INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Trump Budget Proposes Steep Hike in FDA User Fees

President Trump released his first budget blueprint last week, calling for FDA user fees to rise to more than $2 billion for fiscal 2018 — up from the $1.36 billion set for 2017 — and for $1 billion to fund the 21st Century Cures Act.

The current user fee reauthorization package being considered by Congress for devices 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. Both House and Senate committees have user fee hearings scheduled for next week.

Trump's proposed increase would remove the need for new federal budget appropriations to cover pre-market reviews. The increase in revenue from user fees could equal approximately one-third of the FDA's total annual budget appropriation from Congress.

"In a constrained budget environment, industries that benefit from the FDA's approval can and should pay their fair share," the blueprint says. A fuller budget request containing more details is expected before the end of June, according to the White House.

AdvaMed President and CEO Scott Whitaker said the group "would be concerned if the agency were to face significant budget cuts that would negatively impact the approval process." He said AdvaMed remains committed to the medical device user fee agreement as negotiated.

The Alliance for a Stronger FDA called the budget request "neither wise nor realistic."

"User fees have always been intended to supplement the agency's appropriation, never to replace it," the Alliance said.

The chair of the Senate health committee, Sen. Lamar Alexander (R-Tenn.), referred to the president's budget request as a suggestion, and said Congress would act on its own.

"We will not balance the budget by cutting discretionary spending, which is only 31 percent of spending and is already under control because of earlier budget acts," said Alexander, who is also a member of the Senate Appropriations Committee.

The president's full blueprint is available here: www.fdanews.com/03-16-17-BudgetBlueprint.pdf. — Conor Hale

IMDRF Round Up: Forum Plans Guidance on UDIs, SaMD

The International Medical Device Regulators Forum plans to develop guidance on a global unique device identification (UDI) system to help ease the regulatory burden on manufacturers selling medical devices in more than one country.

The document will focus on UDI assignment rules, the structure and format, specifications for device identifier core data elements, and on general principles for exceptions or alternatives when UDI marking is not feasible.

IMDRF members discussed the planned guidance at the forum's March 14-16 meeting in Vancouver, Canada. The European Commission will chair a work group that will lead the development of the UDI guidance.

Unresolved issues with existing UDI rules in the U.S. and elsewhere have presented obstacles to harmonization. For example, the device industry says the FDA needs to revise its UDI rule to clarify how to label devices with multiple components and when design changes require a new UDI (*IDDM*, Oct. 21, 2016).

Software as a Medical Device: The IMDRF also plans to finalize a draft guidance document outlining steps required to generate clinical evidence of effectiveness and safety of software as a medical device (SaMD). The final document is scheduled to be completed in May or June 2017.

The draft IMDRF guidance, distributed by the FDA for public comment in October 2016, addresses stand-alone software designed to produce or extract data, including diagnostic information, in tandem with a medical device. SaMD is not part of a device, nor is it used to operate a device, and would run on general-purpose computing platforms (*IDDM*, Oct. 16, 2016). US industry groups said the guidance might not fit well into the FDA's regulatory regime (*IDDM*, Jan. 20).

In comments, stakeholders noted some terms used in the draft guidance are confusing and may not be relevant to SaMD, and some need to be clearly defined. However, a majority of commenters said the draft document accomplishes its basic purpose.

Upcoming Regulatory Documents from IMDRF Members: At the Vancouver meeting, Singapore's Health Sciences Authority said it will update guidance on preparing medical device registration applications, incorporating elements of the Association of Southeast Asian Nations (ASEAN) Common Submission Dossier Template (CSDT). The CSDT aims to provide a common template for submitting device information to regulatory authorities in ASEAN member countries.

Health Canada's Medical Devices Bureau said it will revise its guidance document on regulation of medical devices manufactured from or incorporating viable or non-viable animal tissue or their derivatives. It also will revise guidance on preparing applications for investigational testing.

Australia's Therapeutic Goods Administration said it plans to release guidance on implant labelling and patient cards, electronic medical instructions for use for implantable devices, and 3-D printing. It also will complete a transition of in-house IVDs by mid-year.

Read the IMDRF UDI guidance document here: www.fdanews.com/03-08-17-UDIguidance.pdf.

Read the draft SaMD guidance here: www.fdanews.com/10-13-16-DeviceSoftware.pdf.

FDA Flags Procedural Failures, Reporting Issues at Trimed

The FDA issued a Form 483 to Trimed, citing procedural failures, as well as labeling and reporting problems.

In a March 2016 inspection of the medical device manufacturer's Santa Clarita, California, facility, the inspector noted the firm failed to properly evaluate complaints of possible device failures, and did not submit an MDR report within 30 days of being informed of risks of a malfunction — a repeat observation dating back to a 2012 inspection.

Read the Trimed Form 483 here: www.fdanews.com/03-17-17-trimedinc483.pdf.

Gottlieb Nomination Draws Positive Reviews, and Some Questions

The administration's plan to nominate Scott Gottlieb as FDA commissioner drew generally positive reactions on Capitol Hill and from device makers — but also some concerns from other stakeholders over his strong industry ties.

The Advanced Medical Technology Association (AdvaMed) said Gottlieb's background and commitment to technological innovation makes him a "strong choice" to lead the FDA. Gottlieb previously served as an FDA deputy commissioner. AdvaMed President and CEO Scott Whitaker said his group looks forward to working with Gottlieb on the medical device user fee reauthorization.

The Association of Clinical Research Organizations said it "applauds the thoughtful nomination," and said it believes Gottlieb will strike the appropriate balance of encouraging innovation while ensuring the safety and efficacy of new drugs.

Sen. Lamar Alexander (R-Tenn.), chair of the Senate health committee that will oversee Gottlieb's confirmation hearing, described his "impressive qualifications," and said he looked forward to discussing the FDA's implementation of the 21st Century Cures Act.

FDA Publishes List Of Class II 510(k) Exemptions

The FDA has released a draft document listing more than 1000 Class II devices, diagnostic tests and reagents it proposes to exempt from 510(k) premarket notification requirements.

In some cases, the agency may limit exemptions to specific devices or tests within a given type. For example, the draft list includes endoscopic magnetic retrievers but limits the exemption to those intended for a single use.

The document consists of two tables. Table 1 lists Class II devices and diagnostic tests such as glucose monitors, catheters, umbilical clamps, enzyme immunoassays, and thin layer chromatography.

Table 2 lists immunological test systems for various types of allergens.

Allyson Mullen of Hyman, Phelps and McNamara said in a blog that the most notable proposed exemption relates to tests for drugs of abuse and includes not just those for professional use, but also some over-the-counter tests.

She also noted that a manufacturer would still have to obtain a 510(k) clearance for an exempt device if it is intended for a different use or operates using a different technology than a legally marketed device of that type.

Read the draft list here: www.fdanews.com/03-15-17-ClassIIexemptions.pdf.

FDA Classifies Glucose Monitors, Sequencers, Vibration Devices

The FDA has classified continuous glucose monitor secondary displays, high throughput genomic sequence analyzers, and vibratory counter stimulation devices as Class II devices with special controls.

The agency has identified several potential health risks associated with glucose monitor secondary displays, including incorrect glucose values that could affect treatment recommendations. Special controls required by the agency include data protection measures and specified labeling requirements.

Genomic Sequencers: Inaccurate test data in high-throughput genomic sequence analyzers can produce health risks. As a result, these devices were classified into Class II with special controls, which include the development of analytical performance information for general validation testing.

Specialized testing equipment would be needed to show suitability for a specific use, such as hematology or oncology. The FDA also established labeling requirements for the devices.

Counter-Stimulation Devices: Vibratory counter-stimulation devices produce mechanical

(See **Classifications**, *Page 6)*

MHRA Issues Guidance on Leadless Pacemaker Clinical Studies

The UK's medical device regulator issued new guidance on the design of pre- and postmarket clinical studies for leadless pacemakers, including patient selection, sampling, and adverse event monitoring.

The Medicines & Healthcare Products Regulatory Agency (MHRA) says manufacturers should work to minimize bias and make inherent design limitations explicit – and statistical assumptions should be agreed to in advance with regulators and not be altered without approval.

Premarket studies should be supplemented by postmarket studies or registries to evaluate longer-term safety and performance, MHRA says. The guidance also says postmarket study and registry requirements should be based on what was learned during premarket evaluation.

Patients who take part in both pre- and postmarket studies should be representative of those who will be treated in clinical practice. Clinical indications for which a pacemaker is approved must be based on evidence gained from equivalent patients included in the premarket study.

Sample size will depend on the nature and seriousness of adverse events, the type of study, and specific performance criteria. Each adverse event should be reviewed by an independent data monitoring committee with the goal of reducing the likelihood of recurrence, MHRA said.

Read the MHRA guidance here: www.fdanews.com/03-13-17-PacemakerGuidance.pdf.

FDA Mulls Establishing Patient Affairs Office

The FDA is considering establishing a new office for patient affairs to support the agency's efforts to engage patients in the device development process.

The agency is inviting comments for 90 days on the proposal, which responds to calls from stakeholders for more centralized patient engagement.

The office is intended to improve patient engagement in the development process across product centers — such as CDRH — with improved transparency and accessibility. It would focus on developing a better understanding of patient experiences with diseases, and on familiarizing patients and advocates with the FDA's regulatory processes.

For the next version of MDUFA, the FDA has proposed establishing a dedicated staff to help device makers use patient input in their device development. Congress will have to craft a legislation package to reauthorize MDUFA before Oct. 1.

Read the notice here: www.fdanews.com/03-13-17-Notice.pdf. — José Vasquez

Clinical Evaluation Reports or Clinical Trials?

Grace Fu Palma, founder and CEO of Boston-based China Med Device, LLC, a firm specializing in commercialization and funding for medtech companies entering China, explains how medtech companies can save time and expense for medical device registrations in China.

China's new requirements for CERs (Clinical Evaluation Reports) and CTs (Clinical Trials) have now been in place for more than two years. Understanding the difference and their appropriate use can save manufacturers significant cost and time to market.

The Regulations for the Supervision and Administration of Medical Devices (State Council Decree No. 650), implemented June 1, 2014, led to a wave of new CFDA regulations, including 100 decrees and guidelines on registration alone.

The new requirements for clinical evaluations or clinical trials have significant implications for any manufacturer's medical device registration costs, approval or rejection.

For a new device registration, the manufacturer must first determine the device classification within the CFDA classification catalogue. U.S. FDA classification does NOT correspond to that of CFDA. A U.S. FDA exempt device could be a class II in China.

Generally, a class I device needs to file with CFDA only. Most class III devices need a clinical trial, especially if the devices are listed in the "Catalogue for Class III Medical Device that Needs Clinical Trial."

After you know the classification of your device in the CFDA classification system, check first to see if you device is on the clinical trial exempt list. Make sure that you refer to the new updated clinical trial exempt list: 1) CFDA Notice No. [2016] No. 133 Clinical Trial Exemption List for Class II Medical Devices, released on 2016.09.27, 2) CFDA Notice No. [2016] No. 133 Clinical Trial Exemption List for Class III Medical Devices released on 2016.09.27.

If a device is not listed on the clinical trial exempt list in class II or certain types of class III, the manufacturer should determine the option of CER or CT and consult the subject expert in China.

Most companies should choose CER instead of CT for several reasons. Most importantly, CT takes more than 12 to 18 months and costs more than $500,000, while CER typically takes 3 to 4 months and costs $40,000 to $100,000.

CERs must comply with CFDA Medical Device Clinical Evaluation Technical Standards. For low risk, matured devices where there is an established manufacturing process and a large amount of available safety and clinical effective data, a CER is a viable option.

Clinical evaluation data typically consist of 1) Clinical Literature — Data from other devices, 2) Empirical Data — Clinical Data done outside China, 3) Clinical Trial — Clinical Data done inside China.

The key questions for an effective CER is the following:

- Is there any predictive device in China?
- Do you have sufficient technical and clinical information for the predictive device?
- Have you done clinical trials outside China?
- Are the clinical trial data sufficient in terms of sample size, indication, coverage, Asian/Chinese data subgroup?

CFDA judges whether or not the CER is sufficient. It is very important that you have a subject expert to evaluate and write the CER.

— Grace Fu Palma | gpalma@chinameddevice.com
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Classifications, *from Page 3*

vibrations to improve the quality of sleep in patients with primary Restless Legs Syndrome. Health risks include pain and discomfort, electrical shock, burns, adverse skin reactions, and interference with other medical devices.

This device and others of its type were classified into Class II with special controls, including labeling requirements; testing to determine electromagnetic compatibility, electrical safety, and thermal safety; software validation; biocompatibility for components that contact the patient; and non-clinical performance testing.

Read the glucose monitor announcement in the *Federal Register* here: www.fdanews.com/03-13-17-GlucoseMonitors.pdf.

Read the genomic sequencer announcement here: www.fdanews.com/03-13-17-GenomicSequenceAnalyzers.pdf.

Read the counter-stimulation device announcement here: www.fdanews.com/03-13-17-Counter-StimulationDevices.pdf.

PEOPLE ON THE MOVE

Dr. Nicholas Medendorp, Jr. was named CEO of **PhotonMD**. Medendorp, founder of PhotonMD, holds more than 80 US patents in LED and lighting products. Previously, Medendorp served as vice president, medical devices at Novan where he led the team responsible for the creation and development of medical devices.

Biolase recruited **James D. Surek** as vice president of sales, Americas. Mr. Surek brings with him more than 24 years of experience in medical device sales and sales leadership in start-up, turnaround and high-growth environments. Most recently, Mr. Surek served as the vice president of sales for Entellus Medical.

ContraFect Chairman and CEO **Steven C. Gilman** has taken temporary medical leave. Dr. Gilman will continue to serve as chairman during his temporary leave of absence. He is expected to return to his CEO role in the third quarter of 2017. Six of the company's executive officers will assume the duties of CEO until his return.

483 Round Up: FDA Cites Three U.S. Facilities Over CAPA, Other Issues

Strata Skin Sciences failed to report a correction or removal to the FDA and committed other violations, according to agency inspectors.

The FDA investigator visited the company's Carlsbad, Calif., facility in December 2016 and observed in a Form 483 that the company failed to report the details of a CAPA action in response to a customer complaint that the company's XTRAC Excimer Laser System fired randomly.

The complaint was submitted to the FDA as a malfunction that could result in serious injury if it were to recur. Although the CAPA states that steps were taken to avoid a recurrence, including a design change, the correction was not reported to the FDA.

The Form 483 also reported that the company failed to review all the circumstances that led to the random firing issue for the Excimer Laser System, including additional complaints for similar issues received during the investigation period. Moreover, the procedure did not require verification of all corrective actions to ensure they were effective.

The inspector also faulted Strata's medical device reporting procedures, which did not require documentation and recordkeeping of information evaluated to determine if an event was reportable.

In addition, the company's risk management process did not include documentation showing that complaints were evaluated to determine new or increased risks to patients.

Other observations included: (1) requirements to ensure that finished devices were held until authorized signatures were obtained and other procedures were completed; (2) complaints were closed without documentation that returned products had been evaluated; and (3) class designations and warnings were not provided in product brochures.

US Endoscopy: US Endoscopy Group failed to properly document CAPA procedures and committed other violations, according to a Form 483.

Following an inspection of the company's Mentor, Ohio, facility in November and December 2016, inspectors observed that the facility did not conduct appropriate CAPAs for two situations.

In a post-production data analysis for the Raptor Grasping device, the company concluded based on an MDR summary, the calculated incident rate was higher than expected. But it failed to document any review or mitigation steps. Another CAPA for defects in gauge needles lacked full documentation of a root cause assessment, including corrective actions, preventive actions and verification/validation activities.

The Form 483 also noted that US Endoscopy's complaint investigation procedure did not clearly define how and when risk assessments were reviewed and updated. For example, documentation stated that a complaint was reviewed and the associated hazards were identified, but there was no documentation of whether the event fit the identified risk profile or if the risk assessment needed updating.

Fundus Photo: The FDA slapped medical device company Fundus Photo with a Form 483, citing procedural and record-keeping failures.

In a December 2016 inspection of the medical device manufacturer's Lenexa, Kans., facility, FDA inspectors uncovered numerous problems with records. For example, the facility did not keep adequate device history records, and failed to maintain formal complaint investigation records or master device records. The agency noted an issue with master records in a previous inspection.

The inspection also uncovered numerous procedural issues at the facility.

Read the Strata Form 483 here: www.fdanews.com/03-13-17-Strata.pdf.

Read the US Endoscopy Form 483 here: www.fdanews.com/03-13-17-USEndoscopy.pdf.

Read the Fundus Form 483 here: www.fdanews.com/03-17-17-fundusphoto483.pdf. — Zack Budryk

BRIEFS

Health Canada Approves Ventripoint's Complete Heart Analysis System

Ventripoint has received a license from Health Canada for the new VMS-PLUS machine and the 4-chamber heart analysis system.

The VMS is already licensed in Canada for use for the right ventricle. The new product is an expansion of the VMS heart analysis product to include right atrium, left atrium and left ventricle chambers of the heart.

The expansion allows for measurement of volume and function for all four chambers of the heart using a 2D ultrasound.

Tryton Medical Gains FDA Approval For Tryton Side Branch Stent

Tryton Medical has received FDA approval for the Tryton Side Branch Stent for the treatment of coronary bifurcation lesions involving large side branches.

The stent is intended for patients with large side branches — appropriate for a ≥2.5mm stent.

The device is available in multiple diameters and is compatible with any conventional drug eluting stent in the main vessel.

NxStage Medical Awarded CE Mark For its NxGen Hemodialysis System

Massachusetts–based NxStage Medical has received CE Mark approval for its next generation hemodialysis system.

The system has touchscreen user interface and an integrated blood pressure monitor designed for ease of use for patients performing home hemodialysis.

The system is currently under review for marketing clearance from the FDA.

FDA Grants Marketing Clearance To Nephros' Endotoxin 10" Filter

New Jersey–based Nephros received clearance from the FDA to market its EndoPur endotoxin 10" filter.

The filter is designed to provide hemodialysis quality water to dialysis machines. The product fits into existing filter cartridge housings of reverse osmosis water systems that provide dialysis clinics with high volumes of ultrapure water.

The company will begin marketing the filter in the second quarter of 2017.

BTG Gains CE Mark for Drug-Eluting Bead

BTG has received Class III CE Mark certification for DC Bead LUMI, which is a radiopaque drug-eluting bead.

The bead can be loaded with doxorubicin or irinotecan for the local treatment of tumors in patients with hepatocellular carcinoma and malignant colorectal cancer metastasized to the liver.

The bead allows real-time confirmation of its location, enhancing the level of control in transarterial chemoembolisation procedures.

FDA Approves Spectral's PMA Module For Treatment of Endotoxemic Septic Shock

Toronto–based Spectral received approval from the FDA for the third module of its rolling PMA submission from the FDA for Toraymyxin (PMX).

PMX is a therapeutic hemoperfusion device that removes endotoxin — which can cause sepsis — from the bloodstream.

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FDANEWS PRESENTS THE
14TH ANNUAL

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
NORTH BETHESDA, MD

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

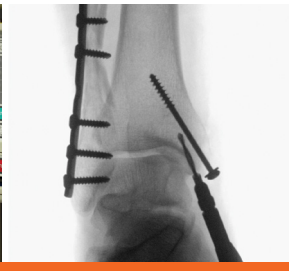
William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA

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.



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	
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	
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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

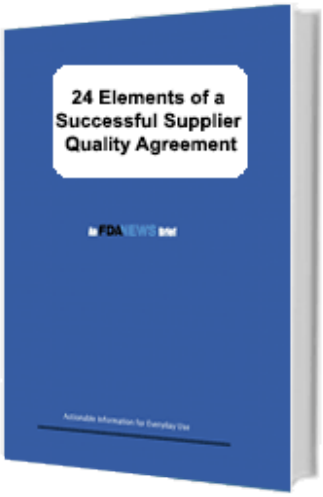
- Quality Assurance/Quality Control
- Manufacturing and Contracting
- Design Control
- Supply Chain Management
- Risk Management and Product Lifecycle Management
- Post Market Surveillance
- Executive Management
- Regulatory Affairs
- Research and Development
- Compliance Officers
- Consultants/Service 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.

FDANEWS



24 Elements of a Successful Supplier Quality Agreement

Supplier quality is a fundamental topic of perennial importance.

Your agreements with suppliers must be written and executed to cover every possible contingency and ensure that the materials that go into your products are exactly what you require and are available when you need them.

Today's minor mistake by your supplier could easily turn into tomorrow's major recall. And if you don't catch all the oversights in your quality agreement, odds are the FDA will.

In this FDANews Brief, 20-year industry veteran Steven Sharf, explains the elements that need to go into your quality agreement:

1. Calibration and Maintenance
2. Batch Documentation
3. Change Control
4. Deviations / OOSs
5. Field Alerts / Recalls
6. Material Inspection / Testing / Release
7. Labeling Controls
8. Rejected Materials
9. Complaint Handling
10. APR / PQR Inputs
11. Audits / Inspections
12. Specifications
13. Subcontracting
14. Dispute Resolution
15. Warehousing and Distribution
16. Technical Transfer
17. Validation / Qualification
18. Record Retention
19. Sample Retention
20. Reprocessing / Reworking
21. Supplier Qualification
22. Stability Programs
23. Contact List
24. Responsibility Matrix

Use this 24-point plan to make sure you've covered all your bases and keep your suppliers well in hand. Order your copy today.

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☑**Yes!** Please send me ____ copy(ies) of ***24 Elements of a Successful Supplier Quality Agreement*** at the price of $177 for each PDF.

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