INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

CDRH Details Processes Used For Medical Device Deficiencies, Appeals

CDRH issued final guidance for industry and agency staff on how to deal with deficiencies the agency identifies when reviewing device marketing applications.

Under MDUFA IV, the FDA committed to updating the guidance to state that all deficiency letters issued by the agency will include a statement of the basis for the deficiencies, as well as the specific scientific or regulatory issue.

The agency also committed to conducting a supervisory review of each deficiency letter to ensure that all cited deficiencies are relevant to the authorization decision.

The guidance describes approaches applicants can use to respond to the identified deficiencies. Updating guidance issued in 2000, the final document outlines the principles that the agency uses for identifying deficiencies, including considering alternative solutions, and requesting the least amount of information necessary.

(See **Deficiencies**, *Page 2)*

Brazil Revamps GMP Inspections To Improve Access to New Technologies

Brazil's National Agency for Sanitary Surveillance is streamlining its process for good manufacturing practice certification to allow faster access to new medical device technologies.

ANVISA will conduct risk assessments for international devices including reviews of technical documents rather than on-site GMP inspections, depending on the level of risk identified. The change will mean greater flexibility in determining risk for certain Class III or Class IV devices.

The agency plans to consider the manufacturing stage of the device, the technology involved, additional control factors, and how much value an on-site manufacturing inspection would add.

(See **Inspections**, *Page 2)*

Deficiencies, *from Page 1*

Separately, CDRH issued final guidance using a Q&A format to clarify the appeals process.

The guidance answers questions about what a "significant decision" is under section 517A of the FD&C Act and what constitutes a "substantive summary" of a decision.

CDRH also clarified that only those firms that have submitted or plan to submit 510(k)s, PMAs, HDEs, IDEs or Breakthrough Designation Requests can request a substantive summary without having to submit a formal request under the Freedom of Information Act.

"Since FDA will only be providing these summaries to the owner of any proprietary information contained therein, generally there should not be any need to withhold trade secret or confidential commercial information (CCI) or any other information in the summary. If someone other than the owner of a device wishes to obtain a substantive summary of a 517A decision regarding such device, that person would need to file a FOIA request," the agency said.

Read the deficiencies guidance here: www.fdanews.com/10-03-17-Deficiencies.pdf.

Read the 517A Q&A guidance here: www.fdanews.com/10-03-17-QA.pdf. — Ana Mulero

Inspections, *from Page 1*

ANVISA said the measures will allow it to prioritize resources to conduct on-site inspections of the facilities that posed the greatest risk.

The move is in line with similar actions by a growing number of international regulatory authorities that are strengthening their relationships by sharing inspectional data to optimize work processes.

Brazil is a founding member of the International Medical Device Regulators Forum (IMDRF). At an IMDRF meeting in Ottawa, Canada, last month, Brazil's representatives discussed measures they are taking to reduce bureaucratic layers and increase efficiency (*IDDM*, Oct. 2).

One of those moves was a proposal to change the expiration date of medical device registration from five years to 10 years (*IDDM*, Aug. 14).

During the September meeting, the IMDRF management council also discussed ways to simplify audit procedures to verify GMP compliance through the Medical Device Single Audit Program (MDSAP) to avoid overlapping inspections by participating countries.

Brazil recently adopted a risk-based approach to inspections for manufacturers and distributors of medical devices, and has engaged in numerous international initiatives aimed at regulatory convergence.

Previously, Brazilian companies seeking licenses had to first request on-site inspections from local health authorities, undergo inspections, and obtain inspection reports before applying for the mandatory federal license. Under the new, risk-based system, low-risk facilities will be exempt from certain pre-licensing requirements.

The new risk-based system also streamlines Brazil's rules for certifying good manufacturing practices. The system is similar to the European Medical Devices Directive 93/42/EEC, which assigns risk under four tiers. Low-risk Class I and II devices are exempt from certain pre-licensing requirements and require less technical data.

Sponsors of high-risk devices have additional obligations prior to licensing, such as the presentation of documents and records of previous inspections. Higher risk devicemakers need to provide a technical dossier that is based on IMDRF standards.

ANVISA reported during the IMDRF meeting that it had awarded 47 GMP certificates using MDSAP audit reports. The agency recently added nine new organizations to its list of auditing bodies recognized to conduct MDSAP audits (*IDDM*, Sept. 11).

Read the ANVISA notice here: www.fdanews.com/10-03-17-Brazil.pdf.

FDA Lays Out Guidance On MDUFA User Fees

The FDA released a spate of new or revised user fee guidance to coincide with the Oct. 1 effective date of MDUFA IV.

The agency revised its April 2013 guidance on user fees and refunds for 510(k) submissions, including frequently asked questions, such as "Are all 510(k)s subject to user fees?" The answer is no.

What if the FDA said a device was eligible for third-party review and the 510(k) was reviewed by a third party, but the agency later determined that the device is not eligible for review by the third party? In such cases, the applicant would not have to pay a user fee. But if a 510(k) was reviewed by a third party and the device was never deemed eligible for third-party review, the applicant would have to pay a user fee, the agency said.

Applicants have to pay a user fee for a submission if they previously received a Not Substantially Equivalent determination for the device, if the submission type is subject to fees.

The agency considers a 510(k) submission withdrawn if the applicant fails to supply an electronic copy. In such cases, the FDA will return the fee.

De Novo Requests

The agency also issued Q&A guidance on user fees and refunds for de novo classification requests. For example, the FDA will not refund a user fee for a de novo request that is accepted for review and then declined. But applicants must pay a user fee if they withdraw and then resubmit a de novo request after it was accepted for review.

If an applicant submits additional information to a pending de novo request there are no additional fees, the agency said.

De novo requests for devices that are only intended for pediatric use will not be subject to user fees. De novo requests submitted by a state or federal government entity for devices that will not be commercially distributed are also exempted from the user fees.

PMAs and BLAs

The agency updated its April 2013 guidance on user fees and refunds for premarket approval applications and device biologics applications. The guidance spells out the types of PMAs subject to user fees, including original PMAs, modular PMAs, premarket reports, licensing agreement PMAs, panel-track supplements, 180-day supplements, real-time supplements, 30-day notices, and periodic reports. BLAs subject to user fees include original BLAs and BLA efficacy supplements.

513(g) Information Requests

In separate guidance on 513(g) requests for classification information, the agency said all of the requests are subject to user fees. What if the product in question does not appear to be a medical device? Or what if an applicant withdraws a 513(g) request? In such situations, the FDA will not issue a refund.

Review Clock and Performance Goals

The agency issued separate guidance on the review clock for PMAs, 510(k) submissions, and de novo requests, in line with the agency's commitments under MDUFA IV.

For example, the FDA commits to reaching a MDUFA decision in 90 days for 95 percent of 510(k) submissions. If the agency does not reach a decision within 100 days — 10 days after the MDUFA goal — it will provide a missed MDUFA decision communication, in the form of written feedback to the submitter to be discussed in a meeting or teleconference, including the major outstanding review topic areas or other issues preventing the agency from reaching a final decision, as well as an estimated time to completion.

(See **User Fees***, Page 4)*

Judge Deals Blow to Boston Scientific in Patent Lawsuit

Boston Scientific Corp. can't defend itself against a rival devicemaker's patent-infringement claim by arguing that the rival's attorney should have made sure a patent examiner fully understood what a document meant when it was invoked in an administrative proceeding, a federal judge ruled.

Judge Vince Chhabria of the U.S. District Court for Northern California granted a motion by Nevro Corp. to strike that element of BSC's defense in the dispute over Nevro's implantable spinal cord stimulation therapy systems. The system is capable of providing high-frequency SCS therapy without creating paresthesia, according to Nevro.

In his Oct. 4 ruling, Chhabria said that even though BSC's argument "is not unreasonable," Nevro's attorney "is not required to make sure that the patent examiner understands" all of the material information.

The document at issue, referred to before the PTO, related to pulse widths. BSC argued that it was clear the examiner misunderstood the reference and that Nevro's attorney should have cleared things up, which would have led the examiner to issue a ruling in favor of BSC.

Nevro filed a federal court lawsuit last year, claiming that BSC began "aggressively trying to mimic Nevro's SCS therapy" after witnessing Nevro's trial results and "rapid success."

The lawsuit states that Nevro tested its paresthesia-free high-frequency SCS system against BSC's low-frequency system during an FDA trial prior to obtaining approval. Results showed that Nevro's system was "nearly twice as effective," which in turn resulted in the FDA awarding it "a rare 'superiority' label—allowing Nevro to claim its high frequency SCS therapy is clinically superior," the lawsuit says.

Read the District Court's ruling here: www.fdanews.com/10-05-17-OrderMotionStrikeNevrovBSC.pdf. — Ana Mulero

User Fees, *from Page 3*

Under MDUFA IV, the agency commits to issuing a decision on de novo requests within 150 days for 50 percent of submissions in FY 2018, increasing to 70 percent in FY2022.

The new MDUFA fees include substantial increases, and — for the first time — fees for de novo requests (*IDDM*, Sept. 4).

Read the 510(k) guidances here: www.fdanews.com/10-05-17-510kSubmissions.pdf, www.fdanews.com/10-05-17-510kUserFeesGuidance-2017.pdf.

Read the PMA guidances here: www.fdanews.com/10-05-17-PMAs.pdf, www.fdanews.com/10-05-17-UserFeesRefundsPremarketApprvlApp.pdf.

Read the De Novo guidances here: www.fdanews.com/10-05-17-DeNovoClassificationRequests.pdf, www.fdanews.com/10-05-17-UserFeesRefundsDeNovoClassificationRequests.pdf.

Read the 513g guidance here: www.fdanews.com/10-05-17-UserFees513g.pdf. — Ana Mulero

What You Can and Can't Say In Advertising Devices

It can be a bit tricky for medical device makers to make sure their advertising materials are following the letter of the law in the eyes of the FDA.

That, says lawyer August Horvath, is because the agency doesn't give device makers many particulars to go on, and instead largely has them adhere to the detailed advertising rules for drugmakers, many of which may not apply very well to devices.

In the recent FDAnews webinar *Advertising Medical Products: Real-Life Scenarios that Illustrate What You Can and Cannot Say*, Horvath outlined some of the differences in advertising regulation for both groups, offered advertising guidance to device makers, and shared an illustrative example of a device maker seemingly flouting the FDA's false advertising rules.

False Claims

"It's obvious that the FDA is not as used to regulating medical devices as it is to regulating drugs," said Horvath, an antitrust partner at the law firm Kelley Drye, with 20 years' experience defending drug and device makers against false-advertising claims. "They don't provide as much guidance for medical devices, and you have to apply the logic that you would use for a drug to the device."

Explained Horvath, like drugmakers, its incumbent upon devicemakers to ensure their advertising materials are not false or misleading in any way, and also that the materials present a fair balance between information about effectiveness and information about risk.

Failure to do this — overstating the efficacy of the product by going either beyond the indication, or exaggerating the extent to which it has been shown to do what it's supposed to do, or understating the side effects — makes your drug or device "misbranded" in the eyes of the FDA.

But unlike drugmakers, said Horvath, devicemakers don't have to submit advertising to the FDA at the time of dissemination, so there's no pre-approval process. This sounds like freedom, but instead it can be a burden for device makers.

Said Horvath, surveillance of device advertising is more post hoc, with the FDA monitoring media and device trade shows for compliance, and following up on the inevitable complaints from competitors.

"I wouldn't say it's the Wild West, but it's a little bit less of a hands-on enforcement regime in medical devices," said Horvath.

SyncThink

It's not too hard to transport the concept of it being false or misleading directly from the drug world, said Horvath. It's where you go beyond that that gets tricky. Horvath used the recent example of the headset SyncThink, a 510(k) device cleared as the substantial equivalent of a device whose indication for use was eye tracking to measure visual tracking impairment.

But SyncThink's makers got a warning letter after allegedly marketing this device as a diagnostic for cognitive impairment, saying that it was used as a concussion diagnostic, and claiming that it would be used for athletes and military personnel to determine whether their head trauma had caused brain injury.

"What they did in the FDA's view was to change the indication, which is a no-no," said Horvath.

After telling the FDA it would stop, the company re-tweeted information about traumatic brain injury. Is this a violation since its product is not cleared for anything related to traumatic brain injury? That's still unclear.

"If you re-tweet something like this and it is in a promotional context and part of a Twitter feed that people understand is for marketing, I think this is still talking about your product being used for concussions in a way that carries some risk," offered Horvath, adding, "This is not

(See **Advertising***, Page 6)*

IMDRF Explores Using Registries To Support Regulatory Decisions

The International Medical Device Regulators Forum is inviting stakeholder comment on a draft proposal for using real-world data from patient registries in regulatory decisionmaking.

Stakeholders should compare the proposal to their current processes and consider closing any evidence gaps, IMDRF said. The assessment elements in the proposal are expected to promote consistency, predictability and transparency in maximizing the use of real-world data in evaluating device safety and effectiveness.

The draft proposes recommendations on the following regulatory uses:

- Primary approval;
- Expanded indications;
- Post-market studies;
- Post-market surveillance;
- Objective performance criteria/performance goals; and
- Device tracking and field safety corrections.

The proposed assessment elements are intended to promote convergence of regulatory approaches, enhance technical capabilities of regulators and stakeholders and generate faster evidence.

The proposed elements for assessing registries for regulatory uses include information on device identification, linkability, transparency and governance, and quality and methodology processes leading to actionable data.

For device identification, the draft document says, unique device identifiers should be used as well as production identifiers. When a UDI is not available, registries should record global trade item numbers, labeler identification codes or processor product identification codes.

The proposal recommends that device registries remain transparent by maintaining a public website that describes the aims of the registry, includes information about the governance processes, and how the registry is funded, as well as how to participate in the registry. Governance policies and processes should include policies on handling conflicts of interest, data access, reports and information, verification of data by regulators, and patient data protection and data security.

A section on quality and methodology processes notes that since registries are usually established for non-regulatory purposes, regulators should carefully consider whether the variables collected by the registry are sufficient in scope for regulatory purposes.

For analysis and interpretation of registry-generated data, a common set of data elements should be used along with a common definition framework and pre-specified time intervals for data collection and outcome analyses.

The list of variables should include demographic factors, medical history/co-morbidities, procedure/device information, operators/physicians, follow-up information and outcomes. In addition, a distinction should be made between the elements that all registries would share and the specifics needed in each specialty area.

The IMDRF's Patient Registries Working Group acknowledged that the data produced by a registry "may be suitable for making one type of regulatory decision but not others," and individual country regulators should assess data independently and decide what actions to take.

Comments may be submitted to the working group until Dec. 1, and a proposed final document will be submitted to IMDRF in February 2018.

Read the draft proposal here: www.fdanews.com/10-04-17-Deviceregistry.pdf.

Advertising, *from Page 5*

a settled area in any aspect of advertising law, whether we're talking about drugs or anything else. It's something we argue about quite frequently in the field."

Access the webinar, Advertising Medical Products: Real-Life Scenarios that Illustrate What You Can and Cannot Say, here: www.fdanews.com/products/54811. — Suz Redfearn

Motion-Capture Company Failed To Report Camera Fix, FDA Says

A California photographic equipment company failed to file a required report with the FDA about a modification made to a camera to reduce a health risk in response to a customer complaint, the agency said in a Form 483 report.

The company, Motion Analysis, of Santa Rosa, also lacked adequate procedures for reporting such incidents and for receiving and investigating complaints, the FDA said in the report on its July inspection. Several of the findings had been noted in a 2016 inspection, the report said.

Motion Analysis manufactures cameras and other equipment to capture and measure the movement of humans and objects. The company sells its products for use in sports and physical training, film and video production, industrial design and other areas.

The FDA citations mostly relate to the company's response to a 2015 complaint from a customer about the malfunctioning of two of the company's Kestrel cameras. The customer said that after the cameras were set up and the power was turned on for the movement-capture system, one camera "shorted, sparked and began smoking" and a second camera did not turn on, the Form 483 said.

A company investigation determined the cause was a screw in the camera assembly that was too long for its intended function, the report said. Motion Analysis replaced the two malfunctioning cameras and notified its customers who might be affected by the too-long screw.

But the company did not report the removal of the screw to the FDA, as it was required the do, the agency said.

Read the Motion Analysis Form 483 report here: www.fdanews.com/10-06-17-motion483.pdf.

FDA Hits French Devicemaker For Complaint Handling, Training

Medicrea Technologies drew the FDA's attention for inadequate complaint processing, employee training and material storage.

The devicemaker's facility in Rillieux-la-Pape, France, received a Form 483 following a February inspection. Investigators found the company did not submit an MDR report within 30 days of becoming aware of information suggesting one of its products may have caused or contributed to death or serious injury.

The company received complaints about its products in March and July of last year, both of which were reported to the FDA as injury MDRs.

The company made a total of nine MDR reports between Jan. 9 and Jan. 30 of this year based on complaints received between April and July 2016, and no corrective actions were taken to cut down on reoccurrence of the reporting problems.

The form also faulted the company for its complaint investigations, which did not sufficiently investigate incidents involving possible failures of devices to meet any of their specifications. Complaint records for surgical instruments did not feature the devices' usage histories.

The company also found inadequate procedures for acceptance of incoming products, and that Medicrea did not regularly evaluate all suppliers to ensure that its received products were within specification.

One of its suppliers of surgical instruments had not been evaluated since its initial acceptance as a supplier.

Lastly, the investigators found the company's design verification for certain products did not confirm design output met design input requirements, and did not properly explain these nonconformities. The company promised to correct all five problems.

Read the Medicrea Form 483 here: www.fdanews.com/10-04-17-medicreatechnologies483.pdf. — Zack Budryk

APPROVALS

Carrot Lands FDA Approval For Smoking Cessation Mobile Device

California-based digital health company Carrot won 510(k) clearance for the first over-the-counter carbon monoxide breath sensor for use in smoking cessation programs.

The Carbon Monoxide Breath Sensor System' mobile breath sensor can be paired with a smartphone via Bluetooth to measure carbon monoxide in exhaled breath. It shows users in real-time how their cigarette smoking behavior is impacting their carbon monoxide levels to help them quit smoking.

The company also launched its own smoking cessation program in a smartphone medical application called Pivot.

CardioFocus Earns CE Mark For HeartLight Excalibur Balloon

Cardio Focus received a CE Mark for its HeartLight Excalibur Balloon for treatment of atrial fibrillation.

The device is based on the company's FDA-approved HeartLight endoscopic ablation system and includes advanced features to optimize tissue contact during pulmonary vein isolation procedures.

The device provides a treatment option for AF patients whose heart arrhythmias are insufficiently controlled with medication.

Novo Nordisk Wins FDA Nod For Fast-Acting Insulin Device

Novo Nordisk received the FDA's approval for its Fiasp insulin aspart injection for fast-acting mealtime insulin. The device is designed to improve glycemic control for adults with Type I and Type II diabetes.

The device is a redesigned formulation of the NovoLog product, with added vitamin B3 to boost initial insulin absorption and trigger its appearance in the blood in 2.5 minutes.

The approval was supported by a Phase IIIa clinical trial involving more than 2,000 individuals with Type I and Type II diabetes.

K2M Wins FDA Clearance For Yukon OCT Spinal System

K2M Group Holdings received 510(k) marketing clearance for its Yukon OCT spinal system.

The device assists surgeons in restoring cervical spine balance, and to facilitate fusion in the occipito-cervico-thoracic regions of the spine. The system can accommodate rods in two diameters.

K2M is a pioneer in the 3D-printing of spinal devices.

Mortise Medical Gains FDA Clearance For LigaMetrics Suture Anchor System

Mortise Medical secured 510(k) marketing clearance for its LigaMetrics suture anchor system.

The device is designed specifically for connecting to and locking suture tape attached either to soft tissue or attached to a conventional suture anchor.

Mortise Medical is a medical device company incubated and operated by Surgical Frontiers.

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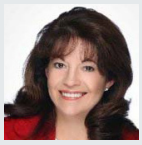
Senior Partner, Director Inspection Readiness Services, BioTeknica

FDA SPEAKERS:

ELLEN MORRISON
Associate Commissioner, OMPTO, ORA, FDA



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

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

DARA CORRIGAN, J.D.
Acting Deputy Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA

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

NOVEMBER 1-3, 2017 | DOUBLETREE BETHESDA BETHESDA, MD (WASHINGTON, DC)

2017 SUMMIT HIGHLIGHTS

NEW FOR 2017!

FDA's ORA Reorg and What it Means for Inspections

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

Building Your Best Internal Audit Team for Quality Results

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

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

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

FEATURED EXPERT SPEAKERS:

JOHN AVELLANET, Managing Director and Principal, Cerulean Associates LLC

KATLIN BACKFIELD, Attorney at Law, Consultant, Backfield PLLC

MARK BROWN, Partner, King & Spalding

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

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

DAN O'LEARY, President, Ombu Enterprises LLC

SUSAN SCHNIEPP, Fellow, Regulatory Compliance Associates, Inc.

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

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

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

Pre-conference Workshops Agenda

WED., NOV. 1 (1–5 p.m.)

DRUGS & BIOLOGICS TRACK

Flawless FDA Inspection Handling and Response

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

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

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

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

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

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

Attendees will learn:

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

BONUS: Attendees will receive:

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

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

MEDICAL DEVICES TRACK

No More 483s - QSIT Secrets to Assure Clean Inspections

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

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

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

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

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

This interactive workshop will dive deep into these key issues:

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

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

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

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

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

Day 1 Agenda

THURS., NOV. 2

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

8:30 a.m. – 8:45 a.m.

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

8:45 a.m. – 9:30 a.m.

FDA's ORA Reorg and What it Means for Inspections

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

Ellen Morrison, Associate Commissioner, OMPTO, ORA, FDA

9:30 a.m. – 10:15 a.m.

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

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

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

10:15 a.m. – 11:00 a.m.

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

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

(cont.)

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

11:00 a.m. – 11:20 a.m. | **BREAK**

11:20 a.m. – 3:30 p.m.

Two Concurrent Breakout Tracks

Track 1 — Drugs & Biologics

Track 2 — Medical Devices

3:30 p.m. – 3:50 p.m. | **BREAK**

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

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

DRUGS & BIOLOGICS TRACK

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

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

11:30 a.m. – 12:15 p.m.

FDA Regulatory Policy Roadmap: FDA Shares its Priorities for 2018

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

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

12:15 p.m. – 1:00 p.m.

Cautionary Tales: Words to the Wise on Compliance

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

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

1:00 p.m. – 2:00 p.m. | **LUNCH**

2:00 p.m. – 3:30 p.m.

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

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

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

Dara Corrigan, J.D., Acting Deputy Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA

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

Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC

Mark Brown, Partner, King & Spalding

3:30 p.m. – 3:50 p.m. | **BREAK**

MEDICAL DEVICES TRACK

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

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

11:30 a.m. – 12:15 p.m.

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

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

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

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

12:15 p.m. – 1:00 p.m.

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

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

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

This presentation will cover:

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

(cont.)

Day 1 Agenda (cont.)

THURS., NOV. 2

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

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

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

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

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

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

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

Dan O'Leary, President, Ombu Enterprises LLC

Ibim Tariah, Technical Director, BSI Americas Inc.

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

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

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

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

Attendees will learn:

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

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

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

Day 2 Agenda

FRI., NOV. 2

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

8:30 a.m. – 8:45 a.m.

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

8:45 a.m. – 9:30 a.m.

FDA's Office of Regulatory Affairs: Enforcement Update

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

Attendees will learn:

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

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

9:30 a.m. – 10:15 a.m.

Building Your Best Internal Audit Team for Quality Results

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

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

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

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

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

How to Deal with Difficult Inspections

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

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

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

12:00 p.m. | SUMMIT ADJOURNS

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

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

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