INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Multi-Part Device Labeling, Other Issues Dog UDI Rule

The FDA's unique device identification (UDI) rule might improve device tracking but is plagued with unresolved issues such as how to label devices with multiple components.

"I think at 20,000 feet, the rule is very good in terms of providing structure to a large extent, but also some flexibility in implementation," Jay Crowley, vice president of UDI Services and Solutions at USDM Life Sciences, said. But he added that several interpretation and implantation problems are giving manufacturers headaches.

For example, he said there has been some confusion about who is actually responsible for UDI – i.e., which entity is the labeler. That issue "causes a lot of angst" because the proper way to identify labelers has not transferred from pharmaceutical regulations as expected, he said.

Crowley also said it remains unclear which parts of accessory components such as infusion pumps, batteries, and power cords

(See **UDI***, Page 2)*

IMDRF Issues New System For Adverse Event Reporting

The International Medical Device Regulators Form has proposed a new system for reporting adverse events related to medical devices that will provide consistency for and reduce the burden on manufacturers.

The new system will include four lists of terms and numerical codes, only one of which (Annex A) has been released. Annex A contains 366 terms and codes for describing malfunctions and other problems with medical devices that have occurred in pre-or post-market contexts such as clinical studies and evaluations.

Annexes B, C, and D will be released shortly and will contain terms and codes for cause investigations, patient problems, and device components respectively.

(See **IMDRF***, Page 4)*

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must be labeled with a UDI. A similar problem arises with non-sterile implants, which can have hundreds of parts, many of them quite small with odd geometries.

In addition, regulation of Class I devices under the UDI rule is "problematic" because it is not obvious whether a given device constitutes a regulated medical product. "Things just haven't kept up as products have evolved, so it's going to be difficult for people to understand whether something is or is not a regulated medical device, and whether there's an adequate product code that describes the device," he said.

Finally, Crowley said that identifying combination products is "very confusing because they do not have specific regulatory authority."

"There has to be a way of determining what a combination product primarily is," he said. "There hasn't been the level of rigor that maybe there should have been as these products have evolved over many years."

Solution in Search of a Problem?

Jennifer Newberger, a director with the law firm Hyman, Phelps & McNamara, said the UDI rule might not be as necessary as the FDA claims.

"Part of me wonders if this is a solution in search of a real problem," she said. "Whether this actually will improve tracking remains to be seen."

Newberger agreed with Crowley that deciding which parts of multi-component products to label is one of the largest compliance hurdles manufacturers will face.

"I think the biggest challenge has been the number of different UDIs that will be needed for what companies have considered a single product," including different models and versions of a given device, she said. "It's not just a matter of, 'Here's the device and here's the identifier that goes with that device.' It's far more complex, and I don't think the FDA fully considered how the rule would work with the variety of devices that exist."

Newberger said agency has indicated that a component of a device does not need its own UDI, but that an accessory that can be sold separately does. But distinguishing between components and accessories is no easy task.

"There's no information in the rule about how to do that," she said. "Manufacturers have to find out by communicating with the help desk on an ad hoc basis, which can lead to more confusion."

Level Playing Field

To address this problem, she said it would help for the FDA to collate information given by the help desk regarding the UDI rule and other issues "so that everyone is on a level playing field."

Some companies receive different answers to a given question than others, "and the extent to which the answers are helpful is sometimes questionable," she said. "It often comes down to interpretation."

Dan O'Leary, president of the consulting group Ombu Enterprises, noted several other potential concerns for manufacturers as they attempt to comply with the UDI rule.

First, he said they will need to update the FDA's Global Unique Device Identification Database (GUDID) database after they discontinue a product. "I suspect that companies aren't going to remember to do that," he said.

Second, O'Leary noted that the UDI rule's record retention requirements are different from those in other device regulations. For example, under the UDI rule, all label information has to be retained for three years after the date the manufacturer stops shipping a given model.

Third, if a company changes a device's design, it needs to determine whether the change

(See **UDI**, *Page 8)*

Greater Clarity on Coverage Urged For Companion Diagnostics Guidance

Draft guidance on companion diagnostics development needs more clarity on what products it covers and greater detail on clinical trial criteria, trade groups said in comments on the draft.

Companion diagnostics are on the rise, the Pharmaceutical Research and Manufacturers of America (PhRMA) observed in its comments to the FDA. Nearly 30 drugs and biologics with an IVD companion diagnostic have been approved as of June of this year, with many more under development by biopharmaceutical companies, wrote Kristin Dolinski, PhRMA's director for science and regulatory advocacy.

"Therefore, it is critical that both biopharmaceutical and diagnostic sponsors have a clear and predictable pathway for the development and regulatory review of such products," she indicated.

Geared toward makers of therapeutic drugs and in vitro diagnostics (IVDs) that "codevelop" drugs and accompanying IVDs, the guidance outlines the regulations that govern the development of these products. It also describes what product developers should consider in obtaining marketing authorization and initiating clinical trials, and the administrative issues involved with submitting a codeveloped IVD/therapeutic product.

Detail on Trial Criteria

Several commenters want more information from the FDA on clinical trials, including what criteria should be set for investigational IVD companion diagnostics that are studied in trials of therapeutic drugs.

To assist product sponsors, PhRMA suggested that the FDA in an appendix to its guidance provide instructive examples on setting risk determination criteria. "Since risk determination is evaluated in the context of a specific therapeutic clinical trial design, risk evaluation for an investigational IVD can be somewhat subjective," Dolinski explained. The appendix could address topics such as using archived versus fresh biopsy material and the types of "invasive" biopsy sampling procedures that pose significant risk, the comment paper suggested.

Although it applauded the FDA's efforts to allow use of clinical trial assays (CTAs) in early phase clinical trials, executives of the American Association for Cancer Research asked that the FDA "provide further guidance on what standards such CTAs will have to meet for use in allocating patients to therapy in clinical trials." This is to ensure that the assays used to help manage trial subjects are accurate, they emphasized.

AdvaMed Seeks Clarity on Scope

AdvaMedDx, a division of the Advanced Medical Technology Association (AdvaMed) whose members produce IVD products, asked how the guidance would address follow-on companion diagnostics—those not associated with the original trial. It also suggested that the FDA offer examples of products the guidance would cover.

"In that vein, we suggest the scope of the guidance be more clearly outlined as not to create indiscriminate application to other diagnostic tests. This will avoid confusion among sponsors not otherwise meeting the definition under the guidance," wrote Khatereh Calleja, AdvaMed's senior vice president for technology and regulatory affairs, technology and regulatory affairs.

The guidance, for example, could be mistakenly applied to a diagnostic that tracks the efficacy of a therapeutic drug by monitoring blood concentrations of certain chemical substances or analytes, Calleja wrote.

For the most part, AdvaMedDx praised FDA's effort, claiming it underscores the agency's expertise in the field of personalized medicine "and is a positive step in supporting innovators who are bringing new safe and effective diagnostic technologies to the U.S. to advance personalized medicine."

Read the draft guidance here: www.fdanews.com/10-21-16-TherapeuticProduct.pdf. Read the comments on the draft guidance here: https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=FDA-2016-D-1703. — Jennifer Lubell

IMDRF, *from Page 1*

Although parts of it could use more development, the document is "a solid start to achieving a common vision for adverse event definitions, designations and coding," said Jack Garvey, principal and CEO of Compliance Architects.

He said adverse event reporting provides "the core, raw data for a company's internal product-risk signal-detection capability," allows regulators to aggregate and review trends and relationships between adverse events, and helps them analyze the role of those events in healthcare delivery.

"This data and the resultant reporting are essential for early identification of risky or dangerous products, and in helping these products to get corrected in the field, or removed from the market," he said.

Garvey noted that quality data are crucial for performing good causal analyses and reaching accurate conclusions.

"By proposing core elements of a uniform, global framework with defined terminology — including improved definitions — along with more precise coding for analysis, both companies and regulators may eventually have larger, higher-quality data sets, permitting increased signal detection capability, giving regulators much earlier insight into product problems," he said.

Nancy A. Pressly, acting deputy director in the Office of Communication and Education at the FDA's Center for Devices and Radiological Health, said the Adverse Event Terminology Working Group will review public comments and incorporate any necessary changes.

The public comment period for all four annexes closes Dec. 2, 2016. It is expected that the final versions will be submitted to the IMDRF management committee in February 2017.

Read Annex A here: www.imdrf.org/consultations/cons-imdrf-terminologies-caer.asp.

Read an accompanying explanatory document here: www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-imdrf-terminologies-caer.pdf. — Jeff Kinney

BRIEFS

Australia Issues Advisory on Insulin Pump

Australia's Therapeutic Goods Administration (TGA) announced that Australasian Medical & Scientific Limited, in consultation with the TGA, is issuing a safety advisory regarding the Animas Vibe insulin pump due because battery compartment damage might affect the supply of power to the unit.

According to the announcement, the pump might lose its waterproof capability and/or the ability to maintain a reliable power connection between the battery and the battery contacts if the compartment is cracked, such as from being dropped or overtightened.

The pump's alarms may fail if the battery power is interrupted, the announcement said. In addition, moisture in the pump can contribute to pump failure and suspend insulin delivery.

Australasian Medical & Scientific Limited advised pump users to regularly inspect their pump for cracks and replace the pump battery cap every six months.

$11.5 Million Raised for EU Device Startups

MD Start, a Europe-based accelerator specializing in developing medical devices, announced that it has raised $11.5 million in a round of funding for its new accelerator, MD Start II.

The round was led by French Tech Acceleration and managed by Bpifrance, the French public investment bank, as well as Medtronic, Sofinnova Partners, and LivaNova.

MD Start II will continue to incept, finance, and develop startup companies aimed at bringing innovative medical device concepts to the market. The companies will be incubated and managed by the MD Start partners until they reach certain milestones and require dedicated management and traditional venture capital funding.

MD Start II is the sixth investment of the French Tech Acceleration fund, which was created in 2014 as part of the French Tech initiative.

Second Recall for Medtronic Catheter

Medtronic has issued a second recall on its brain aneurysm treatment catheter.

The Pipeline device was originally recalled in April 2014, as well as its companion Alligator embolism retrieval device, based on reports that the plastic coating applied to the guidewire can delaminate and detach from the devices. The FDA cleared Pipeline's return to market in August 2014 after the problem was corrected.

The problem has resurfaced, however, leading Medtronic to recall the Pipeline and Alligator products, plus the X-Celerator hydrophilic guidewire and the UltraFlow and Marathon flow-directed micro-catheters.

More than 84,000 units, made from July 2014 to September 2016, are affected by the recall, the company said. The recall does not affect the next-generation Pipeline Flex device, which won FDA approval in February 2015.

FDA Classifies Prosthetic Device as Class II

The FDA is classifying a device with the generic name of "upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components" into class II (special controls).

The device is a prescription device intended to replace a partially or fully amputated or congenitally absent upper extremity. The special controls that will apply include, among others, electronic input, battery, and software testing.

The classification is based on the FDA's approval in 2014 of a prosthetic device submitted by DEKA Integrated Solutions Corporation. According to the agency, any manufacturer that makes a similar device will have to meet the same requirements.

The *Federal Register* notice is available at www.fdanews.com/10-17-16-prostheticdevice.pdf.

New ISO 13485 Expands On QSR Supplier Requirements

What has always been implicit in the FDA's Quality System Regulation is spelled out in detail in the 2016 version of international standard ISO 13485.

The International Organization for Standardization's revision of its purchasing controls requirements, the first in 13 years, closes gaps in supplier management practices left by the less detailed U.S. rule. Consultant Dan O'Leary, president of Ombu Enterprises, noted five key differences between ISO 13485:2016 and the QSR.

First, the QSR states that manufacturers must establish supplier selection requirements. By contrast, ISO 13485:2016 is more specific, providing that they must establish criteria based on a supplier's performance and its impact on the finished medical device.

Second, while the QSR says that manufacturers must evaluate potential suppliers, ISO 13485:2016 emphasizes monitoring and re-evaluation of accepted suppliers.

Third, the QSR requires manufacturers to practice document control in setting supplier specifications, while ISO 13485 says only that they must ensure that purchasing requirements are adequate before communicating them to the supplier.

Even though the ISO standard does not mention document control, O'Leary recommended that manufacturers do it anyway because it is required under the QSR and "is a way for the appropriate people to review and approve these purchasing requirements."

Fourth, the QSR says that, where possible, a change notification agreement should be obtained. ISO 13485:2016 states that purchasing information must include, as applicable, a written agreement that the supplier will notify the manufacturer of changes prior to implementation.

"I suspect that many suppliers are not going to sign up" for the ISO change notification standard, O'Leary said.

Finally, the ISO standard says manufacturers must determine whether changes affect the production process or the finished device. There is no corresponding requirement in the QSR. — Jeff Kinney

Comparison of QSR and ISO 13485 Purchasing Requirements

QSR	ISO 13485:2016
Establish and maintain requirements including quality requirements	Establish evaluation and selection criteria based on: • Ability to meet requirements • Supplier performance • Effect on the medical device • Proportionate to the medical device risk
Evaluate and select potential suppliers	Plan and implement supplier monitoring and re-evaluation
Approve purchasing data in accordance with document control	Ensure that purchasing requirements are adequate before communicating them to the supplier
Where possible, obtain an agreement for notification of changes	Purchasing information includes, as applicable, a written agreement that the supplier notify of changes in the purchased product prior to implementation
--	Determine whether these changes affect the product realization process or the medical device

Source: Ombu Enterprises, LLC

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creates a new version or model and thus requires a new UDI. "Companies might not realize that their design-change procedures need to include this analysis," O'Leary said.

He is seeing this issue crop up with premarket notifications as well. "Companies don't document whether they need a new 510(k), and I suspect we're going to see that same problem, only more frequently, at the UDI level," he said.

Finally, O'Leary said the UDI rule will require manufacturers to significantly revamp their quality management systems to prepare for when FDA inspectors start enforcing the rule.

"My fear is that there will be a lot of warning letters about failure to implement UDI in quality management systems," he said. "I'm concerned that this is a big piece that many companies don't realize is out there."

Permanent Marking

In addition, O'Leary said it is still not clear how to mark such devices with UDI information so the markings do not eventually come off – an issue that applies to the two remaining UDI rule deadlinesin 2018 and 2020.

He also noted the two-year period between the 2016 deadline, which requires UDIs on Class II device labels and packages, and the 2018 deadline, which requires UDIs on devices themselves. Manufacturers must remember to update the FDA's database if they decide to label a device with a different device identifier for the 2018 deadline, he said. — Jeff Kinney

FDA, CMS Parallel Review Program To Be Made Permanent

The FDA and the Centers for Medicare & Medicaid Services are transitioning their pilot program for parallel review of medical devices to a permanent program and are asking manufacturers to submit applications.

The agencies learned two primary lessons from the pilot program.

First, they found that manufacturers benefit from receiving feedback from both agencies at the pivotal clinical trial design phase. This can assist manufacturers in designing pivotal trials that can answer both agencies' evidentiary questions.

The second benefit is that concurrent review by the agencies of clinical evidence can reduce the time from FDA premarket approval or the granting of a de novo request to a national coverage determination.

Under the pilot program, which was launched in 2011, CMS published a favorable final national coverage determination on a product, less than two months after the device received its premarket approval and seven months before the national coverage determination statutory due date.

The notice said the agencies intend to review parallel review requests and respond within 30 days after receipt of the applications. Priority will be given to innovative medical devices, as well as to medical devices expected to have the most impact on the Medicare population.

Read the agencies' notice here: www.fdanews.com/10-21-16-parallelreview.pdf. — Jeff Kinney

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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

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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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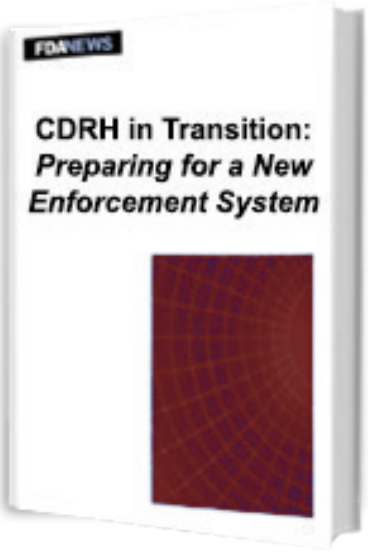
- Legal and Compliance Officers
- Consultants/Service Providers



CDRH in Transition: *Preparing for a New Enforcement System*

The looming realignment of CDRH's programs and retooling of inspection procedures have raised many questions among devicemakers trying to prepare for future inspections.

Currently, devicemakers are used to seeing one "generic" investigator at their inspections and they are used to investigators following the approach set out in the FDA's Investigations Manual and Quality Systems Inspection Technique.

But that's all about to change, creating a "perfect storm" that will leave devicemakers drowning in unfamiliar waters. Now is the time to make preparations to weather that storm, and **CDRH in Transition: *Preparing for a New Enforcement System*** is the place to start. In this report, noted industry expert John Avellanet gives his well-informed perspective on where CDRH enforcement is headed and what adjustments devicemakers will need to survive.

CDRH in Transition: *Preparing for a New Enforcement System* outlines how — and when — CDRH plans to update its programs in the coming years and how devicemakers should respond. Think of it as your to-do list for the next 18 months.

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