INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 3, No. 13
March 27, 2017

IN THIS ISSUE

FDA Center Directors Urge Lawmakers to Advance User Fees

Three senior FDA officials urged the Senate HELP Committee hearing Tuesday to move forward on user fees for devices or risk funding problems at the agency.

CDRH Director Jeffrey Shuren, CDER Director Janet Woodcock, and CBER Director Peter Marks highlighted the achievements of the current generation of user fee programs — such as clearing the backlog of device premarket approval applications and 510(k)s — and said the agency depends on user fees to fund essential programs.

Committee Chair Lamar Alexander (R-Tenn.) said if Congress does not reauthorize the FDA's user fees before July 27, the agency would be forced to begin notifying more than 5,000 employees that they could lose their jobs come October, when the user fee programs expire.

The center directors unexpectedly found themselves in the middle of a partisan debate over repeal of the Affordable Care Act,

(See **User Fees**, *Page 2)*

FDA Delays 'Intended Use' Rule for a Year

Following complaints from industry, the FDA has delayed until March 2018 implementation of a final rule that would broaden the definition of intended uses for medical devices and drugs using a "totality of the evidence" framework.

Industry representatives say the final rule's totality of the evidence standard greatly expands the current regulatory definition of intended use.

Khatereh Calleja, AdvaMed's senior vice president for technology and regulatory affairs, told *IDDM* the final rule's totality of the evidence standard "is inconsistent with the long-recognized definition of intended use and creates substantial uncertainty for manufacturers."

Hyman, Phelps, and McNamara attorney Jeffery Shapiro said the final rule appears to be "a blank check" for the FDA "to find whatever intent it wishes to find, using an unconstrained calculus as to what the 'totality of the evidence' shows."

(See **Delay**, *Page 4)*

User Fees, *from Page 1*

with the committee's Democrats arguing the time spent on user fees would be better spent debating the Republican bill scheduled for a House vote Thursday.

MDUFA IV would aim to collect $183 million in fiscal 2018, increasing annually to $213 million through fiscal 2022. The fees were previously negotiated by the FDA and regulated industry, to cover medical product reviews through fiscal 2022 (*IDDM*, March 20).

In his prepared testimony, Shuren said reauthorization of user fees would expedite the availability of innovative products, cut approval times, improve the agency's use of real-world evidence, and make regulatory decisions more consistent, transparent, and predictable.

He also highlighted accomplishments under MDUFA III. For example, CDRH decreased its average time for premarket approval decisions to 276 days from 427 days in fiscal 2009. The agency now takes an average of 133 days to approve 510(k)s, compared to 150 days in fiscal 2010.

Shuren added that CDRH went beyond its commitments under MDUFA III to reduce the average time to approve an investigational device exemption to 30 days in fiscal 2015, compared to 442 days in fiscal 2011. The average time to reach a decision on do novo classification requests for low- and moderate-risk devices took 259 days in fiscal 2014, down from 770 days in fiscal 2009.

In addition, Shuren said CDRH approved 91 innovative devices in 2016, more than in any year since the user fee program began in 2003.

AdvaMed President and CEO Scott Whitaker said in a statement that MDUFA IV "builds on the progress from the 2012 user fee agreement to further improve FDA's device review process while maintaining robust standards for patient safety." In particular, he said it would lead to greater FDA accountability, and would include two independent analyses of the agency's management of the review process.

The Senate committee has tentatively scheduled another hearing on user fees for April 4, featuring testimony from device manufacturers and drugmakers, as well as from patient representatives.

The FDA's written testimony for the March 21 Senate hearing is available here: www.fdanews.com/03-21-17-FDASenateTestimony.pdf.
— Conor Hale and Jeff Kinney

Upcoming FDAnews Webinars and Conferences

Sharpen your understanding of regulatory compliance at these upcoming FDAnews events. Click on the links below for details.

WEBINARS

Medical Device Clinical Evaluation Reports: Complying with European Guidelines and the New MEDDEV 2.7/1 Rev. 4 Guidance
April 4, 2017, 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/mdclineval

Dealing with Chinese Medical Device Regulatory Authorities
April 19, 2017, 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/chinamdreg

Biocompatibility for Medical Devices
April 20, 2017, 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/biocompatibilitymd

CONFERENCES

14th Annual Medical Device Quality Congress
March 28-30, 2017, Bethesda, Md.
www.fdanews.com/mdqc

Design Control for Medical Devices: Meeting FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing
April 5-6, 2017, Frederick, Md.
www.fdanews.com/mdqci

Data Integrity: The Key to FDA and GMP Compliance
May 9-10, 2017, Arlington, Va.
www.fdanews.com/fdadataintegrity

FDA Offers Best Practices For Pre-submissions

Pre-submissions allow the FDA to provide initial comments on premarket approvals, humanitarian device exemptions, de novo petitions, and 510(k) submissions.

They are especially useful if there are concerns related to novel technology, testing, or the need for a clinical study, Patrick Antkowiak, a biomedical engineer in CDRH's Office of Device Evaluation, said during an FDA-sponsored webinar.

One common problem is failing to provide enough information upfront. In particular, a lack of a device description, especially for devices the FDA has not previously reviewed under 510(k), may hinder meaningful discussion. As a result, a pre-submission should contain:

- A cover letter;
- Background information such as a general device description, bench/animal testing protocols, and clinical study protocols; and
- The proposed intended use and key aspects of the device design.

Pre-submissions for de novo devices also should specify the proposed class (Class I or II) and provide a discussion of the relevant regulations, a risk analysis, and proposed special controls. A pre-submission should not contain data, the agency said.

Other best practices for pre-submissions include:

- Review applicable guidance documents and standards;
- Explain how the proposal compares to those for similar devices;
- Identify and justify the most appropriate regulatory approach for the device;
- Make sure the documents are organized and easy to follow;
- Err on the side of providing more information than might be needed, but do not include circuit diagrams, lines of software code, or a copy of an entire grant; and
- If literature articles are cited, provide copies.

Avoid assumptions. If there is an applicable guidance, standard, or other regulatory precedent, cite it. If not, identify the most appropriate regulatory approach and justify it. For example, not every animal study requires a non-human primate model; some other model and protocol may be better suited to a particular situation.

Ask the FDA to answer specific questions about the device. Examples of good questions include:

- What animal model should we use?
- What should our clinical control group be?
- Does the FDA have any comments on the nonclinical test results?
- What concerns do you have with our proposed animal model?
- Is the selected control group in our proposed clinical trial appropriate?

The FDA typically provides feedback 75 to 90 days after receiving a submission, and will also meet with the manufacturer to discuss the pre-submission if requested.

Expedited Access Pathway

FDA officials also discussed benefit-risk determinations in PMA and de novo application decisions and the Expedited Access Pathway (EAP).

Biomedical Engineer Leigh Anderson in CDRH's Division of Neurological and Physical Medicine Devices said both clinical and non-clinical data can play a role in benefit-risk determinations.

Benefits the FDA considers include the type and magnitude of benefit, the probability that a patient will experience it, and the duration of effects. A risk analysis looks at severity, types, number, and rates of harmful events associated with use of the device.

The EAP is a voluntary, streamlined approval program for certain devices that provide for more effective treatment or diagnosis of serious conditions; represent breakthrough technologies, have no approved or cleared alternatives, or offer meaningful advantages over such alternatives; and are in patients' best interests.

View the webinar materials here: www.fdanews.com/03-23-17-Webinar.pdf.

FDA Expert Panel Seeks Solutions For Peroxide Contact Lens Risks

Peroxide-based contact lens product labels need clearer warnings and instructions for use to prevent adverse events, according to an FDA advisory panel.

The Ophthalmic Medical Devices Panel of the FDA's Medical Devices Advisory Committee and Risk Communications Advisory committee met in Gaithersburg, Md., March 17 to discuss risks associated with peroxide-based contact lens products. According to the panelists, there are many more adverse events — such as burning or irritation — caused by misusing hydrogen peroxide solution than are being reported to the FDA.

Panelists said warning labels and instructions for use should be simpler and more consistent. Most panelists also agreed that the hydrogen peroxide warning statement should be more prominent on the box and label and should include a red label warning sign.

Most panelists said the case and bottle should be redesigned to be functionally dependent to reduce human error. Currently, one can be used without the other.

CDRH will consider the advisory committees recommendations for possible regulatory changes.

Delay, *from Page 1*

The Medical Information Working Group, Pharmaceutical Research and Manufacturers of America, and the Biotechnology Innovation Organization filed a petition last month arguing for more time for public comment because the final rule expands the scope of intended use and raises First Amendment Concerns. "There is no support in existing law for the [totality of the evidence] standard, and it would represent a substantial change with significant constitutional and public health ramifications," the petition says.

Under the current intended-use regulation, if a manufacturer knows or should know that a medical product will be used for off-label purposes, the manufacturer should provide labeling for the additional uses.

A Jan. 9 final rule, which was scheduled to go into effect March 21, amends the intended-use provision to state that if the totality of evidence shows a manufacturer "objectively intends" that a device or drug is to be used for off-label purposes, the company must provide new labeling.

According to the FDA, the changes merely clarify that the manufacturer's knowledge of an off-label use is just one factor the agency considers when determining intended use. Other factors can include evidence such as the product's labeling, promotional claims, and advertising.

No comments have yet been posted in the docket for the final rule.

Read the final rule here: www.fdanews.com/03-20-17-FinalRule.pdf.

Read the *Federal Register* notice delaying the final rule's effective date here: www.fdanews.com/3-20-17-Petition.pdf.

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483 Round Up: Design Validations, Other Issues Noted at Four Companies

FDA inspectors found a DT Medtech facility in Towson, Md., lacked adequate design validation procedures.

In an inspection in October and November 2016, inspectors noted in a Form 483 that the firm's design validation activities for a surgical device were faulty. Specifically, surgical operating conditions were not established before validation activities were performed, and there was no documentation to indicate the device performed as intended. In addition, sterilization activities were inadequate or missing, and a protocol for laboratory and oven conditions for samples contained discrepancies.

The Form 483 also noted problems with documentation of risk analysis and design input requirements. Regarding design inputs, several terms on related documents were not adequately defined, and there was no verification testing to show that the outputs met the inputs.

In addition, DT Medtech failed to adequately implement CAPA procedures and it failed to conduct effectiveness checks for the procedures.

Lastly, procedures to ensure that received products conformed to requirements were not adequately established. For example, there was no documentation that potential suppliers, contractors, or consultants would be evaluated based on their ability to perform as instructed.

MIRA: Mira was cited in a Form 483 for inadequate CAPA procedures, risk analyses, and design verification.

The FDA inspected Mira's Uxbridge, Mass., facility in October and November 2016. Inspectors observed that corrective action had not been taken to address complaints of leaking high pressure gas from a probe used during ophthalmic surgery. This was a known malfunction that occurred under predictable circumstances, the agency said.

Inspectors also observed that no risk analysis was conducted for the effect of probe leaks on patients and users. Moreover, the risk assessment form did not indicate how the risk of leaks would be mitigated.

Mira also failed to verify that design output met design input requirements and probe tip temperature verification did not address unexplained spikes in temperature.

Inspectors further observed that a medical device report was not submitted to the FDA for several complaints listed in two previous Form 483s. The complaints involved gas leaks and other failures.

Other observations on the Form 483 included failure to establish requirements for and to evaluate suppliers of sterilization services, laser welding, and clean room bags, failure to validate processes for cleaning and other activities, and failure to establish proper responsibility for quality audits. In addition, the firm failed to validate designs under actual or simulated use conditions, to control environmental conditions, and to establish procedures for identifying valid statistical techniques.

Med-Hot Thermal Imaging: FDA Inspectors noted several observations during a January 2017 visit to Med-Hot Thermal Imaging's Lakeland, Fla., facility, including poor CAPA procedures.

According to a Form 483, the company's written CAPA procedures required evaluation of complaint information. However, the firm had not evaluated complaint information or document any corrective actions since June of 2009.

In addition, the firm's CAPA procedures did not define requirements for investigating the underlying cause of quality problems or for verifying that corrective actions were effective and did not adversely affect finished devices.

The FDA also said Med-Hot had not developed and maintained written medical device reporting procedures. For example, its current written procedures did not define a standardized process to identify events that had to be reported, requirements for timely reporting, or recordkeeping requirements.

Med-Hot also had no records covering modification of its TotalVision thermography software

(See **483***, Page 6)*

483, *from Page 5*

to support use with the FLIR thermographic camera. The firm had no verification records for the software or validation after modification, even though these were specifically required by the company's written software design procedures.

The Form 483 further noted a lack of written procedures to control hardware design. There also were no records covering development of automated and semi-automated thermographic camera stands, including documentation of design inputs, planning, review, verification, and validation.

The firm also failed to evaluate marketing materials for the TotalVision software and FLIR thermographic camera to ensure users could understand the intended uses of the device. Moreover, the firm did not have written procedures for evaluating design changes to see if pre-market notices had to be submitted to the FDA.

Additional observations included a lack of written procedures for evaluating suppliers, services, and contractors; and a failure to list the reasons for modifications to the TotalVision thermography software.

Illumina: The FDA hit device manufacturer Illumina with a Form 483, citing monitoring, labeling and procedural issues.

In a November 2016 inspection of the device-maker's San Diego facility, the agency uncovered numerous issues, according to the form. For example, the company had no established procedures to monitor and control validated process parameters.

The inspection further found the facility had not developed procedures for controlling environmental conditions, with certain areas of the facility lacking required mandatory programs to monitor and maintain differential pressure, according to the Form 483.

Read the 483s here: www.fdanews.com/03-24-17-Four483s.pdf.

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Innovative Device Approvals Slowed in 2016, Report Finds

The FDA granted fewer first-time premarket approvals for innovative devices last year than in 2015 and approvals took longer.

Just 38 first-time premarket approvals were granted to innovative devices in 2016, down from 51 the year before, the ECRI Institute said. The agency took an average of 18.1 months to grant the approvals, compared with 17.3 months in 2015. Cardiology devices were approved fastest in 2016, taking an average of 13.3 months.

Section 3051 of the 21st Century Cures Act could speed up approvals this year. It requires the FDA to establish a program to expedite the development of innovative devices that are designed to diagnose or treat serious conditions and that have no approved or cleared alternatives (*IDDM*, Dec. 30, 2016).

The agency approved no products in 2016 under the humanitarian device exemption (HDE), which requires a slightly lower standard to prove efficacy. Six HDE approvals were granted in 2015, and four in 2014.

Read the full ECRI report here: www.fdanews.com/03-16-17-ECRIreport.pdf.

Health Canada Looks to Release Device Clinical Information

Health Canada plans to allow public release of some clinical information submitted by manufacturers to support applications for regulatory approval of medical devices.

The agency currently treats clinical data as confidential business information and only releases it if needed to protect public health or safety.

Under the new policy, Health Canada would make certain clinical information publicly available for non-commercial purposes following final device approvals. That would include summaries of all completed clinical studies for Class III and Class IV devices, as well as detailed information of all clinical studies for Class IV devices. Class I and II devices would not be subject to these disclosure requirements.

Clinical information provided in medical device applications would continue to be treated as confidential during the regulatory review process. In addition, certain categories of commercial information would be exempted from public release, and medical device manufacturers would be allowed to suggest exemptions in specific cases. Information that identified clinical trial participants would be removed.

The policy paper notes that the European Medicines Agency and the U.S. Department of Health and Human Services have established or introduced similar initiatives to share clinical information while protecting privacy and commercial interests.

Read the policy paper here: www.fdanews.com/03-22-17-PolicyPaper.pdf.

PEOPLE ON THE MOVE

AdvaMed has made President and CEO **Nadim Yared** chairman of the AdvaMed board for a two-year term. Yared has served on the AdvaMed board since 2011 and on the board of AdvaMed Accel since its inception in 2012.

Motus GI has appointed **Samuel R. Nussbaum, M.D.**, to its board of directors. Dr. Nussbaum is a strategic consultant to EBG Advisors and a senior advisor to Sandbox Industries. He is a professor of clinical medicine at Washington University School of Medicine, an adjunct professor at the Olin School of Business, Washington University and a senior fellow at the University of Southern California Schaeffer Center for Health Policy and Economics.

SPR Therapeutics has named **Michael P. Chuisano** to its board of directors. Chuisano is vice president and chief operating officer for Johnson & Johnson Innovation-JJDC where he has served in various roles over three decades. In July 2016, SPR received clearance from the FDA for its SPRINT peripheral nerve stimulation system for relief of chronic and acute pain.

BRIEFS

CDRH Debuts 2017 Experiential Learning Program

The Center for Devices and Radiological Health (CDRH) announced the 2017 Experiential Learning Program (ELP), which allows the center's staff to visit manufacturing facilities and get a up-close view of the medical device development life cycle.

CDRH is inviting participation from companies, academia, and clinical facilities, medical device incubators and accelerators, health insurers, health technology assessment groups and others, including those that have previously participated in the ELP or other FDA site visit programs.

All sites that participate in the ELP program must have a successful compliance record with the FDA or another agency with which the FDA has a memorandum of understanding.

The submission period for participation in the ELP is March 23 - April 30, 2017. Submissions can be made at www.regulations.gov.

FDA Clears Medtronic's Transcatheter Valve with Advanced Sealing

Medtronic received FDA clearance for its CoreValve Evolut PRO valve for the treatment of severe aortic stenosis for symptomatic patients who are at high or extreme risk for open heart surgery.

The device is designed with an outer wrap that adds surface area contact between the valve and the native aortic annulus to improve valve sealing.

The device is delivered through the EnVeo R delivery catheter system and is indicated for vessels down to 5.5 mm. The 23mm, 26mm and 29mm sizes of the device are available for use in the U.S.

FDA Grants Clearance to BioStable's Aortic Annuloplasty Device

BioStable Science & Engineering has received FDA market clearance for its HAART 300 aortic annuloplasty device.

The device is designed to re-size, reshape and stabilize the aortic annulus to restore valve competence and help prevent recurrent aortic regurgitation.

The device received the CE Mark in 2016.

NICE Recommends Boston Scientific Defibrillators

The UK's National Institute for Health and Care Excellence (NICE) issued guidance recommending the use of Boston Scientific's cardiac resynchronization therapy defibrillators (CRT-D) for treating patients with heart failure.

The device is designed to extend the battery life of Boston Scientific cardiac resynchronisation therapy-defibrillator CRT−D devices.

CRT−Ds are a treatment option for heart failure and life-threatening ventricular arrhythmias.

Enduralife battery technology uses a lithium manganese dioxide (Li/MnO2) battery chemistry, which is claimed to be less susceptible to the variations in voltage and resistance associated with early battery depletion.

NICE concluded the extended battery life observed with the CRT-D is likely to reduce the number of replacement procedures, offering improved outcomes for patients and saving the National Health Service about £6 million ($7.5 million) in the first five years.

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– Rossellen Miller, Product Development Quality Engineer, Terumo Cardiovascular

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– Michael Healy, QA/QC Director, Tryton Medical

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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

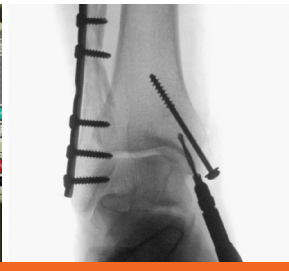
William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA

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.



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 (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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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

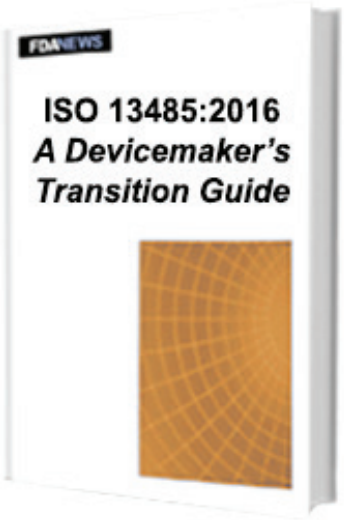
WHO SHOULD ATTEND

- 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.

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
- The role of ISO 13485:2016 in the MDSAP and Canada's plan to adopt it
- 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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