make sure your responses are understood and acceptable, and implement actions according to an established timeline.

Audit response actions need to be tracked until they are fully implemented. The audit report can be closed out when all actions and commitments have been completed.

Resolutions of any problems need to be applied systematically and broadly. An internal audit should be considered more as a gap analysis for processes.

Relying on client audits rather than internal audits to spot problems is a bad idea, because clients are not as familiar with the company and are not necessarily looking for the same things. Moreover, although internal audit results should be shared with appropriate individuals across the organization, sharing them with clients could invite unnecessary scrutiny.

The recorded webinar, Conducting an Internal Audit for Pharmaceutical and Medical Device Companies, is available here: www.fdanews.com/conductinganinternalaudit.

	ISO 9001:2000	ASQ Quality System	Medical Device GMPs
Audits	Internal audits at planned intervals to determine whether the quality management system conforms	Internal audits of the quality system at regular intervals to evaluate the effectiveness of the various quality system elements	Management needs to establish procedures for quality audits of its documented quality system and ensure that they are performed

Valeant Cited for Inadequate Design Validation

Valeant Pharmaceuticals International received a Form 483 for observations related to its organizational structure, design validation procedures, and other issues.

The FDA visited the company's Rochester, N.Y., facility in late August and early September 2016 and noted that the facility was not organized to ensure that devices were designed and produced according to regulatory requirements.

Specifically, responsibility for work performed under the quality management system did not assure that necessary activities occurred prior to approval. Notably, acquired products that needed to be integrated into the QMS were not fully integrated into the design management system. Moreover, products reviewed under the nonconforming product system were not properly evaluated.

Inspectors also faulted the facility's design procedures. For example, design control procedures for integrating existing products failed to define how to do that, and there was no requirement to document a justification for not performing design validation.

The Form 483 further cited Valeant for CAPA issues. For example, corrective and preventive actions surrounding field action for a product did not document how the actions affected product in inventory.

Procedures addressing corrections and removals, critical action committees, and health hazard evaluations did not specify the recall initiation date to ensure the FDA was notified in a timely manner.

In addition, the CAPA procedures failed to define when a health hazard evaluation was required.

Valeant did not respond to a request for comment.

Read the Form 483 here: www.fdanews.com/02-24-17-Valeant483.pdf.

AdvaMed Proposes Safe Harbors For Anti-Kickback Statute

The Advanced Medical Technology Association (AdvaMed) has asked the HHS Office of Inspector General for two new exceptions to the federal anti-kickback statute.

The proposed safe harbors would allow value-based health care arrangements between device manufacturers and buyers that are designed to save money and improve clinical outcomes. Arrangements that presented significant risk of increased costs, waste, fraud, or abuse to federal health care programs would not be permitted, AdvaMed said in a statement.

One safe harbor would protect value-based pricing arrangements. It would allow for price adjustments and for services to be bundled with the product being sold or leased, subject to safeguards.

The second safe harbor would protect value-based warranties. It would allow manufacturers of products to make certain clinical or cost outcome guarantees, and provide a remedy where the outcomes are not achieved.

The proposed safe harbors include elements of the statute's existing discount and warranty safe harbors — such as transparency and disclosure — but expand the types of buyers and sellers that may be parties to value-based arrangements.

As a possible alternative, AdvaMed proposed that the OIG modify the existing discount and warranty safe harbors to provide greater flexibility for buyers and sellers to enter into value-based arrangements.

AdvaMed said the proposals would help modernize the anti-kickback statute and facilitate the shift away from traditional, volume-based (fee-for-service) models toward value-based payment and delivery.

The proposals were developed by AdvaMed's Legal Committee Working Group on Advancing Value-Based Health Care.

Inspectors Find Validation and CAPA Problems at LAR NE

The FDA faulted LAR NE for its validation, corrective and preventive action, and other procedures.

An inspection of the firm's Port Richey, Fla., facility in September 2016 found no validation records for the cleaning and coating process for orthodontic brackets.

In a Form 483, the agency said the company lacked proper CAPA procedures. Specifically, it did not fully define and implement a process for analyzing quality data. The CAPA procedures called for an analysis of quality data sources to identify existing and potential causes of nonconforming products, but the firm lacked records to show this was done.

The FDA also found inadequate procedures to control non-conforming products. The procedures failed to define control for nonconforming products found during production or during in-process and final acceptance testing.

In addition, the company lacked adequate equipment calibration procedures. For instance, the written procedures defining use and verification for calipers and micrometers did not define the frequency for inspecting the instruments.

The agency further noted a lack of acceptance records covering the use of the optical comparator during the machining processes for manufacturing orthodontic bracket devices. This was a repeat deficiency cited in a December 2015 warning letter. The inspection also observed a lack of written procedures for device history records and inadequate quality audit procedures.

LAR NE did not respond to a request for comment.

Read the Form 483 here: www.fdanews.com/02-24-17-LARNE483.pdf.

Medical Energy Cited For Inspection, Other Procedures

FDA auditors noted several problems at Medical Energy's facility in Pensacola, Fla., including an improperly validated manufacturing process, inadequate design procedures, and other issues.

After conducting an inspection in November 2016, the FDA said the firm did not maintain evidence that its optical fiber laser delivery system process was validated.

The firm also failed to establish device load configurations for use during processing, or to establish a procedure for placement of a dosimeter system. The agency also cited deficiencies in sterilization procedures. For example, Medical Energy did not conduct validation to ensure that devices exposed to multiple sterilization cycles functioned properly.

Inspectors also observed that the company did not validate the two-year expiration date labeled on laser fiber devices.

Inadequate Documentation

In addition, the company failed to properly document complaints.

For example, a complaint form did not include the date the complaint was received, or basic information about the complainant, the dates of the investigation, and a justification for why no report was filed to the FDA. Another complaint that resulted in a voluntary product recall was not documented.

Design control procedures were cited because the company did not implement the requirements for signing, dating, and/or revision level identification for several records. Some of these records had to do with sterilization procedures, and others package seal strength verification and verification of incubator temperature.

Inspectors additionally faulted the firm for written MDR procedures that lacked definitions, reporting timeframes, and instructions for electronic submission.

In addition, the records failed to include a justification for not reporting a correction or removal to the FDA. The firm initiated a voluntary product recall due to an alleged deficiency cited in a complaint. The recall letter said the FDA was notified, although it was not.

Medical Energy did not respond to a request for comment.

Read the Form 483 here: www.fdanews.com/02-24-17-MedicalEnergy.pdf.

PEOPLE ON THE MOVE

Annidis has appointed **Gerald Slemko** as executive chairman and interim CEO and newly appointed general manager, **Jason Wright**, will now report to Mr. Slemko. The firm's former President and CEO, **Cameron Bramwell,** has resigned.

Active Implants named **Ted Davis** as president and CEO. Davis succeeds Henry Klyce, who will continue as chairman of the board. Davis has 25 years of experience in the life sciences industry, including as CEO of MicroPort Orthopedics and president of its predecessor, Wright Medical Technology's global OrthoRecon division.

Compu Group Medical US has appointed **Benedikt Brueckle** as CEO. Prior to joining the company, he served with the accounting firm KPMG in Germany and Luxembourg.

Israel-based DarioHealth named **Dr. Yossi Bahagon,** co-founder of Humedica, and **Allen Kamer** to its board of directors. Bahagon and Kamer are managing partners at OurCrowd Qure, which is collaborating with Johns Hopkins University to bring new drug companies and novel ideas to market. DarioHealth produces an i-Phone connected glucose meter.

U.K. –based Cydar appointed **Lord Davies of Abersoch** its non-executive chairman. **Dr. Franz B. Humer** and **James B. Downing** have joined the board as non-executive directors.

BRIEFS

European Council to vote March 7 on MDR

The European Council is set to vote March 7 on the recently finalized EU Medical Device Regulation (MDR), which requires more labeling data for devices, as well as consistency between labels and information found elsewhere in print and online.

After the March 7, vote, the European Parliament will vote on March 20. If passed, the regulations could become effective as early as May. Manufacturers would then have three years to comply with the MDR and five years to comply with the IVDR.

Japan's PMDA Approves HAL for Medical Use

Japan's Pharmaceuticals and Medical Devices Agency approved Cyberdyne's HAL, a device that helps the movement of lower limbs during gait training therapy.

PMDA said non-clinical data on electrical safety, electromagnetic compatibility, and performance of HAL indicated no problems. Clinical testing showed the therapy increased walking distance by about 10 percent.

New Zealand Finalizes Agreement To Use Smith and Nephew Implants

New Zealand's medical device and drug regulator has finalized an agreement to let the country's hospitals purchase about 4,200 orthopedic implants and associated products from Smith and Nephew.

The final agreement would allow Smith and Nephew to supply the products at negotiated prices starting April 1. The original starting date in the proposed agreement was March 1, but the Pharmaceutical Management Agency extended the date to resolve inaccuracies in the schedule of prices (*IDDM*, Feb. 3).

FDA Grants Approval to Intersect ENT's Steroid Releasing Implant Device

California–based, Intersect ENT has received FDA approval for Propel Contour, a dissolvable, steroid-releasing implant device that facilitates treatment of patients with chronic sinusitis in the frontal and maxillary sinuses.

The device is designed to conform to the sinus ostia, has a flexible delivery system to make it easier to access tight areas and deliver the steroid where it's needed.

FDA Clears Expanded Indication For Vidas Brahms PCT Assay

The FDA has cleared the expanded use of the Vidas Brahms PCT Assay to help health care providers determine if antibiotic treatment should be started or stopped in patients with lower respiratory tract infections, and stopped in patients with sepsis.

The test is intended to be used in the hospital or emergency room.

FDA Permits Marketing Of Phenotest BC Kit for Bloodstream Infections

The FDA has allowed the marketing of the PhenoTest BC Kit to identify organisms that cause bloodstream infections and provide information about which antibiotics the organism is likely to respond to.

The test can identify 14 different species of bacteria and two species of yeast that cause bloodstream infections, while also providing antibiotic sensitivity information on 18 selected antibiotics.

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MEDICAL DEVICE QUALITY CONGRESS

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 28-30, 2017 | BETHESDA NORTH MARRIOTT
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Now in its 14th 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 1,800 attendees since 2004, there's simply no other medical device quality event that even comes close.**

Confirmed FDA Speakers

Seth Carmody, Staff Fellow, Office of the Center Director CDRH, FDA

Ann Ferriter, Director, Division of Analysis and Program Operations, OC, CDRH, FDA

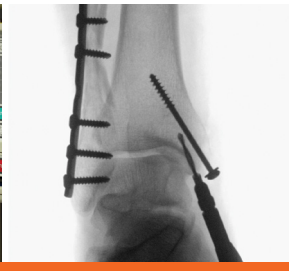
William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA

Robin Newman, Director, Office of Compliance, CDRH, FDA

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

Industry Experts

- Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA (Co-chair)
- Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations (Co-chair)
- John Avellanet, Managing Director & Principal, Cerulean Associates LLC
- Julius Aviza, Executive Director, NSF Health Sciences, Medical Device Quality Systems
- Patrick Caines, Director, Quality & Post Market Surveillance, Baxter Healthcare
- Steven Grossman, President, HPS Group, LLC
- Dan O'Leary, President, Ombu Enterprises LLC
- Grace Fu Palma, Founder, China Med Device
- Joe Pinto, Executive Vice President & Chief Operating Officer, Performance Review Institute
- Ibim Tariah, Technical Director, BSI Americas Inc.



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FDANEWS PRESENTS THE 14TH ANNUAL MEDICAL DEVIC

PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 28

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

8:30 a.m. – 12:00 p.m.

FDA Cybersecurity and Risk for Devices – from Software as a Device to Ransomware

Devicemakers have seen the news of hacked devices, some of which have exposed healthcare facilities to data theft and forced ransom payments to hackers. From 2011, when Barnaby Jack demonstrated how easy it was to hack insulin pumps and pacemakers, hackers have claimed that medical devices are a target rich-environment. Now, FDA is expanding its cybersecurity focus with guidance documents on pre-market and post-market cybersecurity. To FDA, cybersecurity requirements are extensions of design validation, since it already requires both software validation and risk control.

To protect yourself and your customers, you can start with the guidance documents to outline a useful framework, but they don't provide practical design methods and implementation techniques. This pre-conference workshop lays out the basics of what you need to know in order to design and implement your own device cybersecurity program to help avoid FDA-483s, product liability litigation, and public embarrassment.

Participants will learn:

- What to include in your design control SOPs to implement cybersecurity
- The link between risk management and software validation
- Cybersecurity as an element of pre-market submissions – understanding the guidance document and practical concerns
- Cybersecurity as an element of post-market surveillance – understanding the guidance document and real-world implementation
- How to review the evolving case studies to extract lessons and proactively incorporate them into your cybersecurity program
- How cybersecurity updates relate to corrections & removals – when do they become a recall?
- Retaining records of post-market surveillance with integrity to protect yourself against claims of collusion for "losing" relevant cybersecurity data
- How to incorporate cybersecurity into your internal and external quality audits

BONUS MATERIAL: Participants receive a sample cybersecurity policy, a quick guide to implementing a compliant cybersecurity program, a checklist to help build your cybersecurity life-cycle program and several guidance documents.

EXPERT INSTRUCTORS:

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Dan O'Leary, President, Ombu Enterprises LLC

TUESDAY, MARCH 28

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.

Update from the Office of Compliance at CDRH: Priorities and Strategies for 2017

Robin Newman will discuss CDRH's top strategic priorities for FY 2017. This session will update you on progress so far and what is still left to do. He will also touch on some of CDRH's regulatory science priorities, including:

- Establishing a national evaluation system for medical devices by increasing access and use to real-world evidence to support regulatory decision making
- Partnering with patients by promoting a culture of meaningful engagement by facilitating CDRH interaction with patients while increasing patient input as part of the decision making.
- Promoting a culture of quality and organizational excellence
- A Summary of the Regulatory Science Subcommittee's assessment of regulatory science needs within CDRH
- FDA's program alignment plan

Robin Newman, Director, Office of Compliance, CDRH, FDA

2:00 p.m. – 2:45 p.m.

Update on the Critical to Quality Initiative

Part of its Case for Quality, CDRH launched the Critical to Quality (CtQ) initiative. This program allows for the FDA to work with the medical device industry to define what device features and characteristics are most important to the safety and effectiveness of these devices. In this session, you'll hear about the CtQ initiative and the CtQ information documents that have been published.

William MacFarland, Director, Division of Enforcement B, Office of Compliance, CDRH, FDA

2:45 p.m. – 3:00 p.m. | BREAK

3:00 p.m. – 4:15 p.m.

Benefit–Risk Considerations for Medical Devices: Panel Discussion

In June 2016, the FDA released a draft guidance to clarify the benefit and risk factors it may consider in compliance and enforcement actions involving medical devices. This new draft guidance seeks to complement and build upon that existing benefit-risk framework in an effort to improve consistency in the FDA's decision-making across the total product life cycle. Notably, manufacturers will be privy to the factors used by the FDA in considering post-market actions.

Sean Boyd, Program Manager CDRH, FDA (Invited)

4:15 p.m. – 5:15 p.m.

Mock Medical Device Inspections

A mock medical device inspection will be acted out by several presenters, role playing an FDA inspector, director of regulatory affairs, in-house counsel, outside attorney, and director of quality at a medical device company. Instructors will play out the mock inspections which will raise some thorny issues that often develop during an inspection. Following the presentation there will be an interactive discussion with the audience of how those difficult situations could have been handled differently—and better—by both the FDA representative and company officials.

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

E QUALITY CONGRESS

WEDNESDAY, MARCH 29

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) Update

Attendees will hear first-hand about progress on the program from the FDA's Marc-Henri Winter, 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. Additional CDRH representatives will be on hand to address any additional questions regarding MDSAP.

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

9:30 a.m. – 10:15 a.m.

68 Days in Office – What Does the Trump Administration Have in Store for FDA?

President-elect Trump will have been in office for two-thirds of his first 100 days. This expert panel will bring their decades of experience with Washington politics and FDA regulations to share their analysis of the decisions we have seen to date and what is to come.

Steven Grossman, President, HPS Group, LLC

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

European Medical Device Regulations What To Expect: Panel Discussion

European lawmakers and regulators plan to overhaul the legislation on how the EU oversees medical device and in vitro diagnostics. The EU intends to replace the three current medical device directives with two regulations. The Medical Device Regulation and the In Vitro Diagnostic Device Regulation. The new regulations mark significant changes to the current approach. All notified bodies must reapply under the regulations. There will need to be a new version of 13485 and 14971 for the EU, since the references in EN ISO 13485:2016 and EN ISO 14971:2012 respectively will no longer apply.

The EU MDR is also expanding the requirements of the European Database for Medical Devices (Eudamed). This database would now include UDI data, single registration numbers for all economic operators, accreditation and designation data for notified bodies, more post-market surveillance data, notified body conformity assessment applications and safety and clinical performance summaries for medical devices and IVDs.

This expert panel will take you throught the changes and what you need to know to be prepared to continue to market or bring your product to market in Europe.

Additional features of the new Eudamed database would include multiple reporting methods, multilingual operations and web-based data exchange capabilities

Moderator: **Dan O'Leary, President, Ombu Enterprises LLC**

Panelists:

- **Ibim Tariah, Technical Director, BSI Americas Inc.**
- **Julius Aviza, Executive Director, NSF Health Sciences, Medical Device Quality Systems**

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 1:45 p.m.

MedAccred Update: Devicemakers Driving Quality Standards for Their Suppliers

What Rx-360 has done for drugmakers, MedAccred is doing 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

1:45 p.m. – 2:30 p.m.

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

Software has 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

2:30 p.m. – 2:45 p.m. | BREAK

2:45 p.m. – 3:45 p.m.

When to submit a 510(k) Premarket Notification

On August 5, 2016, FDA posted two long-awaited draft guidance documents intended to help industry and FDA staff determine whether a new premarket notification (510(k)) is required upon the modification of a legally marketed medical device.

Patrick Caines, Director, Quality & Post Market Surveillance, Baxter Healthcare

3:45 p.m. – 4:30 p.m.

China Medical Device Regulatory Changes

This session provides an analytical introduction to the regulations on medical device manufacturing in China. You will learn about recent developments in manufacturing regulations, such as new GMPs, self-inspections, foreign inspections, and trends in enforcement. These developments can affect all medical device companies, whether your manufacturing in facilities are in China or abroad.

You will come away with a practical understanding of the following compliance issues:

- Implementation of the new GMPs, including the procedural rules for inspections, preparation, communicating with investigators, resolving issues, and potential penalties.
- Transfer of manufacturing sites and amendment of manufacturing and device licenses.
- Policies and rules on contract manufacturing for medical devices.
- Handling self-inspections and evaluations of past compliance, including recent examples

Grace Fu Palma, Founder, China Med Device

4:30 p.m.

Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY WORKSHOP ON THURSDAY, MARCH 30

MANAGING & AUDITING MEDICAL DEVICE SUPPLIER QUALITY TRAINING

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

8:30 a.m. – 5:30 p.m.

Managing & Auditing 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 can help device manufacturers protect themselves against problems, develop more effective management systems, and control costs. You can start to prepare with important IMDRF 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.

In the Medical Device Single Audit Program (MDSAP), the purchasing process is integral to the other processes. The audit team will assess the affect of purchased product on the quality of the finished device by executing the sixteen purchasing tasks as part of the audit.

ISO 13485:2016 includes significant requirements for purchasing products, services, and managing outsourced processes.

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
- How to select and apply supplier metrics and their role in the QMS
- How to prepare for the supplier portion of an MDSAP audit
- How to deal with recordkeeping and data integrity issues with suppliers

5:30 p.m. | ADJOURN

BONUS: Attendees will receive copies of implementation tools including a sample supplier questionnaire, reevaluation form, several helpful checklists and more.

Expert Instructors

John Avellanet
Managing Director & Principal, Cerulean Associates

John is an award-winning FDA compliance expert known for his business-savvy, pragmatic advice and engaging speaking style. Mr. Avellanet was the lead author of several certification courses on Good Manufacturing Practices (GMP) and Quality System Regulation (QSR) supplier management for the US Regulatory Affairs Professional Society.

Dan O'Leary
President, Ombu Enterprises

Dan has more than 30 year's experience in quality, operations and program management in regulated industries including: aviation, defense, medical devices and clinical labs. He has a Master's Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer and Six Sigma Black Belt; and is certified by APICS in Resource Management.

"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

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MEDICAL DEVICE QUALITY CONGRESS

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 14th 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:
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: $209 (plus 13% tax)
Reservation cut-off date: March 6, 2017

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.FDAnews.com/MDQC

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 **14th Annual Medical Device Quality Congress** on March 28-30, 2017 at the Bethesda North Marriott.

FDANEWS

	Early Bird Fee through February 17	No. of Attendees	Regular Fee After February 17	No. of Attendees
Preconference Workshop Only: FDA Cybersecurity and Risk for Devices	$497		$597	
Postconference Workshop Only: Device Supplier Quality Training Session Only	$997		$1,197	
Medical Device Quality Congress (MDQC) Only	$1,447		$1,697	
Preconference Workshop (FDA Cybersecurity and Risk for Devices) + MDQC	$1,697		$1,997	
Postconference Workshop (Device Supplier Quality Training) + MDQC	$2,197		$2,597	
Preconference Workshop (FDA Cybersecurity and Risk for Devices) + MDQC + Postconference Workshop (Device Supplier Quality Training)	$2,547		$2,997	
TOTAL PAYMENT	$		$	

Attendee 1: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____

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**

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Total amount $ _____
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(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.)

Company Information

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FDANEWS PRESENTS THE

14TH ANNUAL

MEDICAL DEVICE QUALITY CONGRESS

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

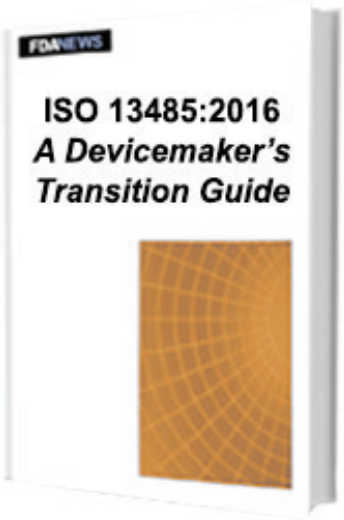
WHO SHOULD ATTEND

- 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.



ISO 13485:2016
A Devicemaker's Transition Guide

The ISO 13485 have rules changed — and you need to know how.

Our team of experts have spent hours parsing out every clause in the new version of the rules and compared them to ISO 13485:2003.

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- The status of EN ISO 13485:2016 and issues related to the product directives
- Some potential concerns related to ISO 13485:2016 and FDA's QSR
- How recent revisions to ISO 9001 compare to the new 13485

The report interprets the four key areas in the 2016 version — risk management, design control, supplier management and corrective and preventive action — and explains what kind of changes the new standard will require.

Based on the insight of one of the world's foremost ISO experts, this report is essential for any devicemaker that hopes to survive the coming transitions. Order your copy of **ISO 13485:2016 — *A Devicemaker's Transition Guide*** today.

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