INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Lawmakers Continue to Press for Answers On Implications of Hiring Freeze for FDA

Two lawmakers behind the Cures Act have asked the Office of Management and Budget to clarify whether the federal hiring freeze applies to the FDA, raising concerns that the freeze could disrupt the implementation of the bipartisan law and the passage of user fee agreements.

The letter, authored by Reps. Fred Upton (R-Mich.) and Diana DeGette (D-Colo.), calls on OMB — which previously released guidance on President Trump's executive order imposing a federal hiring freeze — to specify whether the FDA is subject to the freeze.

Understaffing at the FDA has historically delayed approvals for branded drugs and generics, the lawmakers noted, and a hiring freeze would only worsen delays and keep the FDA from carrying out several of its new responsibilities under the Cures Act.

The freeze could also interfere with the reauthorization of user fee agreements, which will expire at the end of fiscal 2017, the letter said.

(See **Hiring**, *Page 2)*

Risk Rankings Can Help Manage Suppliers, Expert Says

Combining various risk metrics into a single number can help manufacturers rank suppliers according to risk and identify those that might need to be dropped.

Device manufacturers should explore the use of additional risk factors to supplement traditional quality metrics when assessing their suppliers, said James Shore, principal of Quality Lean Solutions**,** in an FDAnews webinar.

Traditional supplier management metrics — such as incoming inspection, on-time delivery, and responsiveness to supplier corrective action requests — are "fine as a foundation" but do not help in monitoring supplier risks, and traditional supplier report cards often fail to show meaningful distinctions between suppliers, he said.

(See **Risk**, *Page 8)*

FDA Dings X-Zeal on Design Validation, Reporting Procedures

The FDA sent medical device manufacturer XZeal Technologies a Form 483, citing issues with medical device reporting procedures and design validation.

In an October 2016 inspection of the company's Kissimee, Florida facility, the FDA found XZeal's design validation process for its Z70 Dental X-Ray device user manual did not ensure that installation instructions were validated for all users that may install the device. For example, design validation activities were conducted using only technicians from device distributors and did not include dentists.

In addition, the company's medical device reporting procedures were observed to be inadequate because they did not contain instructions for conducting a complete investigation of each event and evaluating the cause of the event.

Read the Form 483 here: www.fdanews.com/02-06-17-xzealtech483.pdf.

UK's MHRA Proposes New Medical Device Fees

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) plans to raise its licensing and other fees for medical device manufacturers and notified bodies to help make up a chronic funding shortfall.

Most of the new fees will come from notified bodies to cover designation, auditing, and related activities. However, manufacturers' fees for registering Class I devices, custom-made devices, and in vitro diagnostics also will increase from £70 to £100 ($87-$125).

Given that the MHRA receives about 620 device registrations and 360 registration change requests annually, this relatively small change is expected to increase the MHRA's income from device-related fees from about £241,000 to £462,000 ($300,000 to $576,000).

Read the announcement here: www.fdanews.com/02-06-17-MHRAfees.pdf.

Hiring, *from Page 1*

The lawmakers recommend that hiring funded by user fees be exempt from the executive order, because drug sponsors pay the fees in exchange for FDA commitments on review timelines, meetings, public workshops and guidance documents. Under the latest iteration of one of the user fee agreements, for instance, the FDA committed to hiring 200 employees. Currently, the FDA faces about 1,000 vacancies, the letter said.

Last month, Democratic members of Congress asked President Trump how the hiring freeze would affect the FDA's user fee program, which account for 42 percent of the agency's budget.

Democratic senators penned a letter to the FDA as well, asking whether the agency would exempt any job positions, such as product reviewers, under provisions of the executive order that permit hiring related to public safety (*IDDM*, Feb 3).

Read the letter here: www.fdanews.com/02-07-17-UptonDeGetteLetter.pdf. — José Vasquez

White House Clarifies 'One In, Two Out' Regulations Order

The Office of Management and Budget clarified President Trump's new "one in, two out" regulations order, narrowing its scope to significant regulations with an economic impact of over $100 million per year — and said the release of new guidance documents would be considered on a case-by-case basis.

Regulatory actions required by law may also proceed — such as provisions in the 21st Century Cures Act requiring the FDA and HHS to publish guidance and issue rules — without identifying cuts, if agencies are facing a legal deadline.

Agencies should also "confirm that they will continue to achieve their regulatory objectives," when identifying the two regulations to be cut for each new one proposed, the White House said.

The OMB's Feb. 2 interim guidance memo to federal agencies, posed in a question-and-answer format, explains which types of regulations would be covered or could receive a waiver, as well as how costs and savings would be measured.

The president's Jan. 31 executive order referred to all agencies and all new regulations, but the OMB guidance specifies that the order will only apply to significant regulatory actions for fiscal 2017. Significant regulations are defined as those that could have an annual effect of $100 million or more on the economy — and only to regulations issued after President Trump took office. Those with proposed rules issued before Jan. 20 would also be included.

Waivers may be requested from OMB for emergencies related to health and safety and other reasons, and before the issuance of a rule, the guidance said.

Agencies should consider the compliance costs of reporting and recordkeeping required by new rules, the guidance said. The effects of cost savings — related to adopting more energy-efficient technologies, for example — would not be counted as offsets in most circumstances.

Regulations to be eliminated should be identified in the preambles of new rules, OMB said. But they could be bundled and executed as part of a single regulatory action. If one agency cannot find enough regulations to cut, cuts by another agency could suffice, if approved by the director of the OMB.

OMB is developing further guidance on the executive order's effects for fiscal 2018 and beyond.

Read the full guidance memo here: www.fdanews.com/02-03-17-OMBRegulationGuidance.pdf. — Conor Hale

South Africa Releases Draft Regs For Drug-to-Device Transfers

South Africa's health department released draft regulations for general medicine that include new procedures for transferring a drug registration to a medical device registration.

Drugs and devices are required to be registered with the country's Medicines Control Council (MCC), which operates through external experts. Information for a drug registration may be transferred to a medical device or in vitro diagnostic registration upon request, the draft regulation says.

Transfer applications must be made by the manufacturer's authorized representative and must include the existing certificate, the reasons for the transfer, the proposed device classification, and the prescribed application fee. If the application is approved, the drug registration certificate will be canceled and the MCC will issue a new certificate for the device.

Additional device-related provisions in the draft regulations require the MCC to inform an applicant as soon as possible of the receipt and final disposition of an application, and to retain staff with knowledge of good manufacturing practices and other relevant areas for the purpose of monitoring, evaluating, and otherwise regulating medical devices and IVDs.

Read the draft regulations here: www.fdanews.com/02-06-17-MCCdraftregs.pdf.

Biotronik Gets Warning Letter For Validation, Other Procedures

Germany's Biotronik received a warning letter for inadequate process validation procedures, supplier selection procedures, and other violations.

Biotronik makes catheters, coronary guide wires, implantable pacemakers, and implantable cardioverter defibrillators. Following a March 2016 inspection of the company's facility in Berlin, the FDA found the company had failed to adequately validate a process that could not be fully verified by subsequent testing. Specifically, the company did not properly validate the method used to coat Selectra catheter leads.

The company was also cited for failing to adequately evaluate potential suppliers based on their ability to meet quality and other requirements. Biotronik's procedure required evaluations to be documented before suppliers were chosen, but there was no documentation for the supplier evaluations for the Selectra catheter.

The FDA also noted a failure to establish and maintain procedures to ensure that sampling methods were adequate. For example, there was no statistical rationale to justify the sampling method used for incoming raw material inspection.

In inspectors found deficiencies in the firm's medical device reporting procedures. For example, procedures that involved handling complaints did not include a system for transmitting timely reports. The procedures failed to say how adverse events would be documented and reported to ensure access to information that facilitated timely follow-up by the FDA.

In addition, Biotronik failed to establish and maintain procedures to control environmental conditions that affected product quality, and to notify the FDA in a timely manner of a serious device malfunction.

Read the warning letter here: www.fdanews.com/01-31-17-Biotronik.pdf.

FDA Civil Monetary Penalties Increase with Inflation

The FDA's civil monetary penalties are increasing to adjust for inflation at less than 2 percent.

The maximum of aggregated penalties for all violations related to devices in a single proceeding increased to $1.8 million.

Penalties for violating requirements for post-marketing studies, clinical trials, labeling or Risk Evaluation and Mitigation Strategies increased to nearly $290,000.

False or misleading direct-to-consumer advertising will also incur fines of almost $290,000, with subsequent violations in a three-year period drawing penalties of more than $578,000.

Any individual convicted of bribery, destroying documents, or of obstructing an investigation would be subject to a penalty over $426,000. In cases involving more than one individual, the fine will exceed $1.7 million.

The penalty for a supplier that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made is increased to more than $15,000.

The new penalties — adjusted for inflation at just over 1.6 percent — apply to all future fines for violations that occurred since Nov. 2, 2015.

The HHS final rule updating civil monetary penalties is available here: www.fdanews.com/02-02-17-HHSMonetaryPenalties.pdf. — Conor Hale

Chaffetz Vows Subpoena If Mylan Foot-Dragging Continues

The House Oversight Committee threatened to subpoena Mylan for full documents related to price increases for its EpiPen.

In a letter to Mylan's attorney, Committee Chairman Rep. Jason Chaffetz (R-Utah) faulted Mylan for giving the committee only "a limited subset" of requested documents pertaining to production and distribution of the company's EpiPen.

Chaffetz demanded the full, unredacted requested documentation in-camera by the end of February.

The company, he wrote, will face a subpoena for "anything less than a complete and timely cooperation."

Chaffetz further noted Mylan's failure to provide documents relating to the company's Medicaid rebate payments in the letter. This lack of documentation, he said, "creates the impression that Mylan is attempting to conceal information about its Medicaid rebate payments from the committee."

The Senate is continuing to apply pressure also, with Sen. Charles Grassley (R-Iowa) requesting records from the Centers for Medicare & Medicaid Services pertaining to the agency's notification to Mylan that it misclassified the EpiPen as a generic (*IDDM*, Jan. 27).

Chaffetz's letter also cites the company's slowness to produce email communications in response to committee requests.

Read the full letter here: www.fdanews.com/02-07-17-ChaffetzMylanLetter.pdf. — Zack Budryk

Republicans Plan to Tackle FDA User Fee Reauthorization by June

Congressional Republicans are planning to complete work this summer — possibly the end of June — on a legislation package reauthorizing the FDA's user fee programs.

Work on FDA user fees will follow a similar timeline to the last user fee agreement, according to a source on Capitol Hill. The previous agreement was signed into law on July 9, 2012.

The user fee programs — covering prescription drugs, generics and medical device reviews through 2022 — need to be reauthorized before the end of September. Sharing that deadline are appropriations for fiscal 2018 and the extension of the debt ceiling.

(See **User Fee**, *Page 8)*

Advisory Group Recommends Adding UDIs on Claims Forms

An advisory group has recommended that the device identifier portion of a unique device identifier (UDI) be included on insurance claims forms for high-risk devices.

The Accredited Standards X12 Committee, which comprises hospital and insurance company bill administrators and develops standards for claims forms, said the UDI data will help the FDA determine the long-term safety of medical devices.

The committee is accepting comments on the recommendations through May 2, and it then plans to forward them to the Centers for Medicare and Medicaid services for review and adoption.

Lawmakers and government watchdogs have long advocated including UDI data on claims forms, arguing it would enable more accurate post-market tracking. However, the Advanced Medical Technology Association (AdvaMed) condemned the idea as an unnecessary regulatory burden that could cause more problems than it solves, both for manufacturers and consumers.

"We are concerned that a complex dataset that combines UDIs and hospital and physician claims information would be difficult to analyze appropriately and could generate inaccurate and misleading conclusions about the performance and value of specific technologies," the association said, in a statement.

The FDA announced last September it does not intend to enforce the requirement to use its UDI system for labels on medical devices manufactured and labeled before Sept. 24, 2021 (*IDDM*, Sept. 5, 2016). In final guidance issued Aug. 30, the agency said stakeholders had expressed concern that pharmacies and other entities in the supply chain were not prepared for the transition. The deadline for labeling most Class I and Class II devices was Sept. 24, 2016.

Savaria Concord Lifts Cited For CAPA Procedures

The FDA sent Canada-based Savaria Concord Lifts Inc. a warning letter citing twelve violations regarding corrective and preventive actions (CAPAs), complaint evaluations, software validation, and other areas.

Following a February 2016 inspection of Savaria's Ontario facility, the FDA said it failed to establish adequate CAPA procedures. For example, those procedures did not include requirements for key activities such as analyzing data to identify quality problems, validating CAPAs to ensure their effectiveness, and recording procedural changes to correct and prevent defects. In addition, certain CAPAs were not documented before they were closed.

The warning letter also cited a failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Savaria's procedures did not include requirements to ensure oral complaints were documented upon receipt, and four complaints during fiscal year 2015 lacked a reporting determination.

In addition, Savaria failed to investigate several complaints involving the possible failure of a device to meet its specifications. It did not validate computer software used for documentation and tracking of product design and design change projects, as well as for quality related activities such as complaints, corrective and preventive actions, and non-conformances.

Additional violations cited in the warning letter included failure to:

- Establish and maintain procedures to control non-conforming products;
- Establish and maintain procedures defining responsibility reviewing and disposing of nonconforming products;
- Establish and maintain procedures for rework, including retesting and reevaluation of non-conforming products after rework, to ensure they met specifications;
- Submit timely reports to the FDA regarding serious device malfunctions that triggered field corrections;
- Develop, maintain, and implement adequate written reporting procedures; and
- Submit a report for a correction or removal to reduce a risk to health or remedy a violation caused by a device.

Read the warning letter here: www.fdanews.com/02-03-17-Savaria.pdf.

Form 483 Cites Oxygen Therapy For Acceptance Activities

The Oxygen Therapy Institute was hit with a Form 483 for inadequate acceptance procedures, calibration procedures, and other deficiencies.

Following an October 2016 visit to the company's Jacksonville, Fla., facility, FDA inspectors observed that procedures for acceptance activities were not adequately established. For example, the delivery pressure for an oxygen inhaler unit was not verified, the firm had no established acceptance procedures for components used in its convenience kits or for the kits themselves, and the institute lacked verification documents for components and functions of the unit. For example, there was no documentation to confirm that oxygen was flowing to the mask.

The FDA also cited inadequate procedures to ensure that all products and services conformed to specified requirements. In addition, it said Oxygen Therapy had no calibration procedure for test equipment, such as gauges for testing regulators used in its inhaler units.

Further observations included that the firm lacked internal audit procedures and had not conducted internal quality audits; had not documented complaints and lacked a written procedure for handling them; and had not established procedures to control non-conforming products, conduct corrective and preventive actions, or file medical device reports.

Read the Form 483 here: www.fdanews.com/02-09-17-OxygenTherapy.pdf.

Risk, *from Page 1*

To get a better handle on how suppliers are performing relative to each other, manufacturers should rate them according to risk factors such as:

- The frequency and severity of product failures;
- How effectively the supplier's quality systems detect problems;
- The supplier's overall financial health and strength of its financial controls;
- What percentage of the supplier's business the manufacturer provides; and
- How quickly the supplier can fill orders.

Quality system staff assign a value to each risk factor for each supplier. After assigning each supplier a number for each risk factor — including a design failure modes and effects analysis (FMEA), supplier quality systems detection, financial strength, lead time for deliveries, and order capacity (see chart below) — the suppliers add each risk number to find a total risk factor ranking.

Low TRF numbers indicate lower risk. For example, a supplier with a TRF below 20 would be considered a moderate to low risk supplier, but a supplier with a TRF between 20 and 25 would be a high to moderate risk and would require more frequent monitoring.

"If you only looked at quality specifically, you would be missing out on all the other factors that affect how business is done, and your bias would prevent you from seeing that bigger picture," Shore said.

Manufacturers should also look at the total cost of ownership when doing business with a given supplier. This includes costs associated with quality, delivery performance, inventory, and shipping. The lowest-cost supplier may not be the best option when other factors such as quality and reliability are taken into account.

Weighting and combining these factors will produce a total cost factor, similar to a total risk factor, he said.

A recording of the Jan. 27 webinar is available here: www.fdanews.com/products/53639.

User Fee, *from Page 5*

FDA submitted recommendations to Congress for the legislation package earlier this year, based on negotiations with private industry. But meetings between the FDA and Capitol Hill staffers were postponed when the White House directed agencies to halt correspondence with members of Congress until administration appointees could review the agency's work (*IDDM*, Jan. 27).

Democratic members of Congress have sent letters to the FDA and the White House requesting explanations of how the federal hiring freeze will affect the agency and its mission, and specifically work being done regarding user fee legislation (*IDDM*, Feb. 3). — Conor Hale

Total Risk Factor (TRF) Assessment Criteria Form

	Weighted Approach															
Supplier	Severity (Design FMEA)			Supplier QS Detection			Financial Strength			Lead Time			Order Capacity			TRF
	S	Weight Value	Risk	D	Weight Value	Risk	F	Weight Value	Risk	LT	Weight Value	Risk	OC	Weight Value	Risk	Results
A	8	1.5	12	6	0.75	4.5	2	1	2	4	0.5	2	1	0.25	0.25	**20.75**
B	8	1.5	12	2	0.75	1.5	3	1	3	2	0.5	1	1	0.25	0.25	**17.75**
C	8	1.5	12	4	0.75	3	5	1	5	3	0.5	1.5	1	0.25	0.25	**21.75**

Source: Quality Lean Solutions ©

BRIEFS

FDA Sounds Alarm About Risks Of Fluid-Filled Intragastric Balloons

The FDA has received multiple reports for two different types of adverse events associated with fluid-filled intragastric balloons used to treat obesity.

Intragastric balloon systems are weight-loss systems to treat obesity, which function by taking up space in a patient's stomach.

The first type of adverse event involves the fluid-filled intragastric balloon over-inflating with air or with more fluid in patients' stomachs, resulting in the need for premature device removal. The second type of adverse event is the development of acute pancreatitis, which has also resulted in the need for premature device removal.

Although the root cause and incidence of these complications are unknown, healthcare providers are encouraged to be aware of these potential adverse events should patients report discomfort. Should the device be removed, providers should follow the manufacturer's instructions for device returns or evaluations.

EU Awards CE Marking to Pressure BioSciences' Sample Preparation Instrument

Pressure BioSciences has earned the CE Mark for the Barocycler 2320EXTREME device, which uses pressure cycling to separate components of blood and other fluids.

The device includes data logging options, user-level security, touch screen programming and the ability to customize multiple pressure cycling parameters.

FDA Awards OTC Clearance For Drug-free Musculoskeletal Pain Therapy

Frederick, Maryland–based, BioElectronics gained over-the-counter use FDA market clearance for ActiPatch for the adjunctive treatment of musculoskeletal pain related to plantar fasciitis of the heel and osteoarthritis of the knee.

The device uses low power pulse electromagnetic fields to regulate electrical activity in the nervous system.

Bioness Gains FDA Clearance For the L300 Go System

Valencia, California–based, Bioness received marketing clearance from the FDA for the L300 Go System.

The device provides 3D motion detection of gait and includes a mobile application to track user activity. The system delivers electrical stimulation and uses data from a 3-axis gyroscope and accelerometer.

Patient movement is monitored in all three planes and stimulation is deployed when needed during the gait cycle. An adaptive algorithm accommodates changes in gait dynamics and a high speed processor deploys stimulation within 10 milliseconds of detecting a valid gait event.

FDA Clears Inova Diagnotics' Assays

San Diego–based, Inova Diagnostics has won FDA marketing clearance for its NOVA Lite DAPI ANCA (ethanol) and NOVA Lite DAPI ANCA (formalin) kits for use with NOVA View, a digital IFA (immunofluorescence assay) microscope.

The kits are reagents for the detection of anti-neutrophil cytoplasmic antibodies.

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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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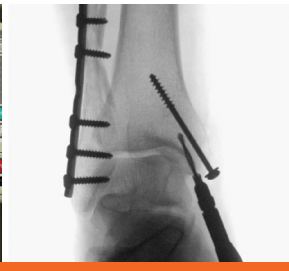

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PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 28

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

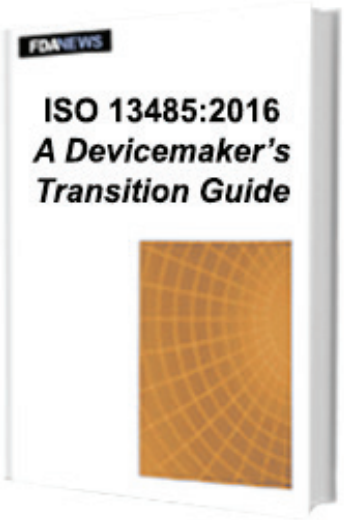
WHO SHOULD ATTEND

- 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.

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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.

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