INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

FDA Finds No Evidence of Trial Misconduct in Bayer Essure Study

An FDA investigation into complaints that Bayer manipulated data in its clinical trials of the controversial Essure contraceptive implant device has found no evidence to back up those claims.

The investigation was prompted by a trade complaint in a citizen petition that alleged the company engaged in clinical trial misconduct by altering clinical records to cast the device in a more positive light.

"Although modifications to the case report forms were identified, our analysts did not find evidence the sponsor purposefully modified patient responses to reflect more favorable data for Essure," the agency said in its report released Sept. 6.

The report chronicles the saga of Bayer's Essure device for which the agency received 9,900 medical device reports. There were 32 deaths reported but six of them were incorrectly coded, the

(See **Essure**, *Page 2)*

FDA Backpedals on UDI Compliance Deadlines for Some Class II Devices

Device manufacturers of certain Class II devices will get two more years to comply with the FDA's unique device identifier rule that was scheduled to become effective Sept. 24.

In a Sept. 6 letter to labelers, the agency announced that it would push back UDI compliance dates to Sept. 24, 2018 for repackaged single-use devices, device constituents of certain combination products, and convenience kits consisting of two or more different devices packaged together that are not individually labeled.

The letter explained that the agency had released draft guidance in January on UDI implementation for collections of two or more different devices packaged together. But the agency needed more time to finalize its interpretation of what constitutes a "convenience kit" (*IDDM*, Jan. 8).

(See **UDI**, *Page 4)*

Essure, *from Page 1*

agency said, and 18 reported deaths related to incidences of pregnancy loss.

The issue first came to light when the controversial implant received negative publicity last year when women reported numerous adverse events after implantation with Essure, such as bleeding, autoimmune diseases, painful sexual intercourse, unplanned pregnancies, weight gain, tooth and hair loss; excruciating pelvic and abdominal pain.

A search of the FDA's Manufacturer and User Facility Device Experience from Nov. 4, 2002 to Dec. 31, 2015, shows 6,989 reports of pain/abdominal pain; 3,210 reports of menstrual irregularities; 2,990 reports of headache; 2,159 reports of fatigue; and 2,088 reports of weight fluctuations.

Patient Registry Recommended

During a September 2015 meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, several women testified about pain and other adverse events they had experienced (*IDDM*, Sept. 25, 2015). The panel recommended that a patient registry be created to document these events.

At the time, the FDA faced harsh criticism from lawmakers and other stakeholders for not taking stronger action such as pulling the device from the market.

The agency ordered Bayer to develop and conduct a postmarket study to help the agency better understand the risks associated with the Essure device versus other birth control options, such as laparoscopic tubal ligation. Specifically, the agency asked for data on the rates of unplanned pregnancy, pelvic pain and surgery to remove the device.

The FDA also issued draft guidance with new labeling recommendations, including a boxed warning label and a checklist for doctors to discuss potential risks of implanted permanent birth control devices with patients.

Those actions have failed to appease Rep. Michael Fitzpatrick (R-Pa.), one of several members of Congress who called on the FDA to remove Essure from the market. He vowed to continue his fight to revoke approval of the product.

"It's unbelievable that it took the FDA since September to make just two recommendations with no enforcement measures and ask the manufacturer to perform another study while leaving Essure on the market," he said (*IDDM*, March 4).

Postmarketing Studies

Two earlier post-approval studies were conducted as part of the 2002 approval, but the agency said it found overall results did not demonstrate any new safety problems or an increased incidence of problems since the device's approval. The agency noted in its report that the post-approval studies only evaluated patients for five years post-implantation.

In its notice, the FDA said that Bayer submitted a postmarket surveillance plan in March, and the agency approved an updated plan on Sept. 2. The postmarketing study will study two cohorts of subjects who chose to undergo either hysteroscopic sterilization (Essure) or laparoscopic tubal sterilization. The final results will come out in September 2023, although periodic reports will be submitted, with the first readout in March 2017.

"The FDA believes that results collected from the approved study plan will help the agency better understand complications associated with the Essure device, as well as the underlying reasons inhibiting the completion of the three steps of the Essure System method (device insertion/placement, use of alternative contraception for three months, and a confirmation of proper location/occlusion)," the report said.

Read the FDA report here: www.fdanews.com/09-07-16-Essure.pdf. — Tamra Sami

China's Changing Device Regulations: What You Need to Know

One of the most important considerations device manufacturers will make before entering China is whether the device will be manufactured locally or not.

Deciding to manufacture abroad — either at a facility or a contract manufacturer — will require having a registration agent to be a liaison with the China Food and Drug Administration.

That agent will help with registration, regulatory compliance and postmarketing surveillance activities, said John Balzano, special counsel for law firm Covington and Burling, during a recent FDAnews webinar. Most companies will also need a separate regulatory consultant as well.

Pursuing Innovation

Over the last eight or so years China has been reforming its device regulations. In the last few years, the country has been actively pursuing innovation, and new regulations reflect that stance. In its 13th five-year plan, there are multiple national-level initiatives to improve scientific innovation, research and development.

To that end, the government is encouraging companies to bring their manufacturing operations to China, mostly because it will help its own domestic industry to evolve.

"Overall, they're going to want to make sure that they have a regulatory structure in place that facilitates the most innovative applications and the applications for devices that are meeting what China considers to be its unmet medical needs, Balzano said.

"If you're domestically manufacturing in China, you're going to have a product license and then you're going to have a manufacturing license that goes along with the facility." Both licenses are subject to GMP requirements.

An imported device has a foreign license holder, and the manufacturing occurs overseas, or part of it occurs overseas, and what's coming into China is a finished device. For imported devices, companies will need to show that their products are approved abroad, and that they're operating as device manufacturers abroad.

There are also restrictions on contract manufacturing devices in China, and the contract manufacturing system is fairly complex.

However, the government grants more leeway for innovative devices and is permitting innovators to hold a license and then contract out the manufacturing.

Devices that are accepted under the innovative device pathway gain a number of distinct advantages. To be eligible for the pathway, the intellectual property needs to be held in China, and the device needs to represent an improvement over existing technology and be clinically significant.

Devices that enter the innovative pathway will also benefit from more communications with the Center for Device Evaluation, Balzano said.

Another big advantage is that the company won't necessarily have to have its own manufacturing license in China. "That is a very significant advantage, because it saves you an additional process," he said.

Inspections A Big Deal

"Inspections are a big deal, and they have become an even bigger deal since 2014 when CFDA revised its GMP regulations," Belzano said, explaining that there are licensure inspections, compliance inspections, surprise inspections and self-inspections.

GMPs for medical devices were initially issued in 2009, and they were experimental. Now, however, GMPs are in full force. If you're applying for a manufacturing license you're going to have to undergo an inspection before you can have the license.

(See **China***, Page 6)*

UDI, *from Page 1*

As a result, the FDA pushed back the deadlines for UDI labeling and Global Unique Device Identification Database (GUDID) submission requirements until Sept. 24, 2018, for convenience kits of two or more different Class II (or Class II and Class I) devices packaged together and not labeled individually.

The same deadline will apply to individual single-use devices that are not individually labeled, and for device constituents of combination products. The extension does not apply to implantable devices, the letter said.

The final rule establishing the UDI system was published in 2013, and is being phased in over seven years based on device classification. The FDA issued draft guidance in July that clarified agency expectations for UDIs, which must appear in two forms on device labels and packages: an easily readable plain-text form and an automatic identification and data capture technology form (*IDDM*, July 29).

The rule became effective for Class III devices in 2014, and for implantable life- supporting devices in 2015. The compliance date for Class 1 devices is in 2018 (*IDDM*, Jan. 29).

The agency also issued final guidance Aug. 30 that clarified it would not enforce the policy that required labelers to remove National Health Related Item Code (NHRIC) and National Drug Code (NDC) numbers from devices until 2021. The agency said stakeholders had expressed concern that pharmacies and other entities in the supply chain were not prepared for the transition (*IDDM*, Sept. 3).

Back in March, the FDA began urging labelers not to be complacent in meeting the target dates for submitting necessary information into the GUDID database, which requires data on the device label, packaging, lot, serial number and expiration date (*IDDM*, March 1).

Read the FDA letter to labelers here: www.fdanews.com/09-07-16-UDIletter.pdf. — Tamra Sami

Failure to File Medical Device Reports Prompts 483 for The Metrix Company

Failure to submit medical device reports for its total parenteral nutrition bags landed the Metrix Company an eight-item Form 483 following a May 2016 inspection of its Dubuque, Iowa facility.

The firm manufactures on contract parenteral nutrition bags, transfusion filters and sets, IV bags and blood bags.

The company's corrective action reports document two separate occasions that found that the compounding bags used for parenteral nutrition would not meet pumping accuracy with the high-speed compounder, the 483 says. The firm contacted a hospital customer and instructed them to scrap the bags, but it did not file a medical device report with the FDA nor did it report that a correction or removal was needed to reduce a health risk.

The Form 483 cites the firm for not establishing design review procedures. Specifically, an engineering validation test conducted in August 2014 noted that the new high-speed compounder failed the compounding accuracy specification when using certain compounding bags. A few months later the compounding unit was released to a customer for commercial use even though the beta testing failed.

In another example, the same compounding machine was tested in May 2015, and it also failed to meet compounding accuracy requirements. One month before that testing, three batches of bags were sold, but there was no documentation that these products passed the accuracy validation test before being released to the market.

The form also cited the firm for process validation failures and for not conducting a complete risk analysis.

The FDA said the test method for validating the compounding unit had not been validated, and there was no SOP documenting the test method. Moreover, there was no documentation showing that the test method was an accurate validation for the fluids that the hospital would be compounding.

The firm was also cited for not analyzing service reports, not establishing procedures for corrective and preventive actions and not establishing procedures to prevent contamination. The Metrix Company did not respond to a request for comment.

Read the Form 483 here: www.fdanews.com/09-07-16-Metrix483.pdf. — Tamra Sami

MDIC Hosts Open Forum On Case for Quality

Device manufacturers will have an opportunity to sit down with the FDA to hear its perspective on the Quality Metrics Initiative during the Case for Quality Public Forum Oct. 26.

The Medical Device Innovation Consortium working groups will present information on the work they have done so far and what the future plans are.

"We're trying to foster a new culture of quality by identifying, developing, disseminating and embracing evidence-based critical-to quality practices throughout the entire product lifecycle," Dwight Abouhalkah, program manager for the Case for Quality, told *IDDM*.

The metrics group unveiled findings from its pilot study in June, and the group has been engaged with sharing information with the FDA's Center for Devices and Radiological Health. The FDA plans to unveil its own quality metrics initiative, and devicemakers will have an opportunity to hear more about those plans at the forum (*IDDM*, Aug. 12).

By engaging in these collaborative forums, device manufacturers are able to form better relationships with the FDA, and "we're finding that we are able to influence the agency more than we have been able to in the past."

For more information, visit: www.fdanews.com/09-07-16-MDICforum.pdf. — Tamra Sami

New York Attorney General Questions Mylan EpiPen School Contracts

The pressure keeps mounting on Mylan for its EpiPen pricing practices, and now the New York attorney general's office is investigating whether Mylan engaged in anticompetitive practices when entering contracts to sell its allergy therapy EpiPen to schools.

New York Attorney General Eric Schneiderman contends the company may have included anticompetitive terms in sales contracts, after a preliminary investigation of EpiPen sales indicated that several local school systems may have reached such agreements.

Those initial findings prompted a complete investigation into the company's contracts with schools, the attorney general said Sept. 5.

Under Mylan's EpiPen4Schools program, the company has dispensed more than 700,000 EpiPen injectors to over 65,000 schools.

Mylan contests the attorney general's allegations, saying its program satisfies "all applicable laws and regulations." Furthermore, the company said its contracts do not require purchases and no longer impose limits on schools purchasing discounted EpiPens.

The investigation follows increased scrutiny on the price of Mylan's EpiPen, which swelled about 400 percent in less than a decade (*IDDM*, Sept. 3).

Despite several efforts to stave off criticism, Mylan continues to face pressure to explain the rise from $100 to $608. — José Vasquez

China, *from Page 3*

There are announced compliance inspections that the provinces conduct, and there's a tiered system of scrutiny of manufacturing enterprises. Unannounced inspections are basically for-cause inspections.

And then there are self-inspections, which are forced self-audits where companies take stock of their compliance over the last few years and submit self-assessments to the local authorities, which are then evaluated by CFDA.

How often companies get inspected is determined by their compliance record.

"Quite often the government is clocking what it sometimes refers to as your credit score, and it's basing your score on noncompliances, but also the risk that you pose potentially because of the complexity of your product.

"Some devices are subject to enhanced supervision because they've had safety issues and sometimes also because they're just more complex products."

A new area is foreign inspections, and CFDA has not issued any guidance on how it plans to conduct foreign inspections.

CFDA has always had the power to conduct surprise inspections, and the agency issued comprehensive regulations on these. Suspicions of GMP violations or a significant record of noncompliance can trigger a surprise inspection. — Tamra Sami

510(k) Guidance Details Recognition Process for Third-Party Reviewers

The FDA issued draft guidance on the 510(k) Third-Party Review Program Friday, focusing on accreditation of reviewers and providing a far greater level of detail, at 34 pages, than the eight-page version issued in 2013.

The guidance is intended to provide a comprehensive look at the agency's current thinking on third-party reviews of devices in the 510(k) program, encouraging global harmonization by incorporating elements of the International Medical Device Regulators Forum's single-audit program. It cites four documents from the forum's Medical Device Single Audit Program as relevant to the draft current guidance. All four focus on assessment and recognition of auditing organizations.

The forum is developing a fifth document, "Competency, Training, and Conduct Requirements for Regulatory Reviewers," that will provide additional detail on the accreditation process, the FDA said.

An initial step in the harmonization process is a set of standard definitions — for example, outlining the difference between a "product specialist" and a "technical expert."

The agency notes that companies can always send 510(k) submitters directly to the FDA, but only those that use accredited third-party reviewers are eligible for FDA review within 30 days.

The guidance outlines the steps of the 510(k) review process:

- Determine device eligibility for third-party review;
- Obtain relevant FDA guidance and information;
- Consult with the relevant FDA branch chief (as needed);
- Ensure a submission is administratively complete;
- Select the appropriate product specialist and technical expert to conduct the substantive review;
- Conduct the substantive review;
- Identify the deficiencies in the submission;
- Document the review;
- Organize and document the submission;
- Submit additional information upon the FDA's request; and
- Dispute resolution.

Read the 510(k) guidance document here: www.fdanews.com/09-09-16-thirdpartyreview.pdf.

BRIEFS

Ovarian Cancer Screen Faulted

The FDA is alerting women about the risks associated with diagnostic tests for ovarian cancer screening tests.

The agency said it was especially concerned that women who show no symptoms might delay effective preventive treatments but could still be at risk for ovarian cancer.

"Despite extensive research and published studies, there are currently no screening tests for ovarian cancer that are sensitive enough to reliably screen for ovarian cancer without a high number of inaccurate results," the Sept. 7 safety notice said. Despite the lack of reliable tests, numerous companies market tests that claim to screen for and detect ovarian cancer.

Read the safety notice here: www.fdanews.com/09-08-16-FDAsafetynotice.pdf.

FDA Elevates Cook Recall to Class I

The FDA has elevated Cook Medical's global recall of 8,750 units of its Roadrunner UniGlide hydrophilic wire guides as a Class I recall, the most serious type of recall.

Cook Medical announced the recall in August due to the possibility of glass particles in the coating of the wire guide units.

(See **Briefs**, *Page 8)*

Briefs, *from Page 7*

Cook requested customers and distributors to quarantine and discontinue use of all recalled units. For a full list of affected products and lot numbers, read the notice here: www.fdanews.com/09-07-16-Cookrecall.pdf.

Novo Nordisk Recalls GlucaGen HypoKits

The UK's Medicines and Healthcare products Regulatory Agency issued a recall notice, warning that certain batches of Novo Nordisk's GlucaGen HypoKits may be defective.

Novo Nordisk discovered a small percentage (0.006%) of needles that detached from the syringe in the GlucaGen HypoKit, making them unusable.

The affected lots were distributed between February and June 2016.

Similarly, Ireland's Health Products Regulatory Authority (HPRA) determined that two batches of GlucaGen Hypokit and two batches of PCO Manufacturing GlucaGen Hypokit are being recalled in Ireland, which represents a total of 8,064 units.

Read the recall notice here: www.fdanews.com/09-07-16-MHRArecall.pdf.

Braun Gets FDA Nod for Xevonta Dialyzer

Braun Medical won FDA 510(k) clearance for its xevonta dialyzer, and it's launching the next-generation filter in the U.S.

The new dialyzer features a filtration membrane designed to filter out smaller toxin molecules in patients' blood while maintaining larger blood components.

Braun expects to offer the xevonta filter in September.

FDA Gives Green Light to Medtronic's Enlite

The FDA approved Medtronic's Enlite sensor for the iPro2 professional continuous glucose monitor. The device is a disposable sensor designed to be worn for six days and is 69 percent smaller than its previous sensor.

The iPro2 professional system is designed to track glucose levels every five minutes, continuously, for as long as six days to help doctors estimate the effectiveness of nutrition, medication and exercise programs. The iPro2 system gained FDA clearance back in November 2011.

FDA Grants EUA for Viracor-IBT Zika Dx

FDA issued an emergency use authorization to Viracor-IBT Laboratories' Zika Virus Real-time RT-PCR test.

The in vitro diagnostic detects RNA from Zika virus in human serum, plasma or urine for patients showing clinical symptoms associated with the Zika virus.

The authorization is effective as of July 19. Read the EUA here: www.fdanews.com/09-07-16-EUA.pdf.

OrthoSera Receives CE Mark for hypACT

Austria-based orthobiologics company OrthoSera has received EU market authorization for its autologous hypACT injection device.

The company has developed a hyperacute serum technology to treat osteoarthritis and other degenerative diseases and is administered through the hypACT device.

The device isolates a specific serum derivative from the patient in a closed system, which is then applied during a same-day-procedure.

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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

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

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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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We know that not everyone can travel to the 11th Annual FDA Inspections Summit, so we have decided to stream it live! It's a great way to see sessions as they happen. Registration is quick and accessing the live sessions is as simple as clicking your mouse. BONUS: Includes six month access to archived session recordings after the conference.

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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.

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