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IN THIS ISSUE

FDA Releases Final Guidance On Interoperable Devices

The FDA unveiled final recommendations for how medical devices should be designed to interact with other devices and IT systems.

The agency wants to encourage developers to consider interoperability issues, according Bakul Patel, CDRH's associate director for digital health. The agency also is encouraging transparency among designers and manufacturers to minimize the risk associated with misuse of interoperable devices.

Failure to provide the information to the user may lead to an inappropriate use of the device interface in a way that can lead to device malfunction, and "may lead to patient injury and even death," Patel said, in a Sept. 6 blog.

The main message the FDA seeks to send to the industry is that interoperable medical devices should be designed with "interoperability as an objective," he said.

(See **Guidance**, *Page 2)*

EpiPen Manufacturer Bungled Response To Complaints of Failures, FDA Says

A company that manufactures EpiPens for Mylan neglected to follow up on hundreds of complaints that the epinephrine injectors failed to operate during life-threatening emergencies, including some that resulted in patients' deaths — and the company did not recall potentially defective injectors from the marketplace even after identifying a fault in a critical injector component, the FDA said in a warning letter.

Representatives of the company, Pfizer's Meridian Medical Technologies, were ordered to meet with FDA regulators to discuss several violations of current good manufacturing processes, the letter said.

The findings were based on FDA inspections of the company's plant in Brentwood, Missouri, in February and March. The FDA noted it had flagged similar GMP violations in a 2014 inspection, which the company said it would correct.

(See **EpiPen**, *Page 2)*

FDA Seeks Entrepreneurs To Join Digital Health Team

CDRH is looking for entrepreneurs to help the agency create digital health regulations.

The Entrepreneur-in-Residence program is meant to help develop the FDA's Software Precertification pilot program announced in August. PreCert is a cornerstone of the agency's Digital Health Innovation Action Plan. It will enable the FDA to develop a "tailored approach" for regulating software as a medical device.

EIR fellows must have at least five years of work experience in software design, clinical trial design, post-market surveillance, or the use of real-world evidence, to qualify for a temporary position in the program. The fellows will work at least three days each week at the FDA's White Oak campus, where they will analyze software business processes, develop and test data collection models; and identify ways to improve processes and policies on data sharing and access. The agency is hiring for six positions, spokesperson Stephanie Caccomo told FDAnews.

The deadline for applications is Sept. 29, 2017.

EpiPen, *from Page 1*

"These repeated failures demonstrate that your facility's oversight and control over the manufacture of these products is inadequate," the letter said.

Epinephrine is intended for emergency treatment of serious allergic reactions, including anaphylaxis.

In February 2016, Meridian Medical identified a faulty injector component among a lot delivered from a supplier — a crucial part that ensures the auto-injector fires properly and delivers the epinephrine, the FDA said. Meridian rejected that lot and told the supplier to fix the defect, but Meridian continued manufacturing EpiPens using other lots of the component while the supplier's investigation was ongoing — and didn't connect the problem to numerous complaints it received about activation failures, the letter said. It recalled the potentially inoperable injectors only after the FDA inspection and repeated meetings with regulators, the FDA said.

Read the warning letter here: www.fdanews.com/09-07-17-EpiPen.pdf. — Gregory Roberts

Guidance, *from Page 1*

The final guidance includes more comprehensive definitions of "interoperability" and "interoperable medical devices," as well as a new list of "levels of interoperability." The agency defines interoperability as "the ability of two or more products, technologies or systems to exchange information and to use the information that has been exchanged."

The agency said manufacturers should consider the following six elements for their interface technology: the purpose of the electronic interface; the anticipated users; risk management; verification and validation; labeling; and use of consensus standards.

The guidance includes recommendations for labeling and premarket submissions.

Read the full guidance here: www.fdanews.com/09-05-17-GuidanceInteroperableMD.pdf. — Ana Mulero

Warning Letter Roundup: FDA Flags Four Devicemakers

The FDA issued warning letters to four device manufacturers for a range of issues, including a failure to seek pre-market approval, to apply for modified intended uses, and quality violations.

SyncThink: The FDA told a Boston eye-movement monitor manufacturer to stop marketing the device as a tool for assessing concussions and other head injuries.

SyncThink, maker of the Eye-Sync device, did not apply for the required premarket approval or investigational device exemption for the Eye-Sync for the head-trauma assessments, which represent a new use for device, the FDA said in a warning letter.

The Eye-Sync has been cleared by the FDA as a prescription device for recording and analyzing eye movements to identify visual impairment. On its web site, SyncThink is promoting Eye-Sync for on-the-spot evaluation of potential concussions, particularly among football players; that amounts to "a major change or modification to its intended use," the letter said.

The company web site lists Texas, Iowa State and Stanford as universities that have adopted the "revolutionary" Eye-Sync for concussion assessment in their athletic programs. The device has been written about in the mainstream media as cutting-edge technology for assessments of sports head injuries.

The device resembles a set of virtual-reality goggles, which are connected wirelessly to a suitcase-sized, portable input processing unit.

QLRAD Netherlands: The FDA moved to block the importation and sale of a Dutch device designed to immobilize the prostate during radiation treatments to target it more accurately and minimize damage to surrounding tissue.

QLRAD Netherlands, maker of the Rectal-Pro Endorectal Balloon, did not apply for the required premarket approval or investigational

(See **Roundup***, Page 4)*

Medical Device Complaint Management Basics

Maintaining an effective complaint handling system requires attention to detail, robust internal audits and a solid training program.

Three of the regulatory requirements related to this system — complaints, MDRs and CAPA — consistently appear in the top five most frequent citations in warning letters issued to device manufacturers. While MDR citations have been relatively flat since 2012, citations related to complaints and CAPA have seen a slight upswing since that time. This means that these are areas that FDA investigators scrutinize during each and every inspection. Under such close examination, any slip-ups are almost certain to be caught

There are a few steps that companies can take to ensure the regulatory success of their complaint handling systems. One is simply to check the procedures. A complaint handling system that meets all QSR requirements must include a large number of procedures, so a check to confirm that all of these are under document control, as laid out in 21 CFR 820.40 – Document Controls, can help catch any details that may have fallen by the wayside.

Likewise, a requirement-by-requirement review of each procedure against the pertinent regulations can help to ensure that the complaint handling and MDR procedures are fully compliant.

For every sentence in the regulations, you should have a place where it's addressed in your procedure, explains Dan O'Leary, president of Ombu Enterprises, a company offering training and execution in operational excellence, focused on analytic skills and a systems approach to operations management. "If you have multiple procedures and work instructions, which often happens, make sure you review them together to make sure that everything is covered and that there are no inconsistencies."

Keeping up with training also can be a challenge. It's essential that everyone involved in the complaint handling process understands how those processes work and who is responsible for. All employees who could potentially be involved in complaint handling must be trained in complaint procedures, and all training must be documented and training records maintained.

Excerpted from the FDAnews book: ***Medical Device Complaint Management***

Roundup, *from Page 3*

device exemption for the balloon, the FDA said in a warning letter.

QLRAD promoted the device for use with radiation therapy on its web site and in brochures distributed at medical conferences in San Antonio and Boston, the FDA said.

Hebei Pukang Medical Instruments: The FDA cut off imports from a Chinese manufacturer of hospital beds, stretchers and operating-room tables after an inspection discovered multiple violations of quality standards, the agency said in a warning letter.

The FDA said the company, Hebei Pukang Medical Instruments, of Baoding, fell short of compliance with current good manufacturing practice requirements, including:

- Lack of written procedures for design control;
- Failure to maintain history records of the manufacture of products to ensure they meet requirements for their production;
- Failure to maintain complaint files and to follow company procedures for the investigation of complaints; and
- Failure to conduct audits of the effectiveness of the company's quality control system.

The FDA said it was taking steps to block imports from the company until the problems are fixed. It also said it may inform other federal agencies, potentially affected the awarding of contracts, and that it will not approve applications from the company to market any new products related to the shortcomings until they are resolved.

Gesellschaft für lichttechnische Erzeugnisse: A German sunlamp manufacturer failed to measure up to several quality standards in an inspection of its plant in Berlin, and the FDA moved to bar imports from the company to the United States, the agency said in a warning letter.

In its inspection of the company, G L E Gesellschaft für lichttechnische Erzeugnisse, the FDA said it determined the manufacturer:

- Failed to establish and maintain controls over the design of its lamps to ensure they meet specified requirements, specifically for its 1000-watt high-intensity UV lamps;
- Failed to set up procedures for undertaking corrective and preventative action; and
- Failed to maintain complaint files, and to establish procedures for review of complaints by a designated unit within the company.

The FDA rejected as inadequate responses to the findings that were received from the company.

Read the SyncThink warning letter here: www.fdanews.com/09-06-17-SyncThink.pdf.

Read the QLRAD warning letter here: www.fdanews.com/09-06-17-QLRAD.pdf.

Read the Hebei warning letter here: www.fdanews.com/09-06-17-Hebei.pdf.

Read the GLE Sunlamps warning letter here: www.fdanews.com/09-06-17-GLEsunlamps.pdf.

— Gregory Roberts

China Looks West for Boost To Medical Device Industry

Grace Fu Palma, founder and CEO of Boston-based China Med Device, LLC, a firm specializing in commercialization and funding for medtech companies entering China, considers CFDA's proposal for exempting certain IVD reagents from clinical trials.

China's medical device industry has seen double-digit growth for many years and Chinese companies across different industries are entering into the medical device sector. These domestic companies have strong financial resources but lack technology, and they are eagerly looking for Western companies to buy or partner with them to shorten their time to market.

In 2015, the China State Council issued a 10-year manufacturing plan, "Made in China 2025", that specifically targets medical devices among 10 domestic industries earmarked for growth. The ultimate goal, based on additional plans for 2025-2035 and 2035-2045 is to be the world's leading manufacturer of medical devices.

One of the major focus areas in the 2025 plan is the biomedical and high-end medical device industry — and the sector is expected to achieve explosive growth in the next decade.

China's device industry is experiencing rapid development due to improving living standards and health awareness. From 2004 to 2014, the compound growth rate of China's medical device industry was 25%, much higher than the 7%-8% global growth rate.

However, the majority of products in China's domestic medical device industry are low-cost, low-tech medical devices. By the end of 2013, there were 16,000 medical device manufacturers in China, 29% Class I, 54% Class II, and only 17% Class III manufacturers. From 2008 to 2013, CFDA has approved 78,784 low-end domestic Class I and Class II medical devices registered, but only 10,316 high-end Class III devices.

The "Made in China 2025" plan is focused on developing domestic high-end, profitable medical devices such as imaging equipment, medical robots, full degradation vascular stents and other high-value medical products.

The government will support domestic manufacturers to improve their R&D and technology innovation in a domestic medical device industry.

On the other hand, since the government is incentivizing the domestic device industry, importers may face more challenges and barriers if the authorities issue policies to restrict imports.

This is a good time for non-Chinese medtech companies to find other ways to enter China, such as through OEM partners, licensing technology, or establishing factories.

— Grace Fu Palma | gpalma@chinameddevice.com
(978) 390-4453 www.chinameddevice.com

U.S., Brazil Add New Auditing Bodies for MDSAP

The FDA and Brazil's National Surveillance Agency have added new auditing bodies to their list of organizations eligible to conduct quality management system audits for the Medical Device Single Audit Program.

The FDA now lists 14 organizations that have submitted applications to be auditors for the MDSAP program, which allows a single audit to satisfy multiple regulatory jurisdictions.

Only accredited auditing organizations under the Canadian Medical Devices Conformity Assessment System were allowed to apply during the MDSAP pilot from January 2014-December 2016.

One listed organization, NSF Health Sciences has not yet been authorized to conduct MDSAP audits. NSF was not allowed to apply until January 2017 and is the only auditing organization

(See **MDSAP***, Page 6)*

MDSAP, *from Page 5*

making it through the first several steps of the recognition process since the pilot concluded.

"We have received a successful Stage 2 Assessment which we are working with the Regulatory Authorities to conclude," says Brian Ludovico, NSF executive director of MDSAP regulatory certification.

Of the 13 organizations cleared by the FDA to conduct MDSAP inspections, only four have received full recognition as MDSAP auditors: BSI Group America, Intertek Testing Services, TUD SUD America and UL Medical and Regulatory Services.

The full list of companies on the FDA's list of eligible auditing organizations includes:

- BSI Group America, Herndon, Va.;
- DEKRA Certification, Arnhem, Netherlands;
- DQS Medizinprodukte, Frankfurt, Germany;
- Intertek Testing Services, Lowell, Mass.;
- Laboratoire National de Métrologie et d'Essais, Paris, France;
- Lloyd's Register Quality Assurance, Houston, Texas;
- National Standards Authority of Ireland, Dublin, Ireland;
- NSF Health Sciences Certification, Washington, D.C.;
- QMI-SAI Canada, Toronto, Ontario;
- SGS United Kingdom, Cheshire, England;
- TUV Rheinland of North America, Newton, Conn.
- TUV SUD America, Peabody, Mass.;
- TUV USA, Salem, New Hampshire; and
- UL Medical and Regulatory Services, Northbrook, Ill.

Current MDSAP participating countries are Australia, Brazil, Canada, Japan and the U.S. The MDSAP program allows regulators in MDSAP participating countries to share data so multiple GMP audits are not required in the participating countries (*IDDM*, July 12).

The International Medical Device Regulators Forum's single-audit program remains on track for full implementation in 2019, and companies should be reviewing their internal auditing processes in preparation.

Brazil Adds Nine New MDSAP Auditors

Meanwhile, Brazil's ANVISA added nine new organizations to its list of auditing bodies recognized to conduct MDSAP audits:

- BSI Group America;
- DEKRA Certification;
- DQS Medizinprodukte;
- Intertek Testing Services;
- Laboratoire National de Métrologie et d'Essais;
- Lloyd's Register Quality Assurance;
- National Standards Authority of Ireland;
- TUV SUD America; and
- UL Medical and Regulatory Services.

Devicemakers selling products in Canada must comply with the single audit requirement by March 2019. Health Canada will expect all device licenses to be supported by MDSAP audits by that time, and if a manufacturer doesn't have a MDSAP certificate, its license will be suspended.

Companies selling devices in other regions covered by MDSAP should be aware that information from the Canadian audit will be shared with the regulators in the other regions. For example, if a company sells devices in Canada, the U.S. and Australia, it will be required by Canada to be certified under MDSAP, and the FDA and the TGA will have access to the audit reports.

Other jurisdictions are likely to require MDSAP audits as the program gains momentum. The EU has not yet signed on because was overhauling its device regulations. As part of that process, it has toughened requirements for notified bodies, which will reduce the number of notified bodies to about 40 (*IDDM*, May 12).

Read the FDA list here: www.fdanews.com/09-06-17-FDAMDSAP.pdf.

483 Roundup: FDA Cites Four Firms Over Complaints, CAPAs

The FDA issued Form 483s to four device manufacturers for issues ranging from responses to customer complaints to record-keeping.

Aero Data Metal Crafters: The FDA hit Aero Data Metal Crafters for inadequate complaint procedures and device history records.

The agency issued a Form 483 to the devicemaker following a June inspection of its Ronkonkoma, NY, facility. According to investigators, the facility did not have medical device reporting procedures for its mammography positioning chair model MPC1000-E, a class I device.

The firm also did not maintain paper or scanned copies of the signed and reviewed device history records for the MPC1000-E, and did not keep labeling records for the device.

The agency also faulted Aero Data on its handling of complaints, noting that its complaint SOPs did not specify the procedure for receipt, review, evaluation and documentation to determine whether CAPAs were necessary.

In addition, the company did not document the CAPA process and a follow-up investigation for at least one rejection report received as part of a 2016 complaint.

American Dental Implant Corporation: American Dental Implant Corporation landed an FDA reprimand for its complaint files, MDR procedures and equipment calibration.

The FDA issued a Form 483 to the devicemaker after a July inspection of its New Castle, Pa., facility. The company, which manufactures dental implants, abutments and bone drills, did not document all complaints it receives or evaluate the undocumented complaints, according to the agency. The company also had no written MDR procedures.

The agency further cited the company for its lack of CAPA or design control procedures.

Caliber Imaging and Diagnostics: The FDA cited Caliber Imaging and Diagnostics over its device software validation, CAPA procedures and design verification.

The agency hit the medical device manufacturer with a Form 483 after a May/June inspection of its Rochester, NY, facility. Investigators found the software validation for an update to one of its products, signed off in September 2016, left multiple sections blank or crossed out with no justification. In the case of some tests that were noted to have failed, the facility did not maintain a record or defect report, the agency said.

The FDA also took issue with the software used during production, noting the company's documentation did not include procedures for validation.

Investigators reviewed 12 CAPA records and found several were not verified or validated as effective. In addition, a revision to the company's CAPA procedures did not include a requirement to validate or verify CAPAs to ensure there were no adverse effects.

Lastly, investigators found verification records for the company's VivaScope 3000 Product Trace Matrix did not specify the verification method used.

Adroit Medical Systems: The FDA issued a Form 483 to Adroit Medical Systems for its record-keeping and device history record procedures.

The agency issued the form following a July inspection of the devicemaker's Loudon, Tenn., facility. It found that the firm's device history record did not indicate that its class II heat therapy pump was manufactured according to the device master record.

Read the Aero Data Metal Crafters Form 483 here: www.fdanews.com/09-07-17-aerodata483.pdf.

Read the American Dental Implant Corporation Form 483 here: www.fdanews.com/09-07-17-americandental483.pdf.

Read the Caliber Imaging and Diagnostics Form 483 here: www.fdanews.com/09-07-17-caliber483.pdf.

Read the Adroit Medical Systems Form 483 here: www.fdanews.com/09-07-17-adroit483.pdf.
— Zack Budryk

Protecting Devices From Cybersecurity Risks

With the recall of 465,000 Abbott pacemakers deemed at risk of getting hacked — marking the first ever device recall for a cybersecurity issue — it's time for a deeper dive on how to protect your product from cyber risk.

In a recent webinar titled "Cybersecurity and Risk Management for Medical Devices: Pre-market to Post-market Process Planning," risk expert Dan O'Leary covered all the bases and then some on the best paths to take.

Cybersecurity is applied risk management implemented in two phases — the pre-market phase in which you're preparing the submission to put the device on the market, and the post-market phase after the device is cleared or approved, and you're in the process of marketing it, explained O'Leary, president of Ombu Enterprises.

During the pre-market phase, he said, one must determine the level of concern, design the device with the applicable safeguards, document the design and include the results in the design history files, then submit a subset of the documentation based on the level of concern.

A deep understanding of FDA's cybersecurity guidance documents is key, he said. Ones to get to know well are Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Software Contained in a Medical Device; and Cybersecurity for Networked Medical Devices with Off-the-Shelf Software.

In addition, during this phase devicemakers will need to do software validation and risk management, which typically will follow rules in ISO 14971:2007.

"There's an intersection between software validation and risk management, and this is where cybersecurity lives," said O'Leary.

In the post-market phase, he said, one should monitor complaints and other sources of cybersecurity information for any threats and vulnerabilities, update the device design, distribute the updated software, and determine whether the update is reportable under 21 CFR 806.

The FDA issued final guidance on post-market cybersecurity at the end of 2016. Its key steps include: identifying cybersecurity hazards, estimating the associated risk, evaluating the associated risk against the acceptability criteria, putting controls in place, and monitoring the effectiveness of those controls. The FDA built these steps using the ISO 14971:2007 model, so they should come as no surprise to devicemakers, O'Leary said.

"The easy way to think about it is that first you're going to do … software validation under [21 CFR] 820.30, you're going to do risk management under 820.30, you're going to combine them for the software, and you're going to take both into account for cybersecurity — and then you're going to do it two times: one in the premarket phase and one in the post market phase.

Access the webinar here: www.fdanews.com/products/54735.

PEOPLE ON THE MOVE

Tactile Systems Technology appointed **Cheryl Pegus** to the company's board of directors. Pegus served as the first chief medical officer of Walgreen from 2010 to 2013, where she assisted in the expansion of its healthcare services, new product launches and data analytics. Tactile Systems Technology is developing medical devices for the treatment of chronic diseases at home such as lymphedema and chronic venous insufficiency.

Integer Holdings Corporation named **Joseph W. Dziedzic** as president and CEO. Dziedzic has served as interim president and CEO since March 2017 and as a director of the company since February 2013. Integer Holdings is one of the largest medical device outsource manufacturers in the world, serving the cardiac, neuromodulation, orthopedics, vascular, advanced surgical and portable medical markets.

FDA Seeks Ideas for Regulations To Cut Under Trump Policy

The FDA is asking stakeholders for help identifying federal requirements that can be repealed or replaced under the Trump administration's deregulatory push.

The agency opened several comment dockets — including one for CDRH — as it seeks to implement Trump's executive order that the federal government identify two regulations for elimination for each new one proposed. The dockets will be open for the next 90 days.

In its request, the FDA said it is looking to achieve "meaningful burden reduction" while fulfilling its public health objectives.

In reviewing the comments, the agency plans to consider whether there have been advancements in science, technology or industry practices that supersede previous regulations in some way. The FDA will also consider regulatory requirements mirrored by consensus standards or third-party organizations, such as the ICH.

Trump's executive order, issued shortly after taking office in January, directs agencies to identify regulations considered to be outdated, unnecessary or ineffective; inhibit job creation; or impose costs exceeding benefits.

The White House later narrowed the scope of the order, clarifying that it only applied to regulations with significant economic impacts of more than $100 million per year (*IDDM*, Feb. 3).

The CDRH docket is available here: www.regulations.gov/document?D=FDA-2017-N-5105.

APPROVALS

FDA Clears 'Industry-First' Mammography Device

GE Healthcare received 510(k) clearance for its "industry-first" mammography remote control device called Senographe Pristina Dueta.

Patients can use the handheld wireless remote control to manage their compression during examinations with GE's mammography system.

FDA Approves Biotronik's Quadripolar CRT Pacemaker

Biotronik secured FDA approval for its Edora HF-T QP MR conditional quadripolar cardiac resynchronization therapy pacemaker (CRT-P).

The device allows physicians to tell the implant an MRI exam is coming up, so the device can automatically engage its MRI safety mode during a scan.

FDA Clears XSTAT to Stop Gun And Knife Wounds in Arms and Legs

RevMedX secured FDA 510(k) clearance for XSTAT 12 and XSTAT 30 devices used to stop severe bleeding from knife and gun-shot wounds in the arms or legs.

The devices are large syringes that quickly push dozens of tablet-sized highly absorbent pieces of foam into a wound. Once the foam tablets are inside the wound, they quickly expand, blocking the blood from escaping and delivering pressure onto the wound from within.

The FDA previously approved the devices for use in civilian and battlefield situations, but only to treat junctional wounds around the groin and shoulders.

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Customer Service (888) 838-5578 • +1 (703) 538-7600 customerservice@fdanews.com

Editor: Ana Mulero +1 (703) 538-7634 amulero@fdanews.com

Ad Sales: Jim Desborough +1 (703) 538-7647 jdesborough@fdanews.com

Multi-User Sales: Jeff Grizzel +1 (703) 538-7669 jgrizzel@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • www.fdanews.com

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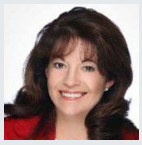

ROBIN NEWMAN
Director, Office of Compliance CDHR, FDA (Invited)

CAROL BENNETT, J.D.
Deputy Director, Office of Regulatory Policy, CDER, FDA (Invited)

DANA CORRIGAN, J.D.
Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)

DOUGLAS STEARNS
Director, Office of Enforcement and Import Operations, ORA (Invited)

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2017 SUMMIT HIGHLIGHTS

NEW FOR 2017!

FDA's ORA Reorg and What it Means for Inspections

Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer's Perspective

Building Your Best Internal Audit Team for Quality Results

Plus twin tracks for drug/biologics and device manufacturers and two pre-conference workshops,focusing on FDA Inspection Management and QSIT Secrets.

Expert panels featuring current and former FDA officials and industry professionals:

- FDA Field Investigators: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)
- The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers
- European Medical Device Regulations — Preparing for the Storm

FEATURED EXPERT SPEAKERS:

JOHN AVELLANET, Managing Director and Principal, Cerulean Associates LLC

KATLIN BACKFIELD, Attorney at Law, Consultant, Backfield PLLC

MARK BROWN, Partner, King & Spalding

CONNIE HOY, Executive Vice President of RA/QA, Cynosure

IBIM TARIAH, Ph.D., Technical Director, BSI Americas Inc.

DAN O'LEARY, President, Ombu Enterprises LLC

SUSAN SCHNIEPP, Fellow, Regulatory Compliance Associates, Inc.

CYNTHIA SCHNEDAR, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA

VICKY STOAKES, President, IntegRx, Inc.; former FDA Chemist, ACNA and Investigator, Atlanta District Office Drug Cadre

KARL VAHEY, Vice President Manufacturing Quality, Patient Monitoring and Recovery, MITG, Medtronic

Pre-conference Workshops Agenda

WED., NOV. 1 (1–5 p.m.)

DRUGS & BIOLOGICS TRACK

Flawless FDA Inspection Handling and Response

Rated #1 Pre-Conference Workshop in Inspection Summit History — Updated for FDA's New Inspection Techniques!

John Avellanet of Cerulean Associates — one of the industry's top inspectional readiness experts — is back to teach proven techniques to manage FDA investigators on-site, how to defend yourself where it's appropriate and craft 483 responses that fend off warning letters.

Plus, in a special portion of this must-attend pre-conference, he'll explain how the FDA's New Inspection Protocol Project inspection technique could trip up companies that have always had good compliance records. He'll profile a company that had years of clean inspections, only to be blindsided with a bad inspection based on NIPP. You can't afford to miss this session!

Compliance pros know that getting an FDA investigator in and out as quickly as possible is the best strategy. The longer an FDA investigator is on site, the more likely you'll be handed a multi-page 483.

And if you think racking up those observations are bad, even worse is crafting a response, plowing it through your internal departments and getting it back to the FDA in just 15 days. Oh, did we mention the response must be detailed, provide a well-documented root cause analysis and spell-out solutions to assure the problem never happens again?

You'll learn how to prepare for an inspection, how to encourage the investigator to see you in a "state-of-control," and how — if the worst happens — to manage a 483 observation and not get a warning letter.

Attendees will learn:

- The results of a case study of how a firm that passed 9 previous inspections suddenly failed under FDA's new NIPP inspection technique
- Critical inspection preparation techniques every member of your team must commit to memory — especially useful for those surprise FDA visits
- Hidden tactics FDA investigators use to test your controls and are taught to probe your answers for weakness
- How to speed the inspection to minimize the risk of 483 observations, while always remaining respectful
- What really needs to be in your regulatory inspection handling SOPs — tips for cutting corporate-speak and unnecessary verbiage that doesn't help
- How to write an inspection response designed to reduce the likelihood of a warning letter — and tips and tricks to get sign-offs quickly from even the toughest groups (like legal)
- What FDA staff look for in your replies and the top red flags they notice

BONUS: Attendees will receive:

- A sample regulatory inspection handling SOP — ready for your immediate implementation
- Three inspection handling and response checklists — ready for you to use right away
- An observation-closure matrix — ready to speed you out of FDA trouble

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

MEDICAL DEVICES TRACK

No More 483s - QSIT Secrets to Assure Clean Inspections

Customized, Interactive and Full Of Valuable Take-Aways, This Pre-Conference Workshop is a Must Attend

Recently, a top FDA investigator — in a candid moment — said "I'm still amazed I can go to a firm and they haven't read the QSIT guide."

After 18 years, too many devicemakers ignore the Quality System Inspection Techniques (QSIT) Guidance to their peril.

FDAnews is proud to have QSIT expert Julie Larsen, Principal/Director, Inspection Readiness Services at BioTeknica, provide her secrets for using the QSIT's details to assure your next inspection is squeaky clean.

Julie knows the QSIT guidance, and how to apply it, to device companies of all sizes and all product classes. In just four hours, you'll learn the hidden traps inside this important inspection technique and several take-away ideas you can put to immediate use.

This interactive workshop will dive deep into these key issues:

- How to use the QSIT's specifics to assure your internal audits have covered and confirmed compliance with FDA's expectations
- Examples of companies that have used the QSIT in both positive and negative ways — many of these will surprise you!
- Tips and tricks for being uber-prepared — especially being prompt with answers to investigators' questions and being able to produce documents in a timely manner
- Best industry tools for internal audits

Unlike other preconferences you've attended in the past, Julie will break attendees into working groups to flush out inspectional problems attendees are having. She'll then offer her insights on the best-in-class tools available and best practices to solve your problems.

BONUS: In addition to Julie's expert tips, attendees will receive these MUST-HAVE reference documents worth the registration fee alone, including:

- A detailed QSIT checklist that attendees can immediately apply to their current inspection prep SOP
- 10 key questions to use in assessing your company's state of readiness for an FDA QSIT inspection

Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica

Day 1 Agenda

THURS., NOV. 2

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

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

8:45 a.m. – 9:30 a.m.

FDA's ORA Reorg and What it Means for Inspections

The FDA reorganized its Office of Regulatory Affairs inspectorate to more closely align inspection efforts with the myriad types of products it regulates — essentially organizing staff by area of expertise instead of geographic region. Will inspections happen more frequently? Does this make inspection outcomes more predictable or less? Will inspections be conducted faster if they are done by experts, or will they take longer to go through more detail? Associate Commissioner Ellen Morrison will discuss the latest developments and talk about what to expect from the changes.

Ellen Morrison, Associate Commissioner, OMPTO, ORA, FDA

9:30 a.m. – 10:15 a.m.

The World of FDA Quality Metrics: Yesterday, Today and Tomorrow

CDER and CBER have the Quality Metrics Submission guidance. CDRH has the Case for Quality initiative. All centers are driving towards a culture of quality within the life sciences industry. Marla Phillips has a unique perspective that comes from working on both sides of the line. With the FDA, she co-led the CDRH metrics initiative, and with PricewaterhouseCoopers, she co-led the pharmaceutical metrics initiative. Her presentation will examine the difference between the two initiatives, their progress, the differences and the similarities in their metrics. From her industry experience, she will examine the potential impacts, the unintended outcomes and how to protect everyone's time from doing busy work that does not achieve the end goal. She will also share her thoughts of where these initiatives are headed.

Marla A. Phillips, Ph.D., Director, Xavier Health, Xavier University

10:15 a.m. – 11:00 a.m.

Postmarket Adverse Event Reporting and cGMP: What You Absolutely Need to Know

The FDA issued two final rules that set forth the postmarket safety reporting and current good manufacturing practices (cGMP) requirements for combination product and constituent part sponsors. This session summarizes key concepts and provides insightful case studies about how the rules work in the real world.

(cont.)

Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC; former Associate Chief Council for Drugs, OCC, FDA

11:00 a.m. – 11:20 a.m. | **BREAK**

11:20 a.m. – 3:30 p.m.

Two Concurrent Breakout Tracks

Track 1 — Drugs & Biologics

Track 2 — Medical Devices

3:30 p.m. – 3:50 p.m. | **BREAK**

3:50 p.m. – 5:15 p.m. |
PLENARY PANEL DISCUSSION

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

DRUGS & BIOLOGICS TRACK

11:20 a.m. – 11:30 a.m. |
MODERATOR COMMENTS

David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office

11:30 a.m. – 12:15 p.m.

FDA Regulatory Policy Roadmap: FDA Shares its Priorities for 2018

The FDA is constantly looking at new and more efficient ways to regulate drugs and medical devices. Under a new commissioner, the Office of Regulatory Policy (ORP) has identified a specific set of priorities that you need to know about. Some issues are very familiar, such as responding to an opioid epidemic that Commissioner Scott Gottlieb has called his "highest immediate priority." Other initiatives are less publicized but just as important. How will the agency modernize its assessment of manufacturing facilities? How does it manage innovations in drug development? Now that Gottlieb has made getting more generic drugs approved a priority, what are the implications for regulatory development? Will initiatives to harmonize efforts with international regulatory organizations mean changes domestically? Carol Bennett, Deputy Director Office of Regulatory Policy at CDER will review the recent actions within CDER and the outline priorities looking into 2018.

Carol Bennett, JD, Deputy Director, Office of Regulatory Policy, CDER, FDA (Invited)

12:15 p.m. – 1:00 p.m.

Cautionary Tales: Words to the Wise on Compliance

Those who fail to learn from the mistakes of others are destined to repeat them. Using real situations encountered by pharmaceutical and biologics firms, discover strategies for staying up-to-date with FDA cGMP regulations. Examples of non-compliance are presented with suggestions for applying these lessons and improving your regulatory compliance strategies.

Vicky Stoakes, President, IntegRx, Inc.; former FDA Chemist, ACNA and Investigator, Atlanta District Office Drug Cadre

1:00 p.m. – 2:00 p.m. | **LUNCH**

2:00 p.m. – 3:30 p.m.

The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers

In March, the US and European Union signed a mutual recognition agreement (MRA) to recognize each other's drug GMP inspections. This is good news for the industry that should see fewer inspections. However, it doesn't come without some concerns. First, each inspection now has greater consequences as any problem will now be a red flag for multiple agencies. Also, if regulatory agencies share information, what does that mean for information confidentiality? Plus, the EMA retained authority to conduct inspections in "extraordinary circumstances," but what does that mean, exactly? The FDA has until November to assess regulatory authorities in eight EU countries to trigger the start of the implementation of the agreement. How close are they? The agreement doesn't mean European GMP regulations are less important — in fact, they are as important as ever. Come hear experts describe the practical implications of this agreement for drug GMP inspections so you're not caught off guard.

Moderator: David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office

Dara Corrigan, J.D., Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)

Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA

Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC

Mark Brown, Partner, King & Spalding

3:30 p.m. – 3:50 p.m. | **BREAK**

MEDICAL DEVICES TRACK

11:20 a.m. – 11:30 a.m. |
MODERATOR COMMENTS

Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica

11:30 a.m. – 12:15 p.m.

CDRH's New Inspection Strategy for 2018: How it Will Impact Your Company

This is not your father's CDRH. There's more emphasis on global activities and a greater expectation of transparency and data security. You'll hear the director of compliance discuss and answer questions about these important issues:

- The new inspection approach/strategy for medical devices in 2017-2018 and its practical impact on your business
- The new CDRH, ORA and the Office of Crisis Management (OCM) streamlined process for medical devices and what it all means for electronic product related consumer complaints and Allegations of Regulatory Misconduct (ARMs)
- The new CDRH and ORA process to measure, document, and report on public health outcome metrics and how it will affect inspection compliance

Robin Newman, Director, Office of Compliance, CDRH, FDA (Invited)

12:15 p.m. – 1:00 p.m.

Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer's Perspective

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you're used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP in October 2016 and their facility in NY (40 people) was audited to the MDSAP in March 2017. Both facilities passed the audit with only minor findings.

Executive Vice President of RA/QA Connie Hoy will take you through the preparation process from the manufacturing perspective. You will also hear what lessons they learned along the way, what they would have done differently and how it compares to a corporate audit versus a small manufacturing plant audit.

This presentation will cover:

- What they did to prepare for the audit
- The audit flow and how it differs from QSIT and ISO audits

(cont.)

Day 1 Agenda (cont.)

THURS., NOV. 2

- The differences and similarities between preparing the two plants
- What they would do differently to prepare now that they have undergone the process

Connie Hoy, Executive Vice President of RA/QA, Cynosure

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

Panel Discussion: European Medical Device Regulations — Preparing for the Storm

Like a line of thunderstorms developed on a weather front, various regulatory agencies will move through your company to check up on the Quality Management System. Each visit will be different because they will look at different aspects. The FDA will check your adherence to US regulations. The MDSAP will help prepare you for Canada, Australia, Brazil and other jurisdictions in the program. The unknown factor is the status of the MDR Notified Bodies (NB). There aren't any yet, as the regulation moves through its transition process. We do know that qualifying NBs will conduct audits that are more rigorous than under the directives. The MDR Annex VII, Section 4.5. Conformity Assessment Activities, lists specific requirements for the NB to cover during an audit.

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

Moderator: Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica

Dan O'Leary, President, Ombu Enterprises LLC

Ibim Tariah, Technical Director, BSI Americas Inc.

Karl Vahey, Vice President Manufacturing Quality, Patient Monitoring and Recovery, Medtronic

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

FDA Field Investigators Panel: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)

Ever wonder what an investigator is thinking when they receive their next inspection assignment? What framework they follow, and what affects their thinking during an inspection? This presentation will give you a glimpse into the inner workings of an investigator's mind before, during and after an inspection.

Attendees will learn:

- What information does an investigator have before he or she shows up at your door?
- Do investigators prepare differently for different companies, plants or products?
- What is the first thing they notice when they enter a plant?
- How do investigators apply QSIT and other inspectional techniques to the QSR?
- Why they include items in the EIR and Form 483 and how they take into account your comments

PLUS, this panel will take your questions (anonymously if you wish). So, here is your chance to ask questions and get answers straight from investigators in the field every day! Don't miss this opportunity to get your answers!

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

Day 2 Agenda

FRI., NOV. 2

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

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

8:45 a.m. – 9:30 a.m.

FDA's Office of Regulatory Affairs: Enforcement Update

This presentation will focus on ORA's Office of Enforcement priorities for 2018, and changes to how the office approaches the process. This session will ensure attendees have the latest information on how they can more proactively prepare for FDA investigators.

Attendees will learn:

- The latest on the FDA's re-organization of the inspectional corps
- The FDA's position on recalls and the possible actions the Office of Enforcement can take in the wake of them
- Effectiveness of criminal sanctions in improving compliance among drug and device company senior management
- Whether 483s and warning letters will be produced more quickly and highlighted for the public as a deterrent to poor corporate behavior

Douglas Stearns, Director, Office of Enforcement and Import Operations, ORA (Invited)

9:30 a.m. – 10:15 a.m.

Building Your Best Internal Audit Team for Quality Results

An internal audit of your quality management system should be a collaboration, not a confrontation, with auditor and auditee working together to spot issues that weaken your system. You need to move your audit team beyond the "blame and shame" mindset that can keep them from openly and honestly sharing the information you need to work out solutions and make your QMS stronger.

Your internal audits can be a positive and productive experience for all if you apply the lessons in this session:

- How to train your employees to handle audits in the most productive way;
- How to select the best auditor to work with your team;
- How to follow the internal audit with corrective action;
- How to report audit findings to management and get them to buy in to suggested solutions; and
- How to evaluate your internal auditing system's effectiveness.

Susan Schniepp, Distinguished Fellow, Regulatory Compliance Associates, Inc.

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

How to Deal with Difficult Inspections

Co-Chair Steve Niedelman and long-time industry expert, David Chesney, will provide real-world scenarios for dealing with tense inspections. Through open discussion and feedback, the audience will work together to come to the correct conclusion for each scenario.

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations

David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office

12:00 p.m. | SUMMIT ADJOURNS

"Great and interesting sessions. Great panel discussions and attendee participation."

— **Johanna Stamates, Executive Director - Research Compliance and Quality Assurance, University of Miami**

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