INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Device Identifiers Would Help CMS Track Defective Products, OIG Says

Medicare spent $1.5 billion and patients spent $140 million as a result of just seven recalled or failed cardiac devices, spending that could be better controlled if unique device identifiers (UDIs) were required on CMS claim forms, according to a Sept. 30 report by the HHS Office of Inspector General (OIG).

The next version of the CMS form due to be released for comment on Dec. 1, and if UDI information is not included in this round of updates, device-specific information couldn't be included until the "end of the next decade," Inspector General Daniel Levinson said.

The OIG said the Centers for Medicare and Medicaid Services does not receive enough medical device-specific information from claims data to properly identify and track Medicare costs related to the replacement of recalled or defective devices.

(See **OIG**, *Page 2)*

Theranos Shuts Down Blood-Testing Facilities, Lays Off 340 Workers

Theranos has announced that it will close its blood-testing facilities.

In an Oct. 5 open letter to stakeholders, CEO Elizabeth Holmes said the company will close its clinical labs and Theranos Wellness Centers, which will impact about 340 employees in Arizona, California, and Pennsylvania – roughly one-fourth of the company's workforce.

"After many months spent assessing our strengths and addressing our weaknesses, we have moved to structure our company around the model best aligned with our core values and mission," Holmes said, adding that the company will be focusing on its new miniLab platform.

"Our ultimate goal is to commercialize miniaturized, automated laboratories capable of small-volume sample testing, with

(See **Theranos**, *Page 4)*

OIG, *from Page 1*

Failed devices of all types cost Medicare billions of dollars and often harm patients both physically and financially, a problem that could be addressed by better documenting which patients receive which devices, the report said.

The report recommended that Medicare claim forms be revised to include the device identifier portion of the UDI for implantable devices. This would help identify recalled or defective devices more quickly, identify the costs to Medicare for those devices, keep patients safe and protect them from unnecessary costs, and safeguard Medicare trust funds, the OIG said.

Jay Crowley, vice president of UDI Services and Solutions at USDM Life Sciences, said the report represents "a new wrinkle in the ongoing discussion about the utility of UDI to CMS and what problems it would cause."

Big Change

On the one hand, he said there would be an "enormous cost" associated with requiring UDI. "To require UDI for implantable devices changes a whole bunch of things, and implementing those things wouldn't be easy," he said.

However, Crowley added that FDA officials and others also see benefits "to the kind of granularity that UDI provides."

The OIG noted the effort and expense required to find out which patients had received the failed or recalled cardiac devices, and then to determine which patients had received replacement devices.

"I think the OIG is pointing out that there are benefits to capturing UDIs for implantable devices that could save CMS money," Crowley said. "We have to get over the hurdle of doing it." The hurdles include, among other things, changing claim forms and updating systems and processes.

"Getting through all that and figuring out what we're going to capture and what it's going to look like is part of the challenge," he said. "I think the problem for CMS is that there are significant costs to doing this, and someone at the department or congressional level has to decide this is worth the investment."

Still, Crowley predicts the changes will be implemented eventually, perhaps in five to eight years. "These things take a long time, but I think it's going to happen," he said.

Read the OIG report here: www.fdanews.com/10-06-16-OIGletter.pdf. — Jeff Kinney

FDA Seeks Veterans' Views on Prosthetic Limbs at Workshop

The FDA is holding a public workshop on Oct. 31 to get feedback from veteran amputees about their experiences with prosthetic limbs.

The workshop also is intended to engage stakeholders involved in research, development, and marketing of prosthetic limbs used by veterans.

CDRH is interested in patients contributing their views, data, and resources to help improve the life cycle for medical devices, reduce adverse events, and improve communication about the risks and benefits that matter most to them.

Topics to be discussed at the workshop include:

- The CDRH Total Product Life Cycle for prosthetic limb devices;
- A focus group to obtain information on priorities for upper-limb prosthetics
- from amputees;
- Presentations from prosthetic limb manufacturers; and
- A question-and-answer session where patients can present their views and ask questions.

The workshop will be held at the FDA's White Oak Campus.

Read the FDA notice here: www.fdanews.com/10-05-16-veterancomments.pdf.

'SkinPen' Doesn't Share Dermabrasion Exemption, Warning Letter Says

A March FDA inspection revealed that Bellus Medical marketed and distributed its SkinPen device without approved premarket clearance or an investigational device exemption.

As such, the agency deemed the SkinPen dermabrasion product adulterated because the Dallas-based firm did not notify the FDA that it intended to commercialize its device.

The SkinPen device is an automated, non-surgical "microneedling" device designed to improve the appearance of wrinkles and scars by delivering "thousands of micro-injuries to the skin," the Sept. 13 warning letter said.

Designed to be used by a licensed practitioner, the device incorporates a sterile microneedle cartridge and bio-sheath for single use. The device punctures the skin to a depth of 2.0 mm.

In general, dermabrasion devices are exempt from premarket notification, the letter said, but the microneedling stamp mechanism that punctures the skin "raises different questions of safety and effectiveness."

The agency expressed concern about the length of the needles and the potential for damage to vessels and nerves as well as the risk of infection and cross-contamination since the device is reusable.

In addition, the FDA deemed the device misbranded because it was marketed as being "FDA-approved." The agency said the statement is misleading and asked the firm to immediately cease marketing the device as FDA-approved.

The firm did not respond to a request for comment by deadline.

Read the warning here. www.fdanews.com/10-06-16-Belluswarning.pdf. — Tamra Sami

Documentation, Contamination Issues Draw 483 for Chinese Implant Company

A June inspection found Guangdong, China-based Implant Dental Technology deficient in numerous good manufacturing practices, according to a seven-item Form 483.

The dental implant manufacturer failed to implement procedures to prevent contamination of equipment or product.

The inspector noted that there was unidentified brown particle accumulation in four different locations in the plant, and the firm was using tap water rather than sterile or purified water.

Process control procedures had not been established to ensure conformance to specifications. For example, there was no documentation of required temperatures and times in the manufacturing process, and values were hand-written and taped to a table, but there was no date, signature or revision control.

Similarly, documentation was lacking for calibration of equipment and for inspections and maintenance activities. The inspector noted that there were no serial numbers, and labels didn't identify equipment that had been qualified. Apparently there was one certificate of calibration but it was not possible to identify which piece of equipment had in fact been calibrated.

The FDA also found acceptance procedures were not established, and the firm did not have a process for identifying acceptance materials. It also did not have a quarantine area for separating products. The 483 noted that "no product was found to have acceptance status identification."

Changes to records also lacked signatures and approval dates, the 483 indicated, and medical device reporting procedures had not been developed or implemented. The firm also did not review customer complaints nor did it document corrective and preventive actions.

The firm did not respond to a request for comment.

Read the Form 483 here: www.fdanews.com/10-05-16-China.pdf. — Tamra Sami

Russia, Iran Sign Agreement On Drug, Device Regulation

Russia's regulatory agency Roszdravnadzor and Iran's Food and Drug Administration have entered into a cooperative agreement on the regulation of drugs and medical devices.

The agreement, signed Sept. 29 by Russian Health Minister Veronika Skvortsova and Iran Minister of Health and Medical Education Hassan Hashemi, was developed at Roszdravnadzor's initiative within the framework of the Russian-Iranian working group on health and aims to enhance the dialogue for regulatory cooperation with regard to medical product quality control, efficacy and safety.

The agreement provides for the exchange of information on topics related to the regulatory treatment of medical products, laboratory and expert control, as well as post-marketing monitoring of drug and device safety, according to RegLink Associates.

"The Russian medicine and medical equipment market is worth $24 billion annually, 80 percent of which is supplied by imports. This gives Tehran and Moscow a promising opportunity for cooperation," Hashemi said after the signing. — Tamra Sami

Tute Genomics Halts Crowdfunding For DNA Sequencing Due to FDA Letter

Tute Genomics has suspended a crowdfunding campaign for genome testing after receiving an FDA letter about the company's direct-to-consumer marketing.

The campaign was intended to extend both focused and comprehensive DNA sequencing services to consumers. "We're proactively engaging with the FDA and working on the right path forward to make this happen," the company said.

Tute Genomics pursues fundraising after reviewing its DNA sequencing process and concluding that the process "does not involve what the FDA considers a 'medical device,' avoiding the need of a premarket review."

The Tute campaign had raised nearly $75,000 before it was suspended. — José Vasquez

Theranos, *from Page 1*

an emphasis on vulnerable patient populations, including oncology, pediatrics, and intensive care," the CEO said.

She said the company has a new executive team working toward "obtaining FDA clearances, building commercial partnerships, and pursuing publications in scientific journals." Theranos unveiled its miniLab platform in August at the American Association for Clinical Chemistry meeting.

The miniLab technology miniaturizes analytical testing equipment across different testing methods, including hematology, immunology, clinical chemistry, immunochemistry, and nucleic acid amplification.

Holmes discussed the company's Zika nucleic acid amplification-based assay for which the company hoped to secure FDA emergency use authorization. The firm later withdrew its request for emergency use authorization following an FDA inspection that found irregularities in protocols for trials conducted in the Dominican Republic.

CMS Sanctions

CMS sanctions prohibit Holmes from owning or operating a lab. The company has announced plans to appeal the CMS sanctions imposed on the company's Newark, Calif., lab following multiple quality control failures at the blood testing company.

CMS also revoked the company's Clinical Laboratory Improvement Amendments certificate, imposed monetary penalties, suspended the lab's approval to be reimbursed by Medicare and Medicaid and said it would oversee a directed correction plan for the beleaguered company (*IDDM*, July 18).

Following a CMS noncompliance determination in March, Theranos rescinded test results from the past two years for its Edison blood-testing diagnostics. The company issued corrected test results to doctors and patients and also voided results for some tests. In addition to filing a plan of correction, the company suspended further testing (*IDDM*, May 23). — Tamra Sami

Device Manufacturers Seek Faster Track For Antimicrobial Susceptibility Tests

The FDA, pharmaceutical companies and device manufacturers are looking to close the lag time between approvals of new antibiotics and 510(k) clearance of related antimicrobial susceptibility tests, which assist clinicians in determining which drug and dosage to select for treatment.

At an FDA workshop, industry representatives called for simultaneous approvals, an expedited regulatory pathway for the devices — similar to what has already been done with the Fast Track designation in drug development.

The GAIN Act, passed by Congress in 2014, includes prioritized review and marketing exclusivity for qualified antibiotics applications. But in the clinical setting, some physicians are reluctant to prescribe new antibiotic treatments without the results of a related test.

"New drugs are coming, and that's great," said Amy Mathers, an associate professor at the University of Virginia, at the workshop Sept. 29. "But it's really hard to use these drugs when you don't have susceptibility testing."

The FDA recently published draft guidance encouraging coordinated development of the drugs and tests, including early and frequent communication with both CDER and CDRH. The agency stressed that it is pursuing coordinated development, not co-development, and that the process would be different from the approval process for *in vitro* companion diagnostic tests (*IDDM,* Sept. 26).

The draft guidance can be read here: www.fdanews.com/09-29-16-FDADraftGuidanceASTs.pdf. — Conor Hale

Failure to Report Design Change Draws FDA Warning for Collagen Matrix

Failure to report a design change and to conduct proper design validation for its porcine xenograft particulate in syringe landed Collagen Matrix an FDA warning letter.

The Oakland, N.J.-based company manufactures collagen-based finished devices for use in oral/maxillofacial, neurosurgery and orthopedic-spine surgery.

The Sept. 30 warning letter said the instructions for use for the Zcore porcine xenograft syringe indicate that the porcine material in the syringe is hydrated with osseous coagulum, patient blood or sterile saline by pulling and pushing the syringe stoppers.

The firm conducted a functional assessment study, but no design validation study was conducted to ensure that the product conformed to defined user needs, the letter said.

Complaints indicated that the porcine material in the syringe was difficult to eject, and the firm later removed the product from distribution.

The agency said the product was adulterated because the company didn't have an approved premarket application or an investigational device exemption. The FDA also said the product was misbranded because the firm failed to notify the agency of modifications before marketing.

Specifically, the firm made significant design changes to the MatrixOss Granules (Zcore porcine xenograft particulate) since its initial 510(k) clearance in July 2014, and "such changes could significantly affect the safety and effectiveness of the device," the letter said.

The FDA explained that when the agency cleared the product, it was in a plastic jar surrounded by an outer blister package. But packaging the Zcore product in a syringe presents "biocompatibility and sterilization validation concerns," the FDA said, noting that another 510(k) is required to demonstrate that the polymers used in the syringe applicator don't give off leachables or extractables that could contaminate the biocompatibility of the materials.

In addition, sterilization validation via a 510(k) is required to demonstrate acceptable sterility assurance for the syringe in new packaging.

Read the warning letter here: www.fdanews.com/10-06-16-Collagenwarning.pdf.
— Tamra Sami

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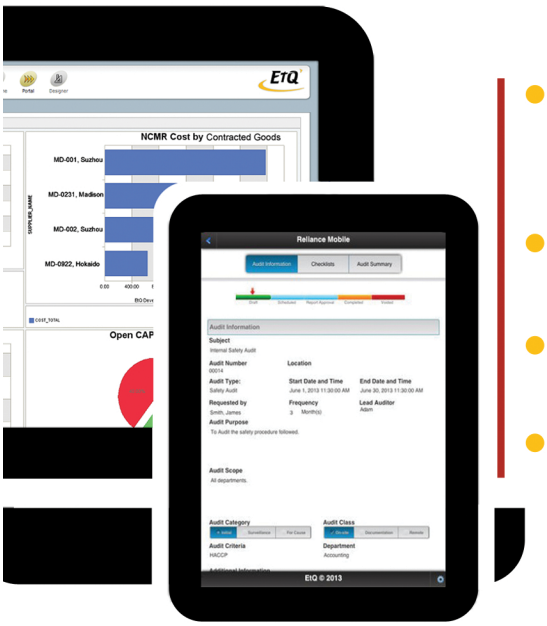

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FDA Releases Guidance for Blood Glucose Monitoring Systems

The Food and Drug Administration is scheduled to release final guidance describing studies and criteria that are recommended when submitting premarket notifications (510(k)s) for blood glucose monitoring systems (BGMSs) for prescription point-of-care use in professional healthcare settings.

The FDA also plans to release separate, similar guidance for self-monitoring blood glucose test systems (SMBGs) intended for over-the-counter home use.

According to a notice scheduled for publication in the Federal Register Oct. 10, historically the FDA has not recommended different types of information in 510(k)s for BGMSs used by healthcare professionals as compared to SMBGs for lay users. However, it has become clear that these different groups of users have different needs that can impact device design specifications, and thus separate guidance is warranted, the notice said.

For example, because BGMSs are intended for professional healthcare settings, they are more likely to be used on multiple patients, which could lead to the transmission of blood-borne pathogens if proper procedures are not followed.

In addition, the FDA said concerns have been raised about whether currently cleared BGMSs are effective in professional healthcare settings, because these devices have not been adequately evaluated in some of the populations in which they are being used.

For example, patients in professional healthcare settings "can be acutely ill and medically fragile and are more likely to present physiological and pathological factors that could interfere with glucose measurements relative to lay-users," the agency said. As a result, BGMS accuracy problems are more likely to result in serious harm to hospitalized patients.

To address these issues, the guidance describes certain design features and capacity for cleaning and disinfection to prevent the spread of blood-borne pathogens. It also describes studies that can demonstrate the performance of BGMS for devices intended to be used in diverse professional healthcare settings on subjects in various states of health.

The FDA said that while it recommends that the information described in the guidance be included in premarket submissions for BGMSs, submissions containing alternative information may be sufficient if a manufacturer can demonstrate substantial equivalence to a device that is already legally marketed.

Read the BGMS guidance here: www.fdanews.com/10-07-16-BloodGlucose.pdf.

Read the SGMS guidance here: www.fdanews.com/10-07-16-BloodGlucoseOTC.pdf.
— Jeff Kinney

Vascular Solutions Issues Class I Recall of Twin-Pass Catheters

Vascular Solutions has issued a nationwide recall of its Twin-Pass dual access catheters, which FDA has classified as a Class I recall – the most serious type of recall because use of the device could lead to serious adverse events or death.

The company said the product was recalled because there is a potential for excess manufacturing material to remain at the tip of the catheter or within the distal portion of the rapid exchange lumen. The excess material could separate and pose a potential risk of embolism. No injuries have been reported.

The recalled products are all unexpired lots of model numbers 5200, 5210 and 5230. They were manufactured from October 2014 to August 2016; 15,896 products were manufactured, and 5,784 were distributed in the U.S.

Healthcare facilities were advised to remove the products from their inventory and return them to Vascular Solutions. The condition that led to the recall may affect 9.2 of the recalled devices.

Read the recall notice here: www.fdanews.com/10-05-16-Recall.pdf.

BRIEFS

Positive Results for Somahlution's DuraGraft

Somahlution's DuraGraft vascular graft treatment significantly improves long-term outcomes in coronary artery bypass grafting (CABG) surgery, the company said at the European Association for Cardio-Thoracic Surgery (EACTS) annual meeting.

DuraGraft treatment for 2,436 patients who underwent CABG surgery has shown a statistically significant reduction in risks for non-fatal myocardial infarction, repeat revascularization, and a composite of major adverse cardiac events.

DuraGraft is currently not available in the U.S. market.

J&J Warns Insulin Pump Users of Cyber Risk

Johnson & Johnson is warning patients of a small risk that hackers could target its Animas OneTouch Ping insulin pump, after learning of a bug causing a potential cybersecurity risk.

Jay Racliffe, a "white hat" hacker for J&J, discovered that hackers could break into the unencrypted communications between the Animas OneTouch Ping's remote control and insulin pump, potentially forcing it to deliver unauthorized insulin doses.

St. Jude's Spinal Stimulation Device Approved

The FDA approved St. Jude Medical's BurstDR stimulation device, which is a physician-operated form of spinal cord stimulation (SCS) to provide relief for patients with chronic pain.

The device sends out intermittent "burst" pulses designed to mimic the body's natural nerve impulse patterns.

Chronic pain affects approximately 1.5 billion people worldwide.

Xeltis Implants Pediatric Heart Valves

Xeltis has successfully implanted three pediatric patients with the first heart valve enabling cardiovascular restoration.

The patients have been enrolled in the "Xplore-I" clinical study of Xeltis bioabsorbable pulmonary heart valve, which is studied on patients from 2 to 21 years of age.

The Xeltis technology is an investigational device and is not yet approved for sale.

Elixirgen Launches Neuron Differentiation Kit

Elixirgen has launched its Quick-Muscle 1.0 kit, which develops skeletal muscle cells from human stem cells in just a few days.

The device kit promotes rapid and efficient production of skeletal muscle cells from human embryonic stem cells and induced pluripotent stem cells in only four to five days.

Quick-Muscle 1.0 is now available for purchase in the U.S.

Edwards Hypotension Indicator Gets CE Mark

Edwards Lifesciences received the EU CE Mark for its Acumen Hypotension Probability Indicator (HPI) that alerts clinicians to potential hypotension in surgical and critical care patients before it occurs.

HPI is compatible with Edwards' minimally invasive, hemodynamic monitoring solutions. A targeted commercial release is planned for the device in Europe in 2016 and a full launch in 2017. It is not approved for commercial use in the U.S.

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2016 SUMMIT HIGHLIGHTS

4 panels featuring current and former FDA officials, including:

- **New for 2016** - FDA Inspections – A New, Modern Record Review Technique
- **New for 2016** - After the Election: A Look Ahead to What a New Administration Could Bring and the Impact on the FDA
- Effective Management of Front and Back Inspection Rooms – Secrets You've Never Heard and Answers to Questions You've Always Wanted to Ask
- A Day in the Life of an FDA Field Investigator – How Inspectors Prepare and Approach Assigned Inspections

How the FDA's Realignment Program Impacts You

The Latest on the FDA's Re-organization of the Inspectional Corps and How Could it Impact Your Daily Operations and Your Upcoming Inspection

Measuring the Real Business Impact of Quality Metrics

Plus twin tracks for drug/biologics and device manufacturers and 2 pre-conference workshops, focusing on drugs and devices.

FEATURED EXPERT SPEAKERS:

MARC-HENRI WINTER, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA (invited)

ARMANDO ZAMORA, Deputy Director, Office of Enforcement and Import Operations, Office of Global Regulatory Operations and Policy, ORA, FDA (invited)

DAVID CHESNEY, Principal and General Manager, DL Chesney Consulting, LLC

BRYAN J. COLEMAN, Senior Director Pharmaceutical & device Consulting Services, EAS Consulting Group

TERESA GORECKI, VP Global Business Quality, Janssen Pharmaceuticals

STEVEN GROSSMAN, President of HPS Group, LLC, former Deputy Assistant Secretary for Health, HHS, former Health Staff Director, Senate HELP Committee

KAY HOLCOMBE, Senior Vice President, Science Policy, Bio

DAN O'LEARY, President, Ombu Enterprises

JOHN TAYLOR, Principal, Compliance and Regulatory Affairs, Greenleaf Health LLC

KARL VAHEY, Senior Director , Manufacturing Quality, Europe and Asia, Medtronic

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Pre-conference Workshops Agenda

WEDNESDAY, NOVEMBER 2

DRUGS & BIOLOGICS TRACK

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

FDA warning letters begin with a summary of the failed inspection, and then quickly dismiss a firm's effort to respond. In a very public way, FDA categorizes one company after another as "inadequate," "insufficient," "lacking" and worse.

Handling an inspection successfully requires a strategy designed to get the FDA investigator in and out as quickly as possible. The longer an FDA investigator is on site, the worse your chances are of avoiding a FDA 483.

And when the 483 arrives, do you know how to respond in less than 15 days to avoid a warning letter?

A defensible response can be hard to assemble – and get through internal review – with enough time to beat the enforcement clock at FDA.

This workshop gives you proven, practical techniques for fast, flexible and flawless inspection handling and responses that exceed FDA expectations and support your side. 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 go from 483 observation to FDA's coveted untitled letter – and avoid the warning letter publicity.

Attendees Will Learn:

- Critical inspection preparation techniques to take – even if you get surprised by FDA
- Hidden tactics FDA investigators use to test your controls
- How to speed the inspection to minimize the risk of 483 findings
- Key elements of a realistic regulatory inspection handling SOPs
- How to write an inspection response designed to reduce warning letter likelihood
- Red flags FDA looks for in your inspection response

Attendees Will Receive:

- A sample 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

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

ISO 13485:2016 – Understand the Concepts of Risk and Their Applications

The new QMS standard, published in March, alerts manufacturers to the presence of risk in almost all operations—from design control to supplier management to software validation and more. While it does not specifically address the concept of risk management (you'll find that in ISO 14971:2007), ISO 13485:2016 makes it clear that manufacturers must be aware of the opportunity for risk in all they do.

This workshop examines the concept of risk as presented in the new standard and explains how to apply it in the quality management systems. Through examples that illustrate ISO 13485:2016's requirements, interactive exercises that help solidify understanding, and a unique set of checklists that cover all the QMS bases, attendees will learn:

- How the QMS standard integrates with the risk management standard in ISO 14971:2007
- How the implementation timeline may differ from country to country
- How inclusion in MDSAP could impact inspections of U.S. manufacturers
- How the European version differs from the international version

Quality systems expert Dan O'Leary explains ISO 13485:2016's concept of risk in clear terms that will prepare you for the changes ahead.

Dan O'Leary, President, Ombu Enterprises

What Past Attendees Have Said About the FDA Inspections Summit:

"This Summit is in the top 3 meetings I have attended. Looking forward to next year."

"I loved the ease to interact with FDA investigators and others involved in the conference."

"I really enjoyed having the opportunity to ask FDA investigators questions in a long open session."

Day 1 Agenda

THURSDAY, NOVEMBER 3

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

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson John Avellanet, Managing Director & Principal, Cerulean Associates LLC

8:45 a.m. – 9:30 a.m.

FDA Realignment Program Is In Effect: How That Impacts You

Under its recent organizational changes, FDA is developing specific action plans to align its centers and the Office of Regulatory Affairs with new strategic goals and increased demands. The plans include critical actions to fulfill the agency's mandate in training; compliance and enforcement; imports; and information technology, all of which will affect all areas of medical products inspection and poses these vexing questions:

- What impact will the transition to a commodity-based and vertically integrated regulatory program have on inspections?
- What will be the major changes in MDSAP?
- How will new training and certification requirement impact medical product inspections?

9:30 a.m. – 11:00 a.m.

FDA Inspections – A New, Modern Record Review Technique: A Panel Discussion

It is becoming more common for investigators to review your documents and data maintained in your QMS in real time. An investigator may request electronic copies of your records on a memory stick. Or request the ability to browse through your complaint management system to review documentation. Are you prepared?

This panel will discuss:

- FDAs new ability to analyze your data – by sorting it and spotting trends which they can then link to potential issues in other quality management systems.
- The lack of SME preparation – as you don't know what they will look at you can't rehearse each document and be ready when questioned.
- Increased document challenges – some documents don't stand on their own without significant explanation.

(cont.)

- The importance of writing plain, simple English – all documents need to convey what you need without interpretation. Writing clearly and consistently has never been more important.

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

11:30 a.m. – 12:15 p.m.

Understanding OPQ's New Inspection and Reporting Plan and Organizational Structure

This session will discuss how CDER's new "super" Office of Pharmaceutical Quality plans to divvy up inspections among its three offices, and how it will incorporate pre-approval inspections into the OPQ team review to standardize quality assessments.

Attendees will learn about OPQ's new inspection protocol that will focus on expert investigator-developed questions and assessment practices and how mobile technology will be incorporated to support investigators during inspections

12:15 p.m. – 1:00 p.m.

Quality-Driven Data Integrity Approach In the EU and US Inspections

Data integrity requirements have been strongly enforced in recent years by almost every regulated agency in the pharmaceutical environment: the expectations have been clarified in a number of guidances issued by MHRA, WHO and most recently by the FDA. Therefore, the requirements for data integrity are now considered a fundamental expectation and strictly connected to the relevant predicate rules.

This presentation will provide real life case studies and examples you can use to base your control measures upon the potential impact of data on product quality and patient safety.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

How to Deal with Difficult Inspections

Co-Chair Steve Niedelman 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.

3:30 p.m. – 3:50 p.m. | BREAK

MEDICAL DEVICES TRACK

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

11:30 a.m. – 12:15 p.m.

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

This is not your father's CDRH. There's more emphasis on global activities and a greater expectation of transparency and privacy. 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 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

12:15 p.m. – 1:00 p.m.

Medical Device Single Audit Program Pilot (MDSAP) In Full Swing

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the U.S., Canada, Australia, Brazil, the EU and Japan.

So far, one audit has been conducted and others are in the pipeline, and responses from participants have been positive.

One big advantage to the MDSAP is that because audits aren't performed by the U.S. government, their results aren't public record — and there's no Form 483 that can be requested via the Freedom of Information Act.

Attendees will hear first-hand 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.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask: A Panel Discussion

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms
- Handling data requests, particularly for electronic records — best practices from inspectional veterans

(cont.)

- Being a SME in your job doesn't make you an inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

A Day in the Life of FDA's Field Investigators — Current Field Investigators Explain What They Look For and Why: A Panel Discussion

Ever wonder what an investigator is thinking when she receives the next inspection assignment? Investigators typically create inspection plans based on a company's previous Form 483s, warning letters, responses to warning letters, consumer complaints and recalls. But they also study a company's website, including literature, products manufactured and recent press releases.

This presentation will give you a glimpse into the inner workings of an investigator's mindset before, during and after your inspections.

Attendees will learn:

- What does an investigator's prep package contain?
- What research – both internal and external – do they use to prepare themselves for your company, plant and products?
- What do they look for once inside your plant?
- How they 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

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

8:00 a.m. – 8:30 a.m. | BREAKFAST

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson

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 2017, and how the office approaches the enforcement process. This session will educate attendees on how they can more proactively prepare for FDA investigators before they arrive.

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

9:30 a.m. – 10:15 a.m.

The Regulatory Intelligence Platform

Being prepared for inspections means that you understand both the internal and external data that affect your products. Now more than ever there is an expectation that companies are analyzing and acting on this data

In this session, you'll learn:

- What is regulatory intelligence and how does it affect your business
- How to leverage regulatory intelligence as integral part of inspection readiness
- What data is available through open systems and what you should be looking at
- What should be included in your regulatory intelligence platform

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

After the Election: A Look Ahead To What a New Administration Could Bring and the Impact on the FDA

In this election year, if almost anyone tells you that they know who the next president is going to be or exactly what's going to happen at FDA in 2017 and beyond is probably just whistling in the wind. But these panelists bring incredible inside knowledge and decades of experience in the nitty-gritty of Washington politics to provide an educated analysis of FDA operations. Here's what you'll hear discussed at this lively, interactive session about the future of FDA:

- Will there be increased efforts at global regulatory harmonization or more country-by-country compliance
- Will there be increased agency enforcement or more reliance on voluntary industry compliance
- Will there be increased legislation or rollbacks in regulation

12:00 p.m. | CONFERENCE 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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The FDA Inspections Summit — now in its 11th year — has fast become the "go-to" event for regulatory, compliance and quality assurance professionals and the one place to discover the tools and techniques to improve your inspectional readiness.

Join us for this rare opportunity to interact with top officials from CDER, CDRH, the Office of Regulatory Affairs and other outstanding industry leaders to discuss debate and uncover the latest priorities, expectations and best practices.

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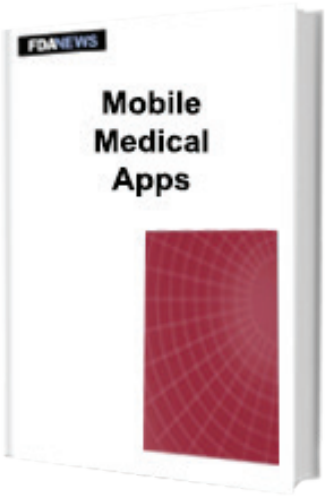
- Legal and Compliance Officers
- Consultants/Service Providers



Mobile Medical Apps: *Keeping Up with the FDA's Evolving Requirements*

Just because an app is running on an unregulated phone or tablet doesn't mean that the app itself isn't a medical device in the FDA's eyes.

Where does the agency draw the line between unregulated products and those it must approve?

The final guidance for *Mobile Medical Applications* helps clarify the FDA's position on regulating mobile apps, but leaves several areas open to interpretation.

You need to know:

- How the FDA categorizes mobile apps and decides how — or whether — to regulate them as medical devices.
- How the FDA evaluates an app's "intended use."
- How to interpret the FDA's promise of "enforcement discretion" for certain types of apps.
- Who can be considered a mobile medical app developer and what regulations affect them.

This management report interprets the FDA's evolving stance on mobile apps and explains how the FDA sorts mobile apps into three categories:

1. **Administrative health information technology** (e.g, billing, claims processing, general communication and scheduling): This is not a medical device and not regulated by the agency.
2. **Health management information technology** (e.g., medication management, data capture, electronic access to clinical results, provider order entry): This is under FDA jurisdiction but generally so low risk that the agency can exercise enforcement discretion and not apply regulations.
3. **Medical device health information technology** (e.g., computer-aided detection and diagnosis, robotic surgical planning, remote display of bedside alarms, radiation treatment planning): This is actively regulated under Class I, Class II and Class III medical device rules.

Mobile Medical Apps explains what the FDA means by enforcement discretion and how it considers an app's intended use in category assignment.