INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

At Last: New EU MDR Regulations Near Final Approval

After two decades of work, the EU's new medical device and in vitro regulations are nearing their final approval stretch.

The European Council is set to vote on the regulations on March 7, and the European Parliament will vote on March 20. If passed, the regulations could become effective as early as May. Manufacturers would then have three years to comply with the MDR and five years to comply with the IVDR.

The two documents, which total 566 and 477 pages respectively, completely revamp the EU's existing regulatory framework.

The MDR will require risk management and quality management systems, the use of unique device identifiers and tighter control over distribution chains. It replaces EU Directives 90/385 (Active Implantable Medical Devices) and 93/42 (Directive Concerning Medical Devices) (*IDDM*, Oct. 28, 2016).

(See **MDR**, *Page 2)*

CDRH Focuses on Patient Preference in IDE Applications

CDRH officials this week reiterated that investigational device exemption applications should include information on patient preferences.

Patient perspectives are vital for determining the risks and benefits of IDE applications, said Karen Ulisney, a policy analyst in CDRH's Office of Device Evaluation, in a webinar held last week to help explain the agency's January IDE guidance.

Additional patient information could include electronic tools such as charts and graphs to enhance informed consent, as well as patient-reported outcomes, and information about how patients experience using a particular device.

Owen Faris, director of CDRH's Clinical Trials Program, said the patient voice in the clinical trial evaluation and device approval decision-making process "could use some strengthening," and the agency

(See **IDE**, *Page 2)*

MDR, *from Page 1*

One of the most significant provisions in the EU's new MDR restricts the types of clinical data manufacturers can use in clinical evaluation reports.

Previously, clinical data for new devices have been drawn mainly from available literature for equivalent or partially equivalent devices. By contrast, the MDR requires manufacturers to perform their own clinical evaluations for higher-risk Class III and implantable products, according to Gert Bos, executive director and partner at Qserve Group.

The evaluations must include an analysis of the relevant scientific literature, an analysis of the results of all available clinical trials, and a consideration of any currently available alternative treatment options. But there is an exception for Class III devices that have merely been modified and are substantially equivalent to currently marketed version.

Existing clinical evaluations for equivalent products can be used for Class II devices, but only if the data were collected according to the MDR's standards. Manufacturers relying on equivalence will need to ensure they have access to relevant post-market surveillance data – especially clinical data – and fill in any gaps in collection or analysis.

Another key change in the MDR is that sufficient clinical data need to be presented for each product, clinical claim, and clinical indication. Under the EU's previous device regulations, manufacturers often use a mix of data that was biased toward specific products, clinical claims, and/or clinical indications. The MDR provides that if no additional data are being generated for specific claims and indications, those claims and indications will need to be dropped.

Many companies have not been writing clinical evaluation reports in line with the MDR's requirements or the associated guidance, Gos said. These companies will need to essentially start over and develop all-new procedures.

For example, in their quality management systems, manufacturers should include a process for writing clinical evaluation reports, along with criteria for deciding when clinical studies are needed and what they should focus on. A QMS also should include templates and guidance on how to write clinical evaluation plans and collect the appropriate data.

In addition, manufacturers should communicate early and often with their notified bodies to ensure that their clinical data will be accepted.

Read the MDR here: www.fdanews.com/02-23-17-MDRegulations.pdf.

Read the IVDR here: www.fdanews.com/02-23-17-InVitroDiagnostics.pdf.

IDE, *from Page 1*

wants to move in that direction. Patients are "the most important stakeholder," but they don't always have the loudest voice in the process, he said.

The FDA has reduced its approval time for IDE applications from 400 days in 2011 to 30 days today, in part by communicating with sponsors about risks and benefits sooner in the process, Ulisney said.

In January, the FDA released final guidance on assessing the risks and benefits of investigational device exemption (IDE) applications for human clinical studies (*IDDM*, Jan. 13).

Materials from the webinar are available here: www.fdanews.com/02-23-17-FDAwebinar.pdf.
— Jeff Kinney

FDA Expands Clearance For Brain Surgery Technology

The FDA granted a new and updated marketing clearance for two patented technologies made by NICO Corporation that are used in brain surgery on its Myriad tissue removal and BrainPath devices.

The clearance provides Myriad specific disease state approval for primary and secondary brain tumors, vascular abnormalities and malformations, and intraventricular tumors and cysts. BrainPath is cleared for use in specific disease states such as high grade gliomas and glioblastoma multiforme that has only a 15-month survival rate, secondary metastatic tumors, and vascular abnormalities.

Experts Outline Steps to Maximize Device Reimbursement

If reimbursement is already available for a predicate device, a 510(k) clearance is most appropriate, because it is faster and more predictable, although it limits the potential for higher payment.

By contrast, a premarket approval could lead to higher reimbursement over the long term, but it requires more robust outcomes and economic data to drive new codes, expanded coverage, and improved payment, said attorney Stephen Terman of Olsson, Frank, Weeda, Terman, & Matz , and Gordon Schatz of Schatz Reimbursement Strategies, in a webinar hosted by FDAnews.

Manufacturers should position a product for reimbursement or seek higher reimbursement well in advance of a 510(k) or PMA submission. As a part of this effort, they should initiate discussions with doctors and other clinical investigators who can become credible "reimbursement champions" for a device with their specialty societies, CMS, and private payers.

Other tips for maximizing reimbursement include:

- Determine the product's overall value proposition – more advanced products receive higher payment but generally are more resource-intensive to use;
- Structure clinical trials to obtain the health outcomes and economic data needed to support product claims;
- Implement coordinated coding, coverage, and payment strategies; and
- Re-engage with CMS annually as codes, coverage, and payment change.

Terman cautioned that using an incorrect billing code for a procedure could open manufacturers, hospitals, and doctors to liability under the False Claims Act, if the Justice Department determines that the error was an attempt to generate a higher payment.

"It's very important to stay 100 percent consistent with your FDA-approved labeling when you're providing coding information," he said.

Schatz said the Trump administration will seek to streamline the FDA's approval process, but any changes probably will not result in higher reimbursement. However, now is a good time to ramp up FDA lobbying activities, because FDA employees might be more amenable to industry concerns during a Republican administration.

Order the recorded webinar here: www.fdanews.com/products/53762.

India Warns Stent Makers to Supply Products Despite Price Controls

India's National Pharmaceutical Pricing Authority says coronary stent manufacturers must continue supplying all brands of stents they supplied before price controls went into effect on Feb. 14.

In January, the NPPA decided to impose the price controls five months after placing stents on the National List of Essential Medicines. The authority added stents to the list in July after numerous meetings with stent manufacturers, cardiologists and non-governmental organizations. At the time, experts urged the government to consider price controls (*IDDM*, Jan. 6).

The NPPA has issued guidance reminding stent manufacturers they should have issued revised price lists by now and should have sent them to distributors and hospitals, with copies to state drug regulators and the NPPA. The guidance warned manufacturers and suppliers that they must provide all types of stents, including higher-quality models that are more expensive to make.

The price controls are effective on the date of billing rather than the date of an angioplasty. As a result, if a patient had an angioplasty performed before Feb. 14 but was billed on or after that date, the patient should be billed according to the new prices.

Read the guidance here: www.fdanews.com/02-21-17PriceControls.pdf.

EMA Calls for Better Combo Product Clinical Data

The European Medicines Agency wants the EU to require better clinical data to support marketing authorization applications (MAAs) for drug-device combination products.

Because of the wide variety of combination products and differences between EU device and drug legislation, the data supplied with MAAs are often inconsistent and incomplete, the EMA said, in a concept paper.

A related problem is that EU regulators sometimes do not fully account for the characteristics of the drug component of a combination product where the drug and device are provided separately, the EMA said.

There has been a sharp increase in the number of MAAs, especially for commercially available novel devices with automated functions that can be used at home, the agency said. This has increased the potential for errors and indicates a need for better clinical data on safety and effectiveness.

The EMA called for requiring clinical data to be submitted with MAAs showing that combination products have been appropriately designed and can be used correctly. Device complexity, intended clinical settings, and targeted patients and caregivers should be taken into account. Separate data requirements may be required for integrated combination products compared to those in which the device is a stand-alone component.

The guidance should consider the information to be included in product literature, such as patient information leaflets and labeling. It should also include requirements when a specific medical device must be used with a drug – such as nebulizers or anesthetic delivery equipment – but where the devices are available separately, and often from a different manufacturer.

The concept paper is open for public comment for three months. EMA will then issue draft guidance with a six-month comment period. The agency has not yet set a timetable for release of final guidance.

Read the concept paper here: www.fdanews.com/02-22-17-EMAconceptpaper.pdf.

Manufacturers Must Give France's ANSM More Product Info

A recently implemented decree by France's Agency for the Safety of Health Products (ANSM) requires manufactures of Class III and implantable medical devices to provide new summaries of product characteristics when a device is put into service.

Summaries must include basic product characteristics such as the device's name and classification, purpose, targeted users, principles of operation, accessories, and version descriptions, according to Elisabethann Wright of Hogan Lovells. Manufacturers are also must submit a summary of the device's clinical evaluation and post-market surveillance plan.

Devices that are substantially modified are subject to the decree as well.

According to Wright, some of the required information previously was not communicated to ANSM unless the agency requested it. As a result, the decree represents an additional administrative burden for manufacturers and their authorized representatives, to which the mandate also applies.

HMD Biomedical Faulted For Design Validation

Taiwan-based HMD Biomedical received a warning letter for inadequate procedures for device design validation, process control, and control of environmental conditions.

An inspection of the company's facility in March revealed a failure to establish and maintain procedures for validating device design.

In one instance, a software validation test report contained six columns for evaluation of six meters, but only two meters were marked with "OK" test results. The report did not include written justification for testing of only meters 3 and 4 during the design software validation.

In addition, the FDA said HMD failed to describe process controls necessary to ensure conformance to specifications where errors were possible due to the manufacturing process.

Inspectors noted, for instance, that machines in the company's blood glucose test strip manufacturing area were not properly monitored, and there no documentation that the machines were operating properly.

Inspectors also noted a failure to establish and maintain procedures to control environmental conditions, where environmental conditions could reasonably be expected to have an adverse effect on product quality.

For example, the company did not inspect its temperature and humidity monitoring system's alarm to verify that it could trigger an audible alert for temperature and/or humidity problems.

HMD did not return a request for comment.

Read the Form 483 here: www.fdanews.com/02-24-17-HMD.pdf.

PEOPLE ON THE MOVE

Nephros named **Andrew Astor** as chief financial officer. Astor previously served as managing director at Synechron. Prior to that role, he was a vice president at Asurion.

Relief Therapeutics has a new interim CEO, **Gael Hedou**, the company's former COO. **Raffaele Petrone** has resigned from his role as CEO and **Timothy Snyder** will be relinquishing his duties as chief financial officer on Aug. 31, 2017.

Edge Therapeutics recruited **Alyssa Wyant** as senior vice president for regulatory affairs. Most recently, Wyant served as vice president of global regulatory affairs at PTC Therapeutics.

Harpoon Medical hired **Laura Brenton** as vice present of clinical affairs. She brings more than 25 years of clinical research experience, with the last decade at Harpoon.

Abbott Gains FDA Approval For its Assurity MRI Pacemaker

Abbott received FDA approval for magnetic resonance (MR)-conditional labeling for both the Assurity MRI pacemaker and the Tendril MRI pacing lead.

Patients implanted with the low-voltage devices will be able to undergo full body MRI scans.

EU Expands CE Mark For Dako Companion Diagnostics

Agilent Technologies has receive an expanded CE mark for its Dako PD-L1 IHC 22C3 pharmDx which can now be used to determine PD-L1 expression status to inform the first-line treatment of metastatic non-small cell lung cancer patients with Keytruda.

The intended use allows PD-L1 IHC 22C3 pharmDx to detect PD-L1 expression in both untreated and previously treated metastatic patients.

Narishige Design Control Procedures Faulted

FDA inspectors observed various problems at a Narishige medical device facility in Tokyo, including inadequate design control procedures and other violations.

After visiting the firm's Toyko facility, inspectors cited the company because the design control procedures did not state that design changes would be validated or verified.

The design history file for one product did not include verification that the design output met the design input.

The design history file for a separate product included design inputs, but there was no documentation to verify that the design output matched the design input.

Read the Form 483 here: www.fdanews.com/02-17-17-narishigecoltd483.pdf.

MicroPort Orthopedics Notes Ceramic Head Manufacturing Defect

A manufacturing defect in MicroPort Orthopedics' Biolox Forte 36 mm Alumina ceramic heads may cause surgical complications, according to Australia's Therapeutic Goods Administration.

The ceramic heads replace the ball part of the joint in total hip replacements. An investigation following a complaint by a surgeon found that the ceramic heads are 2 mm shorter than other 36 mm MicroPort femoral heads.

As a result, patients who received hip replacements using Biolox Forte 36 mm Alumina ceramic heads may be at increased risk of requiring revision surgery due to dislocation or looseness of the hip joint, TGA said.

The company said the product has been distributed for more than 15 years, and the rate of dislocations involving the components is just 0.225 percent.

Implant Dental Tech. Warned About Contamination

The FDA hit Guangdong, China-based Implant Dental Technology with a warning letter citing equipment contamination, production deficiencies, and other violations.

After inspecting the company's facility in June 2106, the FDA said the company failed to prevent contamination of equipment. For example, four steam cleaners – located in clean rooms and used to clean dental implants – had unidentified green or brown particulate accumulation in the water tanks.

The company also failed to develop production processes to ensure that devices conformed to their specifications. For example, Implant Dental's procedures lacked instructions for using furnaces to heat metals and process porcelains for dental implants. In addition, the firm did not document times and temperatures for the processes.

The warning letter further cited Implant Dental for failing to establish and maintain procedures to ensure that equipment was routinely calibrated, inspected, checked, and maintained. For example, there was no evidence that equipment used to measure the wall thickness of ceramic teeth was calibrated.

The company also failed to ensure that incoming products were properly marked for temporary storage or use during manufacturing.

In addition, the warning letter said the company failed to implement corrective and preventive actions and requirements for analyzing quality data to identify causes of nonconforming products.

Lastly, the FDA faulted the company's document control procedures, citing a failure to maintain records of changes to documents and other deficiencies.

Implant Dental did not return a request for comment.

Read the warning letter here: www.fdanews.com/02-16-17-ImplantDental.pdf.

MHRA Issues Guidance On Infections from Heater Cooler Units

Heater cooler units used in cardiopulmonary bypass and extracorporeal membrane oxygenation can generate potentially infectious aerosols containing a range of harmful bacteria, some of which can be fatal, according to an ongoing UK investigation.

The UK's Medicine's and Healthcare Products Regulatory Agency has issued new guidance on how healthcare providers can lessen the risk of infection from the units.

NHRA said users should ensure that a full local risk assessment is conducted and a local quality assurance program is implemented for the use of HCUs, that the units are monitored for harmful bacteria, and that suitable cleaning and disinfection regimes are used.

The MHRA or another appropriate agency should be notified of HCU-related issues, including problems encountered in cleaning and disinfection, patient harm, and new cases of M. chimaera infection, the agency said.

Read the guidance here: www.fdanews.com/02-21-17HCUs.pdf.

Audit Procedures, Other Problems Flagged at Isolux Facility

Isolux received a Form 483 for not adequately establishing procedures for quality audits, for not implementing a supplier evaluation procedure, and other observations.

In a September 2016 inspection of the firm's Naples, Fla., facility, the FDA observed that Isolux's internal audit procedures did not ensure all applicable quality system requirements were reviewed.

In addition, quality audits were conducted by individuals with no direct responsibility for the matters being audited, corrective actions were not taken when necessary, and audit reports were not reviewed by management having responsibility for the matters audited.

Moreover, the company had not conducted any internal audits. The FDA noted this was a repeat observation from another Form 483 issued in January 2010.

The FDA also said Isolux did not implement one of its supplier evaluation procedures. Specifically, it failed to document the evaluation of most of its current suppliers and contractors on file, and there was no documentation that its suppliers and contractors had agreed to notify the company of changes in products or services.

The Form 483 also noted that the firm had not developed adequate written reporting procedures. For example, the existing procedures did not include definitions of medical device reportable events, electronic reporting requirements and instructions, or a reporting time frame of five business days when requested in writing by the FDA.

Inspectors also faulted the company's design change procedures for not including validation or verification requirements, its complaint handling procedures for improper documentation, its servicing procedures for not requiring that serviced devices conformed to specifications, and its inadequate training procedures.

A spokesperson for Isolux declined to comment.

Read the Form 483 here: www.fdanews.com/02-23-17-Isolux483.pdf.

UK's NICE Says More Evidence Needed for HumiGard

New guidance from the UK's National Institute for Health and Care Excellence (NICE) says Fisher and Paykel Healthcare's HumiGard shows promise for preventing hypothermia during abdominal surgery, although there is not enough evidence to support routine use.

HumiGard humidifies and heats carbon dioxide used to fill the peritoneal cavity during laparoscopic abdominal surgery. Its purpose is to avoid problems caused by using dry, cold CO2 gas, including tissue desiccation and intra-operative hypothermia. HumiGard is designed to be used both independently and in addition to other warming measures applied externally, such as forced-air warming.

NICE recommended more research on how much HumiGard costs and whether it can help avoid adverse surgical outcomes.

Read the guidance here: www.fdanews.com/02-22-17-HumiGardguidance.pdf.

BRIEFS

Medtronic Wins Japanese Approval Of Transcatheter Pacing System

Medtronic has received regulatory approval in Japan for its tiny pacemaker, the Micra transcatheter pacing system (TPS).

The Micra TPS is less than one-tenth the size of traditional pacemakers. The device received FDA approval in April 2016.

Philips Gains FDA Marketing Clearance For Intellivue Guardian Solution

Netherlands–based Royal Philips has received FDA marketing clearance for the Philips Wearable Biosensor.

The device is designed to aid clinicians in the early detection of subtle signs of patient deterioration, by measuring heart rate, respiratory rate, posture and detecting falls.

The data is then transmitted to the device, which analyzes the measurements over time and notifies the clinician when preset limits are exceeded.

The device received a CE mark in 2016.

FDA Awards Voxello Marketing Clearance For Speech Generation Device

Coralville, Iowa–based Voxello has won FDA marketing clearance for the Noddle speech generation device, used to detect voluntary gestures in hospitalized patients.

The device enables patients to control up to three different devices with a single touch.

DiaCarta Nabs CE-IVD for its Non-Invasive Colorectal Cancer Test

California–based DiaCarta has achieved CE-IVD approval for ColoScapeTM, a colorectal cancer mutation detection kit.

The device is designed to detect mutations in DNA extracted from solid tumor, plasma or stool samples. The device can complete an assay in less than 2.5 hours.

Zimmer Biomet Recalls Comprehensive Reverse Shoulder

Zimmer Biomet has issued a recall for its comprehensive reverse shoulder because the shoulder replacement devices have been fracturing at a higher rate than expected.

The manufacturing dates of the recalled device are between Aug. 25, 2008 and Sept. 27, 2011.

Illumina Receives CE Mark For VeriSeq Analysis Software

San Diego–based, Illumina has qualified for the CE mark for an expanded VeriSeq NIPT analysis software for clinical laboratories in the European Union.

The software is designed for larger batches of 48 samples versus the current 16 samples. It generates quantitative scores to aid in the detection and differentiation of fetal aneuploidy status for chromosomes 21, 18, 13, X and Y by analyzing data generated from cell-free DNA fragments isolated from blood specimens in pregnant women of at least 10 weeks gestation.

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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
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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

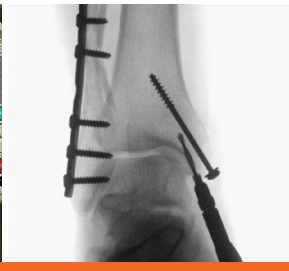
William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA

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.



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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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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.

Using the MDSAP Model to Win International Device Approval

Are you one of the 75% of device manufacturers who conduct internal audits solely "because you have to — because the FDA and ISO regs say so?"

Instead of cringing at the idea of conducting an internal audit, consider implementing the Medical Device Single Audit Program (MDSAP) model. It's a single audit of your quality management system and satisfies medical device regulatory authorities.

Currently, Australia, Brazil, Canada, Japan and the United States are participating in the program. If you pass one MDSAP inspection then you will be ready to pursue marketing authorization in five separate countries.

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