INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Industry Groups Criticize Proposed Home-Use Device Database

An FDA proposed rule establishing a centralized public database of labels and package inserts for some home-use medical devices might cause confusion if those versions differ from versions on manufacturers' websites, industry groups have said in public comments.

The rule would require manufacturers of Class II and Class III devices to submit electronic copies of the labels and package inserts for those products to the database. According to the agency, this would help reduce adverse events caused by lost instructions.

The database would be run by the FDA or a partner with links to other FDA information concerning home-use devices, such as premarket submission information, adverse event reports, alerts, notices, and recalls, as well as FDA information concerning the manufacturer (*IDDM*, Oct. 18, 2016). The agency received nine comments by the close of the comment period on Jan. 17.

(See **Home-Use**, *Page 2)*

Senators Ask if FDA Will Fill Reviewer Vacancies Despite Trump's Hiring Freeze

Eight Democratic senators have sent a letter to the FDA, airing their concerns over the effects of the government-wide hiring freeze on the agency's mission.

The authors asked whether the agency would exempt any job positions, such as product reviewers, under provisions that permit hiring related to public safety.

"We are deeply concerned that a hiring freeze at the FDA will have a negative impact on the development programs and applications reviews of new drugs and medical devices," wrote the senators, who all serve on the Health, Education, Labor and Pensions Committee that oversees the agency.

The letter, addressed to Acting Commissioner Stephen Ostroff, also cites the recent 21st Century Cures Act that grants the FDA

(See **Letter**, *Page 2)*

Letter, *from Page 1*

broader hiring authority, as well as a boost to its operating budget, and asks whether the freeze will stop the agency from meeting required deadlines, such as the development of new industry guidance documents and policies.

The senators also questioned the effects on upcoming FDA user fee legislation — which Congress must pass before the end of the summer — that will provide additional funding to hire reviewers over the next five years. Specifically, they asked the agency whether the hiring freeze would affect its ability to meet commitments promised under previous legislation.

The senators requested a response by Feb. 10.

The senators' letter can be found here: www.fdanews.com/01-30-17-SenateLettertoFDA.pdf. — Conor Hale

Home-Use, *from Page 1*

Advamed said the database might end up with different versions of documents than those on manufacturers' websites. If a home-use device user seeks labeling information for a specific product and finds labeling information on both the manufacturer's website and the proposed database, the user may not know which information is accurate in the event the labeling has been updated and FDA has not updated the database, AdvaMed said.

The association also said the FDA should exempt home-use software devices with embedded labeling that is never lost. Over-the-counter, single-use devices should also be exempt because they do not remain in the user's home indefinitely and are unlikely to be separated from their labeling, the industry group said.

In addition, the final rule should clarify that when multiple parties — such as a contract manufacturer and an importer — are involved with one device, only one copy of the label and package insert is required and the parties should be able to choose who is responsible, AdvaMed said.

In separate comments, Procter & Gamble said requiring the submissions of labeling for consumer products obtained at retail would not provide a public health benefit commensurate with the regulatory burden. It said an exemption should be provided for products that have a low potential for misuse because they are well-known to the public and are purchased frequently.

Abbott Medical called on the agency to allow manufacturers to provide information in electronic formats as the sole means of conveying device labeling, as is permitted for prescription devices used in healthcare settings.

MHRA Guidance Addresses Assistive Technology

An assistive technology device must have a corrective function that directly links to a particular user's needs to be considered a medical device, according to new guidance from the UK's Medicines and Healthcare Products Regulatory Agency.

Assistive technology devices are intended to compensate for or alleviate an injury, handicap, or illness, or to replace a physical function. They can include mobility, communication, and hearing aids; posture and pressure management devices; moving and handling systems, such as hoists and slings; hospital beds; and therapy equipment.

Some assistive technology products like shower chairs are considered aids for daily living rather than medical devices because they do not directly compensate for a user's injury or handicap, or because their primary purpose is for personal hygiene rather than to address a medical or mobility problem.

Safety issues surrounding assistive technology devices can result from shortcomings of the device itself, inadequate instruction for use or repair, poor maintenance, and problems with storage.

Read the guidance here: www.fdanews.com/01-27-17-AssistiveTechnology.pdf.

FDA Postpones User Fees Meetings, Pending White House Review

The FDA has had to postpone meetings with Capitol Hill staff to discuss upcoming user fee legislation, after the Trump administration directed agencies to halt correspondence with members of Congress.

A memo sent to the heads of HHS agencies and centers Jan. 20, including the FDA, said that there would be no official communication with Congress before at least Feb. 3, unless specifically authorized by White House appointees.

It also states that no proposed or final regulation, notice or guidance document can be published until it has been reviewed by the acting secretary of HHS, Norris Cochran. Trump's pick for secretary, Rep. Tom Price (R-Ga.), is currently waiting to be confirmed by the Senate.

The actions largely implement the government-wide freeze on new regulations and guidances, handed down on President Donald Trump's first day in office.

Before the end of the Obama administration, HHS Secretary Sylvia Burwell informed Congress of the FDA's recommendations for user fees covering medical devices. Congress' deadline to pass legislation reauthorizing MDUFA IV through 2022 is Sept. 30.

The HHS memo is available here: www.fdanews.com/01-27-17-HHSMemo.pdf. — Conor Hale

UK's NICE Recommends Sinus Dilation System

The UK's National Institute for Health and Care Excellence (NICE) is recommending the use of the Entellus Medical XprESS multi−sinus dilation system for treating uncomplicated chronic sinusitis.

The system uses using balloon dilation to open narrowed or obstructed sinuses. In new guidance, NICE said the treatment leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes, and improved quality of life compared with endoscopic surgery.

XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis, the guidance states. In these patients, XprESS works as well as alternative treatments, is associated with faster recovery times, and can more often be done under local anesthesia.

NICE said the National Health Service could save about £7.4 million (US$5.9 million) annually by 2020 using the Entellus product, mainly by shifting to outpatient treatment.

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

New Zealand Proposes to Use Smith and Nephew Implants

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

The Pharmaceutical Management Agency's (PHARMAC) proposal would allow Smith and Nephew to supply the products at negotiated prices starting March 1.

District Health Board hospitals would continue to be able to purchase other suppliers' brands of orthopedic implants and associated products, the agency said.

The proposed products would have tiered prices that could be lower than listed prices depending on the number purchased. According to PHARMAC, the agreement would save DHBs nationally $550,000 (US$400,780) per year at a minimum.

This is the third provisional agreement for the supply of orthopedic implants and associated products that PHARMAC has proposed, with further agreements expected over the next few months. Previous agreements were reached with Stryker (*IDDM*, Dec. 16, 2016) and Zimmer Biomet (*IDDM*, Dec. 30, 2016).

CFDA Spells Out Cybersecurity Requirements

Manufacturers who want to register networked medical devices in China need to assess the devices' cybersecurity, according to new guidance from the China Food and Drug Administration.

Manufacturers should adopt a cybersecurity risk management system that identifies vulnerable devices, any cyber threats that could harm patients, the level of risk, and necessary control measures, CFDA said.

The guidance, supplements the CFDA's Guidelines for the Review of Medical Device Software Registration Technology, applies to Class II and III medical devices that connect to networks for the purpose of exchanging or storing data, or for remote control.

Cybersecurity measures must be maintained throughout a product's lifecycle and should be integrated into a manufacturer's quality management system, CFDA said.

Companies need to consider user authentication methods, user types and permissions, and software updates. In addition, the method of data exchange the device uses should ensure patient confidentiality while ensuring the device remains useable, especially if it will be operated via remote control.

Manufacturers can use encryption, digital signatures, firewalls, intrusion detection systems, and other means to ensure the security of networked devices.

The guidance states that off-the-shelf software may be used as long as it meets cybersecurity requirements and other requirements of the manufacturer's QMS.

Cybersecurity information in a product registration application must include information about the purpose and functions of the product, the type of software it uses, it should also include a risk analysis, validation test results, maintenance plans, and instructions for use that impact cybersecurity, CFDA said.

Protech Professional Criticized For Design Control Procedures

According to a Form 483, Protech Professional Products Inc. did not establish procedures for design control, corrective and preventive actions, and control of non-conforming products at one of its facilities.

A visit to the company's Boynton Beach, Fla., facility produced several observations, including that Protech did not have a procedure for design controls that included provisions for inputs, outputs, reviews, verification, validation, transfer, and changes. In addition, documents provided to inspectors as part of a product's design history file did not include several of these categories. This observation repeated a deficiency in a warning letter in July 2014.

Inspectors further observed that procedures for corrective and preventive action (CAPA) were not established. For example, a CAPA procedure did not include requirements for investigating and determining the root cause of a non-conformity, and seven of 11 documented CAPA actions lacked such a determination. In addition, all 11 CAPA forms reviewed did not include evidence of verification and validation activities.

The Form 483 also faulted Protech for not establishing procedures to ensure that all received products and services conformed to requirements. Specifically, the firm did not ensure that the contract manufacturer for its ProTech Plus Self Cure Hard Reline and Repair Acrylic Powder and Liquid devices validated manufacturing processes required to ensure consistency.

Inspectors further observed that procedures for acceptance activities and for handling complaints were not adequately established. For example, the complaint handling procedure did not include requirements for documenting oral complaints or determining whether the complaint had to be reported.

Finally, the Form 483 said procedures to control labeling activities were not established.

Read the Form 483 here: www.fdanews.com/01-30-17-Protech.pdf.

PHARMAC Allows Contraceptive Implants Without Prescription

Healthcare providers in New Zealand may give levonorgestrel subdermal contraceptive implants directly to patients without a prescription so they do not have to visit a pharmacy.

Under a proposal recently adopted by New Zealand's Pharmaceutical Management Agency, the devices will be funded up to a limited amount by the agency.

The change is designed to provide women easier access to the implants — a form of long-acting reversible contraception — and to encourage their use.

The implants are inserted below the skin in the upper arm and provide up to five years' contraception. Until recently, the devices required a prescription, a trip to a pharmacy, and then another visit to a doctor to perform the procedure.

PHARMAC acknowledged that clinicians need to be specifically trained to administer the implants.

Read the notice here: www.fdanews.com/01-27-17-Contraceptives.pdf.

Malaysia's MDA Addresses Authorized Representatives

Every medical device imported into Malaysia for sale must have a single authorized representative, according to a new circular from the country's Medical Device Authority.

An authorized representative is a Malaysian resident or a firm incorporated there, provided the representative or firm carries on its business principally in Malaysia.

The representative's role is to help foreign manufacturers comply with Malaysian medical device regulations.

Foreign manufacturers that sell more than one device in Malaysia may appoint more than one representative.

Read the circular here: www.fdanews.com/01-27-17-Registration.pdf.

Rapid Release Gets Warning Letter for PMA

Rapid Release Technologies received a warning letter for failing to apply for premarket approval (PMA) or an investigational device exemption (IDE) for a massage device.

The company's Rapid Release Massager was classified under regulations pertaining to therapeutic vibrators and powered heating pads, both of which are generally exempt from premarket notification.

During an inspection of Rapid Release's Santa Ana, Calif., facility in May 2016, the FDA discovered evidence that the company's device was actually marketed for uses different from those of these generic device types.

Generic therapeutic vibrators are meant to relax muscles and relieve minor aches and pains, while generic powered heating pads are meant to provide dry heat therapy. By contrast, the Rapid Release Massager was marketed for release of soft tissue, relaxation of spasms and cramps, increased circulation, and other purposes. As a result, Rapid Release's device was not exempt from premarket notification, the FDA said.

The FDA also released warning letters for two medical device companies located in Korea.

Shina Corporation did not establish and maintain proper corrective and preventive action (CAPA) procedures. For example, it failed to document an investigation of complaints of white residue on certain gaskets, or what corrective actions it took to fix the problem.

Incyto Co. Ltd. was warned for its CAPA procedures. During the inspection, four CAPA's revealed a lack of details about investigations and effectiveness checks related to a liquid injection failure and other problems. The warning letter also noted improper complaint reviews and other violations.

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

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

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

Inovar Gets Form 483 For Product Certification

Inovar Inc. received a Form 483 for failing to provide a product certification, evaluate complaints, and other observations.

Following an October 2016 visit to the company's Logan, Utah, office, FDA inspectors observed that Inovar failed furnish to the dealer, at the time of delivery of a product, a certification that completed laser systems conformed to all applicable standards.

Specifically, the labeling applied to the systems did not include a statement of certification of conformance to performance standards. Inovar's product engineer said Inovar does not provide any other form of certificate of conformance to the customer.

The Form 483 also said that not all complaints were reviewed and evaluated to determine whether an investigation was necessary.

The company's procedures did not include requirements for evaluating each complaint to determine if an investigation was necessary or if the complaint needed to be reported to the FDA.

Complaints

Twelve complaints reviewed did not have a justification for not investigating the issue or a medical device reporting determination.

In addition, customer complaints that were not required to be directly handled by Inovar but were provided as feedback are not recorded as complaints. Other than how these complaints were received, there was no documentation, including an investigation.

Inspectors also faulted documentation of corrective and preventive action (CAPA) procedures. CAPA records were closed after the due date and/or did not include an appropriate verification of effectiveness.

CAPAs also did not show a history of activity, especially between the implementation of corrective actions and verification of effectiveness. In addition, one of the thirteen device history records reviewed did not include completed verification steps and QA signatures for final release and distribution of the unit.

Lastly, the Form 483 said Inovar did not adequately establish procedures to control non-conforming products, procedures for device history records, and procedures to control environmental conditions.

Read the Form 483 here: www.fdanews.com/01-26-17-Inovar.pdf.

PEOPLE ON THE MOVE

True Health Diagnostics has appointed **Robert J. Rossi** as a senior vice president and chief compliance officer. A former Chief Deputy Attorney General of Pennsylvania overseeing the state's Medicaid Fraud Unit, he has served in various capacities for healthcare services companies, including Quest Diagnostics, PLUS Diagnostics and Calloway Laboratories, among others. In addition, he has served as an adjunct professor at Bay State College in Boston, Mass.

Siemens Healthineers North America has named **Hanno Dotzel** as vice president of its radiation oncology imaging business. Prior to his current role, Dotzel served for three years as sales director for magnetic resonance in North and South America. Previously, he was responsible for sales and marketing in seven European countries. He began his career at Siemens Healthineers in 2007 and served in various positions in business management and development.

GenePeeks announced the appointment of **Matt Posard** as president and chief commercial officer. Posard has more than 25 years of experience in commercializing technologies in life science and molecular diagnostics. He formerly worked in various roles at Illumina, Trovagene, and Alere. The GenePeeks technology predicts the genetic risk profile of a future child by analyzing the DNA of both parents.

BRIEFS

bioMerieux Recalls Reagents And Accessory Products

bioMerieux is recalling the NucliSENS reagents and accessory products due to a quality problem of the magnetic silica (MagSil) component.

MagSil is used to extract and purify genetic material from patient samples. Kits with the affected lots of the magnetic silica may not be able to fully extract nucleic acids from the sample and detect infection or provide proper diagnosis.

The distribution dates are from May 03, 2016 to August 18, 2016.

Neural Analytics Receives CE Mark for the Lucid System

Los Angeles–based, Neural Analytics has gained a CE Mark for its advanced ultrasound device, the Lucid M1 transcranial doppler ultrasound system (lucid system), which is a portable all-in-one ultrasound system designed for rapid triaging and monitoring of patients with brain disorders.

The device system is a battery-operated, medical-grade tablet. It uses a type of ultrasound called transcranial doppler to assess the brain's blood vessels from outside the body.

The device received FDA marketing clearance in October 2016.

Cambridge Cognition Awarded FDA Marketing Clearance for Cantab Mobile

Neuroscience digital health company, Cambridge Cognition has achieved FDA marketing clearance for its Cantab mobile.

The device is designed to detect clinically-relevant memory impairment in older adults at the point of care. It includes a computerized test of visuospatial associative learning (CANTAB PAL) to assess episodic memory with optional mood and functional assessments.

The touchscreen test takes less than 10 minutes to complete.

Bard Peripheral Vascular Issues Recall For Halo One Thin-Walled Guiding Sheath

Bard Peripheral Vascular Inc. is recalling the Halo One Thin-Walled Guiding Sheath because the sheath body may separate from the sheath hub while removing the device from the patient's leg.

The company also reports that the sheath may kink, and that its tip may become damaged during the procedure.

The device is used to introduce and/or guide the placement of interventional and diagnostic devices into veins and arteries through an incision made on a patient's leg.

The distribution dates are June 24, 2016 to July 12, 2016.

FDA Grants Clearance To GEO Bone Screw System

Dallas–based, Gramercy Extremity Orthopedics (GEO) has received FDA marketing clearance for the GEO Bone Screw System.

The device can be used for bone fractures, osteotomies, arthrodesis, osteochondritis and tendon reattachments.

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– Michael Healy, QA/QC Director, Tryton Medical

MARCH 28-30, 2017 | BETHESDA NORTH MARRIOTT
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Seth Carmody, Staff Fellow, Office of the Center Director CDRH, FDA

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

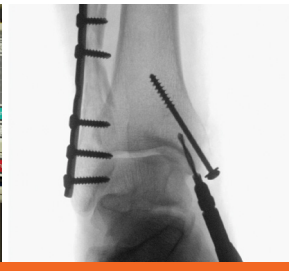
William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA

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

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

Industry Experts

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



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FDANEWS PRESENTS THE 14TH ANNUAL MEDICAL DEVIC

PRE-CONFERENCE WORKSHOP: TUESDAY, MARCH 28

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

8:30 a.m. – 12:00 p.m.

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

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

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

Participants will learn:

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

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

EXPERT INSTRUCTORS:

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Dan O'Leary, President, Ombu Enterprises LLC

TUESDAY, MARCH 28

12:00 p.m. – 1:00 p.m. | REGISTRATION

1:00 p.m. – 1:15 p.m.

Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations

1:15 p.m. – 2:00 p.m.

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

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

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

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

2:00 p.m. – 2:45 p.m.

Update on the Critical to Quality Initiative

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

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

2:45 p.m. – 3:00 p.m. | BREAK

3:00 p.m. – 4:15 p.m.

Benefit–Risk Considerations for Medical Devices: Panel Discussion

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

Sean Boyd, Program Manager CDRH, FDA (Invited)

4:15 p.m. – 5:15 p.m.

Mock Medical Device Inspections

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

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

E QUALITY CONGRESS

WEDNESDAY, MARCH 29

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

8:30 a.m. – 8:45 a.m.

Welcome and Introduction by Co-chair Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

8:45 a.m. – 9:30 a.m.

Medical Device Single Audit Program Pilot (MDSAP) Update

Attendees will hear first-hand about progress on the program from the FDA's Marc-Henri Winter, who will share lessons learned from the pilot program. Devicemakers will learn what to expect from an audit and how multiple sites should be audited. Additional CDRH representatives will be on hand to address any additional questions regarding MDSAP.

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

9:30 a.m. – 10:15 a.m.

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

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

Steven Grossman, President, HPS Group, LLC

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

European Medical Device Regulations What To Expect: Panel Discussion

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

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

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

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

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

Panelists:

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

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 1:45 p.m.

MedAccred Update: Devicemakers Driving Quality Standards for Their Suppliers

What Rx-360 has done for drugmakers, MedAccred is doing for devicemakers. The goal of the program is to qualify each of the critical processes in the supply chain. To get there, devicemakers are working together to set standards via consensus for those processes and to devise auditing checklists for their suppliers. This session will give you an overview of the work done so far and how you can get involved.

Joe Pinto, Executive Vice President & Chief Operating Officer, Performance Review Institute

1:45 p.m. – 2:30 p.m.

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

Software has become a critical part of medical devices. More and more medical devices have software embedded or interface with another device or healthcare system that has software as an integral part. Given the increased complexity of medical device software, best practices in risk management and cybersecurity are critical and challenging.

Attendees will learn:

- What the FDA's latest initiatives on device software risk management and cybersecurity are
- How a device manufacturer overcomes technical as well as regulatory compliance challenges
- What resources and tools are available
- What the industry's best practices are

Seth Carmody, Staff Fellow, CDRH, FDA

2:30 p.m. – 2:45 p.m. | BREAK

2:45 p.m. – 3:45 p.m.

When to submit a 510(k) Premarket Notification

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

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

3:45 p.m. – 4:30 p.m.

China Medical Device Regulatory Changes

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

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

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

Grace Fu Palma, Founder, China Med Device

4:30 p.m.

Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY WORKSHOP ON THURSDAY, MARCH 30

MANAGING & AUDITING MEDICAL DEVICE SUPPLIER QUALITY TRAINING

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

8:30 a.m. – 5:30 p.m.

Managing & Auditing Medical Device Supplier Quality

The development of extended supply chains raises major issues for device manufacturers. While regulators are looking more closely at device supplier management issues, companies are recognizing the issues of supply chain complexity in meeting the regulatory requirements. There are powerful tools can help device manufacturers protect themselves against problems, develop more effective management systems, and control costs. You can start to prepare with important IMDRF guidance documents: Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008), Risk Management Principles in a QMS (GHTF/SG3/N15R8), and Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010). These guidance documents provide the foundation, but lack implementation details.

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

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

This workshop provides the practical means and methods you need for a compliant and cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management – product risk, business risk, supplier caused recalls, and liability risk
- When and how to conduct an on-site supplier audit applying a rapid risk management technique
- How to qualify and monitor suppliers that are virtual companies
- How to select and apply supplier metrics and their role in the QMS
- How to prepare for the supplier portion of an MDSAP audit
- How to deal with recordkeeping and data integrity issues with suppliers

5:30 p.m. | ADJOURN

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

Expert Instructors

John Avellanet
Managing Director & Principal, Cerulean Associates

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

Dan O'Leary
President, Ombu Enterprises

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

"I really liked the examples, scenarios and practical examples. The 'real life' examples were a great way to drive home the points and examples."

– Tanya Taft, Sr. Manager, Post Market Clinical, Fresenius Medical

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