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GAO: FDA Overlooked Cancer Risks in Medical Devices

The FDA's approval of morcellators put women's health at risk, says a report from the Government Accountability Office.

Over two decades, the FDA approved 25 power morcellators, although the agency knew they could spread uterine cancer, according to the report.

The agency was aware of the risk, but decided the danger — estimated to affect 1 in 350 hysterectomy or fibroid surgery patients — was not sufficient to warn women or doctors.

The report faults the FDA reporting system for devices as a whole, noting that procedural gaps either kept doctors and hospitals from alerting regulators to risks or kept regulators from reading those warnings.

The FDA did not issue a warning about gynecological morcellators' risk of exacerbating uterine cancer until 2014, more than

(See **GAO**, *Page 8)*

WHO Announces Plans For Essential Diagnostics List

The World Health Organization will develop an essential diagnostics list to help countries prioritize which in vitro diagnostics they offer through their national health systems.

The new list will complement the WHO's existing Essential Medicines List and initially will include IVDs for tuberculosis, malaria, HIV, and hepatitis B and C, all of which currently have strong programs for diagnosis and management.

The list will later be expanded to include other diseases from the EML, as well as other important diseases that do not have medicinal treatments but for which diagnostics play a critical role in disease management.

The essential diagnostics list is intended to make IVDs more affordable by facilitating bulk and advance purchases, increase individual countries' laboratory capacity to help prepare for future outbreaks, and

(See **WHO**, *Page 8)*

FDA Cites Neo Vision For Design Controls

South Korea-based Neo Vision received a warning letter for failing to establish proper design controls, monitor production processes, maintain device history records, and other violations.

Following a May 2016 inspection of Neo Vision's facility in the central Korean city of Wonju-Si, the FDA said the contact lens manufacturer failed to implement design controls and establish a design history file for some of its products.

Neo Vision also failed to develop, conduct, control, and monitor production processes to ensure that devices conformed to their specifications. A review of 11 device history records pertaining to soft contact lenses manufactured for the U.S. market revealed the firm did not have data to show that required testing was performed. In addition, there were no written procedures for testing certain raw materials.

The warning letter said the company had not established procedures for maintaining device history records, and 11 device history records from 2015 to 2016 pertaining to soft contact lenses were found to be incomplete.

FDA inspectors also faulted the company's reporting procedures. The warning letter said the company did not establish internal systems for identifying reportable events, provide for timely transmission of reports to the FDA, or say how record-keeping requirements would be addressed.

Read the warning letter here: www.fdanews.com/02-08-17-NeoVision.pdf.

FDA Observes Faulty Procedures at OMT Facility

OMT landed a Form 483 citing its handling of complaints, design controls, and other issues.

After visiting the company's Hollywood, Fla., facility in November 2016, the FDA inspector observed that a complaint regarding a device that malfunctioned during surgery was not evaluated according to OMT's procedures and was not reported to the FDA.

The inspector also found the facility did not properly implement design control procedures. One product's design history file did not include approved inputs, there was no evidence that design changes were validated, and the results of a design risk analysis were not adequately documented.

In addition, the company was cited for not implementing its supplier control procedures, including on-site audits of "critical suppliers." OMT also did not verify that a supplier used proper sterilization procedures, signed a written agreement, and completed and approved installation of equipment.

Inspectors further observed that OMT did not verify or validate corrective and preventive actions, as required by the company's procedures. For example, the corrective action in response to one complaint was to add additional instructions to a device. However, there was no evidence that doing so would resolve the root cause of the complaint.

Other observations on the 483 included failure to follow procedures for acceptance activities, document changes to procedures, establish and follow adequate training procedures, and implement an internal audit procedure.

Read the Form 483 here: www.fdanews.com/02-10-17-OMT.pdf.

PEOPLE ON THE MOVE

Genmab named **Judith Klimovsky** as chief development officer. She has had a distinguished career in drug development, most recently serving as senior vice president and global head, oncology clinical development, at Novartis.

TSO3 appointed **Mark Pasmore** as vice president of research and development. He previously held leadership positions in biofilms, sterilization, sterility assurance and microbial control for pharmaceuticals and medical devices for Baxter Healthcare and STERIS.

Integrity Applications has named **Sami Sassoun** as chief financial officer. He joins the company from Bedrock Enterprises. Integrity's former CFO, Eran Hertz, is expected to remain with the company for an undetermined period to assist in the transition.

New Bill Would Harmonize FDA Device Inspections

A bipartisan bill introduced last week in the Senate seeks to harmonize FDA's medical device inspections process worldwide by eliminating variations between countries.

The bill (S. 404), sponsored by Sens. Johnny Isakson (R-Ga.) and Michael Bennet (D-Colo.), would adopt a risk-based approach to inspections.

Other provisions would allow the FDA to inform manufacturers in advance of documents needed for audits, and provide an approximate time that audits would be conducted.

The bill claims the lack of transparency undermines confidence in U.S. standards.

In particular, it says inspections are not consistently risk-based, which can unduly burden facilities with strong compliance records. It also notes that foreign inspections are often conducted much faster than domestic ones.

The proposed bill would require the FDA to issue guidance documents providing templates for communication between the agency and manufacturers, establish a standard timeframe that applies to domestic and foreign inspections, and identify practices for the FDA and manufactures that will help inspections run smoothly.

In addition, S. 404 would change the process for granting export certificates to foreign countries for companies that seek to market their devices internationally.

For example, it would allow manufacturers to keep their export certificates if they can show the FDA that they have plans to address deficiencies found by agency auditors.

In a statement, the Advanced Medical Technology Association (AdvaMed) praised the bill as a needed update to the FDA's inspections process.

The legislation's risk-based approach would improve patient safety and help focus the FDA's limited resources on facilities that have the most potential to impact public health, AdvaMed said.

(See **Bill***, Page 4)*

Gynetech Cited For Reporting Procedures

Gynetech received a Form 483 for untimely reporting procedures, risk analyses that were not performed, and 12 other observations.

FDA inspectors visited the company's Richmond, Virginia, facility in September 2016 and found that a medical device report was not submitted within 30 days of receiving complaints that its Manipulator and Manipulator Pro surgical devices had seriously malfunctioned and caused surgical complications.

They also found that the firm had failed to document design risk analysis of the devices before a certain date. In addition, the firm's procedures required high-risk suppliers to be audited, but no audit criteria had been established.

Gynetech also was observed not to have established design transfer procedures. Design transfers of the devices were not documented during certain design projects.

The Form 483 additionally noted that customer complaint procedures did not ensure timely and uniform processing. None of the complaint records reviewed contained an adequate determination of whether a complaint indicated malfunctions that could likely contribute to a death or serious injury.

Auditors also observed that the firm lacked a medical device reporting procedure and had not adequately established plans that described or referenced design and development activities and defined responsibility for their implementation.

Other observations included a lack of procedures for addressing incomplete, ambiguous, or conflicting design input requirements, and inadequate procedures for design review, management review, and auditing.

Read the Form 483 here: www.fdanews.com/02-03-17-Gynetech.pdf.

India Finalizes New Regulations Specifically for Devices

India has finalized new regulations that separate out devices for the first time from broader drug regulations.

Effective on Jan. 1, 2018, the regulations will free device manufacturers from compliance with regulations written for pharmaceuticals. For example, India's drug regulations mandate four-phase clinical trials, whereas the new device regulations require two-phase trials.

Starting on Jan. 1, 2022, all medical devices sold in India will require a unique device identification (UDI), including a device identifier and a production identifier. A device identifier is a global trade number. A production identifier would include a serial number, lot or batch number, software version, and manufacturing and/or expiration date.

The new regulations specify fees for a variety of licenses and permissions for device importation, manufacturing, clinical investigations, and registration.

Before licenses are granted, notified bodies must audit manufacturing sites in India and must check for compliance with quality management requirements.

Device licenses and registration certificates obtained before the regulations are implemented will remain valid until they expire, or 18 months after implementation, whichever is later, India's Ministry of Health and Family Welfare said, in a Jan. 31 notice in India's regulatory Gazette.

Read the new regulations here: www.fdanews.com/02-07-17-Indiamedicaldevicerules.pdf.

Bill, *from Page 3*

S. 404 was referred to the Senate Health, Education, Labor and Pensions Committee. AdvaMed spokesman Mark Brager told *IDDM* the bipartisan measure could pass either a stand-alone bill or as a rider to the MDUFA reauthorization. However, there currently is no companion bill in the House.

Read the bill here: www.fdanews.com/02-17-17-IsaksonBennetbill.pdf.

NICE Guidance Calls for More Data On Body Composition Monitors

New guidance from the UK's National Institute for Health and Care Excellence (NICE) says there is currently not enough validation or clinical-outcome data to determine whether body composition monitors (BCMs) are effective for guiding fluid management in people on dialysis with chronic kidney disease.

The devices work by sending small, painless electrical signals through the body by way of electrodes. The electrodes also measure the opposition to the flow of the electric current from body tissues. The measurements are used to calculate hydration.

UK hospitals that are currently using BCMs should collect data, and those that are not should do so only as part of a research study, NICE said.

Currently, the fluid status of a person on dialysis is typically determined by clinical assessment, taking into account clinical features and symptoms that suggest overhydration or underhydration. However, individuals who are over- or underhydrated are often asymptomatic.

BCMs may help clinicians determine how much fluid to remove during dialysis. The guidance encourages BCM manufacturers to collect and publish data on both the validity of their device's underlying fluid models to calculate fluid overload and the associated clinical outcomes.

NICE recommends additional research into the clinical effectiveness of BCM-guided fluid management in individuals with chronic kidney disease who are undergoing dialysis. Further research should collect clinical outcome data in the following populations: adults (aged 18 years and over) having peritoneal dialysis; babies, children and young people (aged 18 years and under) having haemodialysis; and babies, children and young people (aged 18 years and under) having peritoneal dialysis.

Read the guidance here: www.fdanews.com/02-17-17-BCMguidance.pdf.

UK's NICE Recommends Intrabeam Radiotherapy System

The UK's National Institute for Health and Care Excellence (NICE) recommended the Intrabeam radiotherapy system (IRS) for treating early invasive breast cancer and HeartFlow FFRCT software for estimating fractional flow reserve from coronary CT angiography.

The Intrabeam is a mobile system that delivers a single dose of targeted low-energy radiation during surgical removal of a tumor. According to NICE draft guidance, the device costs less and is potentially more efficient than standard radiation treatments because it delivers radiation directly to the tumor bed.

The Intrabeam guidance calls for data to be collected on patients treated with IRS, such as tumor types, adverse treatment effects, and survival rates. The data will be used to inform future treatment decisions for other cancer patients.

NICE invited public comments on the Intrabeam draft by March 1.

NICE also issued final guidance recommending the HeartFlow FFRCT as a way to estimate fractional flow reserve using standard coronary CT angiography image data. The technology is thought to be non-invasive, safe, and accurate.

The device should be considered as an option for patients with stable, recent-onset chest pain, as it may avoid the need for invasive coronary angiography and revascularization. NICE also said using HeartFlow FFRCT may save £214 ($268) per patient, or at least £9.1 million ($11.4 million) by 2022 compared to invasive treatments.

Read the Intrabeam draft guidance here: www.fdanews.com/02-09-17-radiationtreatment.pdf.

Read the HeartFlow FFRCT final guidance here: www.fdanews.com/02-13-17-HeartFlow.pdf.

CFDA Establishes Permanent Device Recall Program

The China Food and Drug Administration (CFDA) has established a permanent medical device recall program that replaces a pilot program launched in 2011.

The permanent program, which will go into effect on May 1, expands the definition of "defective medical device" to include products that pose an unreasonable risk to human health or safety, do not meet regulatory standards or technical requirements, or fail to comply with quality management standards.

The program requires manufacturers to establish quality management systems that include adverse event monitoring. If a manufacturer discovers a defect and initiates a voluntary recall, it must publish a notice advertising the recall, and develop a detailed recall plan including the quantity of devices affected. The company must also file a report with the CFDA so the plan can be evaluated and must report on a recall's effectiveness.

New Survey Bullish On U.S., EU Device Markets

Medical device manufacturers expect strong sales growth in the U.S. and Europe this year but they are less enthusiastic about China and other developing markets.

Optimism for U.S. and European markets increased significantly between January 2016 and January 2017, according to a survey of more than 3,000 industry representatives, conducted for Emergo's Global Medical Device Industry Outlook for 2017. For example, 51 percent of respondents expected strong U.S. growth in 2016, compared to 60 percent in 2017.

Growth expectations for medical device markets in China, Brazil, and India declined for 2017 compared to last year. In particular, optimism for China's market fell from 44 percent of respondents in 2016 to 33 percent in 2017.

Read the survey here: www.fdanews.com/02-14-17-EmergoIndustrySurvey.pdf.

China Targets Sterile Devices, Implants and IVDs for Inspection

Grace Fu Palma, founder and CEO of Boston-based China Med Device, a firm specializing in commercialization and funding for medtech companies entering China, explains how medtech companies can use a new guideline from the China FDA to help secure fast track approvals for innovative medical devices.

In the previous column, I talked about China's fast track for innovative medical device approvals and how products can qualify under a new guideline issued in December 2016. This time I will look at how China's regulatory system is structured and at the China Food and Drug Administration's approach to medical devices.

China's State Council is the highest authority, so it is above the CDFA, which is the national authority for food and drugs. But each province has its own food and drug authority, and it is the provincial authorities, not the national authority, that have oversight of Class I and Class II medical devices.

Medtech is heavily regulated in China but the QMS and GMP requirements only date back to the 2000s, with major updates in 2009, 2013 and 2014. Compared to the mature U.S. regulatory system the Chinese system is still in development — a teenager, I would say.

But there is a lot of regulatory activity. The CDFA released 71 documents related to medical devices in 2016, including 19 decrees, 6 working reports, and 46 guidelines. Under China's centralized government, anything the CFDA says is mandatory, whether it's called a working document or whatever.

CFDA's main inspection focus is on sterile devices, implants and IVDs. Because they are high risk and invasive devices, they have well-defined requirements and are especially targeted for onsite inspection.

CFDA follows ISO standards, but it is often an older version of the ISO standard. For medical devices, China follows ISO 13485, but it follows the 2003 version, not the 2016 version, which means the requirements are different.

Under the China GMP there are more inspections, for example. It's very important to know the revision differences as it impacts how you prepare and test your equipment in China, which in turn impacts your approval schedule.

Different Inspection Requirements

There are many differences in inspection requirements in China compared with other countries. For a 510(k) in the U.S., for example, there is no requirement for an onsite inspection. But in China, if a domestic manufacturer wants to register a new product, there is onsite inspection, especially for new products.

More detailed standards of production, manufacturing, and quality systems started to be introduced in 2009, but actual supervision and monitoring from CFDA was very weak.

In February 2014, the State Council issued Medical Device Supervision and Administration Regulation (State Council #650), which went into effect on June 2014. The CFDA also issued a series of new regulations, guidelines and updates for medical devices. GMP is one of the key areas, with more than 18 regulations released already.

In summary, China's revised GMP and overseas on-site inspections and domestic unannounced inspections call for manufacturers to be more diligent and to make sure they are in compliance with the regulations.

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Editor's Note: Grace Fu Palma presented an FDAnews webinar titled **China Medical Device Regulatory Changes** on Jan. 31. A recording of the webinar is available here: www.fdanews.com/chinamdregulatorychanges.

WHO, *from Page 1*

help industry and regulators prioritize new IVDs for development and review.

The IVDs listed in the EDL will cover all levels of a healthcare system, and different IVDs for the same condition may be recommended depending on where they will be used.

In contrast to drugs, additional details on the characteristics of the IVDs will be needed to account for variations in training among users, such as staff in a reference laboratory versus health care workers in the field. In addition, a fast-track approval mechanism may be needed to list IVDs developed in response to infectious disease outbreaks.

The exact format of the new list has yet to be determined but it could be based on target diseases, the technologies used, the healthcare system level, or a combination of these, the WHO said.

The WHO Expert Committee on the Selection of Use of Essential Medicines will meet in March to consider the next steps. The EDL is scheduled to be finalized in 2019.

Read the announcement here: www.fdanews.com/02-14-17-EDL.pdf.

Powers Medical Devices Cited For Supplier Evaluations

The FDA cited Powers Medical Devices in a form 483 for failing to implement its supplier evaluation or internal audit procedures.

The agency inspected the company's Boca Raton, Fla., facility in late August and early September 2016, and found had not conducted a supplier audit for its contract manufacturer and contract engineering firm.

The company also failed to issue a supplier corrective action request to its contract manufacturer to investigate the cause of customer complaints regarding loose screws in its Pacifier Activated Lullaby (PAL) device. In addition, it did not ensure that its contract manufacturer implemented the quality system regulation regarding this issue.

In addition, the company failed to report that an updated user manual with additional warnings was sent to customers, or that a new warning label was affixed to PAL devices.

The agency also faulted Power Medical's procedures for reviewing complaints. For example, one complaint cited cracks in the plastic housing of PAL units, which the company blamed on rough handling by the customer, without documenting evidence to that effect. The company did not issue a corrective and preventive action to investigate and resolve the cracking issue.

The Form 483 also said the company failed to implement its internal audit procedure or conduct any quality audits.

Read the Form 483 here: www.fdanews.com/02-16-17-PowersMedical.pdf.

GAO, *from Page 1*

20 years after approving the first device. After receiving the first adverse event reports concerning the devices in December 2013, the FDA updated its safety guidance for the devices and encouraged manufacturers to update their labeling protocols. By December 2015, the agency had begun hospital inspections to ensure compliance with device reporting rules.

Beyond the inspections, the FDA assembled a team to evaluate and respond to morcellator safety issues and conducted a literature review to improve its understanding of the risks of uterine fibroid surgeries. In addition to the initial guidance update, the agency issued a safety communication in April 2014 discouraging the use of morcellators for myomectomies and hysterectomies.

Despite the steps taken by the FDA, the report notes numerous questions remain about the devices and the relative risks they pose. For example, there is a lack of information on how manual morcellation using a scalpel affects the risk of spreading cancer as compared to using power morcellators.

Read the GAO report here: www.fdanews.com/02-09-17-GAOReport.pdf. — Zack Budryk

BRIEFS

FDA Grants PMA Approval For Hologic Assay

Massachusetts–based, Hologic has received PMA approval from the FDA for its hepatitis C virus assay for measuring viral load and confirming infection.

The Aptima HCV Quant Dx assay uses real-time transcription-mediated amplification (TMA), which provides sensitive and specific performance for diagnostic use, and measures sustained antiviral response across all major genotypes.

The assay runs on the automated Panther system, which reduces hands-on time with random and continuous access.

The assay is CE-IVD marked for diagnostic and viral load monitoring in Europe.

Biolase Gains FDA Clearance For its All-Tissue Laser System

Biolase, has received FDA marketing clearance for its Waterlase Express all-tissue laser system.

The company said the product will be available to dentists in the U.S. as well as in Europe, the Middle East and Asia.

Health Canada Approves Medtronic's Drug-Coated Balloon

Medtronic Canada has obtained a license from Health Canada for its IN.PACT Admiral drug-coated balloon.

The endovascular device is used in patients with peripheral artery disease in the thigh and behind the knee.

A compressed balloon is inserted into the artery, inflated to re-open the blockage and then removed. The device leaves behind medication that helps prevent the artery from narrowing.

Abbott Issues Recall on StarClose SE System Due to Potential Faulty Clip

Abbott Vascular has issued a recall of the StarClose SE Vascular Closure System. The device may fail to deploy the StarClose SE Clip, which can lead to prolonged surgical procedure times.

Abbott advised healthcare providers to immediately stop using the devices and return unused devices.

Biotronik's Coronary Stent System Gets FDA Approval

Biotronik's pro-kinetic energy cobalt chromium coronary stent system has gained FDA approval.

The device is designed to expand coronary luminal diameter in patients with new and reoccurring blockages in the coronary arteries.

The strut thickness of this stent allows for deliverability under the most extreme conditions of bended areas and calcification.

It is indicated for patients who have a blockage in arterial vessels between 2.25 and 4.0 mm in diameter and lesion lengths up to 31 mm.

CareFusion Issues Recall For Faulty Air-In-Line Sensor

CareFusion recalled the Alaris Syringe Pump because of a faulty air-in-line sensor which could generate a false alarm and cause the syringe pump to stop supplying an infusion to the patient, which could cause serious adverse health consequences or death.

The device delivers fluids such as nutrients, blood and medications in controlled amounts.

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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
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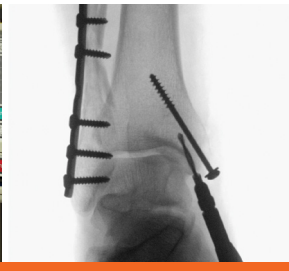

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PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 28

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 (MDQC) Only	$1,447		$1,697	
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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	
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"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

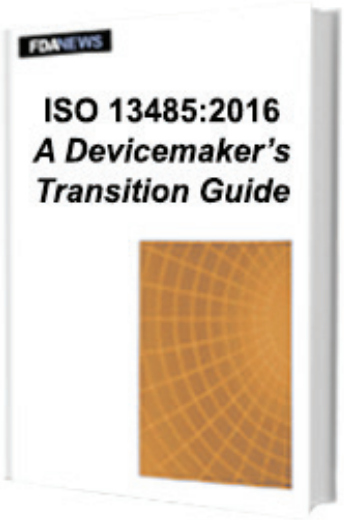
WHO SHOULD ATTEND

- 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.

ISO 13485:2016 — *A Devicemaker's Transition Guide* saves you valuable time. It has a clause-by-clause, line-by-line, 46-page comparison of the old and new versions of 13485 that shows you exactly what and where the new requirements are.

In this management report you will also learn:

- The major differences between ISO 13485:2003 and ISO 13485:2016
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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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