INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

CDRH Leading the Way On Agency-Wide Policy

Policy advances at CDRH are "going viral" across the entire agency, FDA Commissioner Scott Gottlieb said in his keynote speech on Sept. 26 at the 2017 AdvaMed Medtech conference.

CDRH has been busy this year implementing components of the FDA's new Digital Health Innovation Action Plan aimed at encouraging innovation and speeding up the pre-market process for quality medical technologies.

The FDA plans to use some of the new policies and regulatory concepts that the center has put into practice as models for agency-wide adoption as the medical device area has been able to advance innovation at a faster pace for several reasons.

One of the more obvious reasons, Gottlieb noted, is that the innovation process for devices is "more iterative" as they "are constantly being adapted and improved based on feedback from the end users and from their performance in clinical practice."

(See **Policy**, *Page 2)*

Apple, Fitbit Among FDA's Picks For Device Software Pre-Certification Pilot

The FDA announced the nine participants selected for its first digital health software pre-certification pilot program, ranging from startups to giants in the space.

Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Alphabet's Verily were chosen to provide the agency feedback through the program, launched earlier this year, to reduce the time and cost of market entry for digital health solutions.

CDRH associate director for digital health Bakul Patel told FDAnews the agency purposefully selected emerging companies in digital health as well as legacy tech companies to learn from

(See **Software**, *Page 2)*

Software, *from Page 1*

development perspectives from different sides of the sector.

Patient safety, clinical responsibility, delivering high-quality products and being proactive are some of the principles the FDA considered when deciding on which companies to pick, Patel said. There were a total of 103 applicants.

Pear Therapeutics is the first company to have received FDA marketing clearance for a mobile app intended for treatment of substance abuse disorder (*IDDM*, Sept. 18).

California-based Fitbit is looking to take "a more integrated role in personal healthcare," co-founder and CEO James Park said in announcing the company's participation in the program. "We are hopeful this will allow us to accelerate FDA regulated features and software development."

Tech giants Apple and Samsung just recently began wading into the healthcare space. Earlier this year, Apple was awarded a patent for an electronic health data device and Medtronic's Intellis platform for patient monitoring was approved by the FDA to be managed on one of Samsung's tablets.

To help the FDA develop its expertise on digital health software, participants in the pre-cert pilot program have agreed to provide information on how they are currently developing, testing and maintaining their software products, and on their quality management systems.

The companies have also committed to being available for site visits from agency officials throughout the duration of the program, which is a cornerstone of the FDA's new Digital Health Innovation Action Plan.

Ultimately, the agency aims to use the feedback provided through the pilot program to tailor a regulatory framework that differs from its traditional approach to reviews in that the focus will be on a company's digital health software rather than the product.

To fulfill this goal, the agency will seek to:

- Gather information that can help determine whether to precertify a company that has demonstrated compliance with quality standards;
- Determine key metrics and performance indicators that could allow precertified companies to submit less information before marketing a new product; and
- Consider "whether and how" some precertified companies could be exempt from having to submit a product for a premarket review.

The collaboration with traditional and non-traditional medical device manufacturers will help the FDA and industry come to a consensus on the "standard of excellence" for digital health software, Patel said. — Ana Mulero

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Policy, *from Page 1*

The agency issued final guidance on the use of real-world evidence for developing medical devices to help industry understand how it can be used at the FDA to support regulatory decision-making (*IDDM*, Sept. 4).

When evaluating submissions based on RWE, the agency has used "robust evidence that was generated in less time and at a lower cost than in the past, in some cases saving one to two years of development time," Gottlieb said. RWE was used to approve or clear more than eight medical devices and expanded the use of upwards of six technologies in 2015, he said.

The policy set forth with the RWE guidance for the medical device industry will be applied to all FDA-regulated products, he said.

Another lesson learned from CDRH is its approach to reviews, product and manufacturing quality as well as post-market surveillance. CDRH launched a pilot called Total Product Life Cycle Office to shift to this approach, which Gottlieb described as "more holistic" as products are evaluated throughout the entirety of their lifecycle. — Ana Mulero

FDA Goal to Bring Puerto Rican Device Manufacturing Back Online

Following the destruction by Hurricane Maria in Puerto Rico, FDA Commissioner Scott Gottlieb said one of the agency's main goals in the recovery effort is to bring the island's medical product manufacturing plants back into operation.

The FDA has convened a special hurricane task force is also working to ensure the safety of the medical products, blood and food supply needed by residents.

"The island is home to a substantial base of manufacturing for critical medical products that supply the entire world," Gottlieb said in a statement, describing the drug and medical device sectors as key to Puerto Rico's long-term economic recovery.

The agency has been working with firms to determine which facilities have been damaged or could continue to function on generator power. — Conor Hale

FDA Approves First Pre-Calibrated Glucose Monitoring System

The FDA approved the first factory-calibrated personal continuous glucose monitor, manufactured by Abbott Diabetes Care.

Diabetic patients typically have to prick their fingers multiple times per day to test a blood sample or to calibrate their monitoring device. Abbott's FreeStyle Libre Flash glucose monitoring system is the first device of its kind that does not require fingersticks for calibration or testing.

Users wear a sensor on their arm that can read glucose levels for up to 10 days.

The company pointed to two published clinical trials and real-world evidence that showed users of the FreeStyle Libre system test their glucose levels at least 15 times on average per day, which results in fewer episodes of hypoglycemia or hyperglycemia.

Glucose readings are captured by scanning a hand-held reader over the personal glucose sensor and they can be delivered through clothing.

The system allows diabetic users, who must be at least 18-years-old, and their physicians to identify trends in glucose fluctuations with a visual snapshot, while also avoiding possible interference by acetaminophen — which can falsely elevate glucose readings.

However, the FDA cautioned there may be instances where the FreeStyle Libre system could also provide inaccurate information.

Abbott said the device will be made available by year end at major retail pharmacies.

Read the FDA announcement here: www.fdanews.com/09-28-17-glucose.pdf. — Ana Mulero

FDA Finalizes Guidance on Drug/Device Combination Product Classifications

The FDA finalized guidance on its process for assigning applications to a specific regulatory center, hoping to answer frequently asked questions from industry sponsors regarding whether their product will be classified as a drug or as a device.

The final document replaces two drafts published in June 2011, encompassing product classification issues, requests for designations, the legal definition of a medical device and interpreting the term "chemical action."

The guidance is divided into two sections: information for sponsors seeking a formal determination of their product's classification and obtaining feedback from the FDA on related questions; and on the general concepts and definitions relating to the agency's decisionmaking process.

The agency added several examples to illustrate the differences between products that achieve their primary purpose through chemical action and those that do not. Aspirin, beta blockers and antibiotics would be considered drugs, as would mineral replacement therapies for certain deficiencies.

Other products would include certain topical surgical adhesives — wound-closing resins that approximate skin tissue, for example. While

(See **Guidance**, *Page 4)*

AAMI Offers Devicemakers a Tool for Managing Service-Level Agreements

The Association for the Advancement of Medical Instrumentation released a service-level agreement template to help original equipment manufacturers and healthcare providers improve their working relationships.

The tool can be used to create a custom contract to specify responsibilities for training, parts availability and service access.

The template suggests that the following items should be clarified before crafting a service-level contract: owners of the agreement; stakeholders; who will administer it; equipment lists; duration; scope of service; exclusions; availability of customer and service provider; types and depth of service required; quality and performance metrics expected; financial expectations; warranty expectations; who will mediate discrepancies; and expectations on termination of the agreement.

Service agreements should also cover service scope, including repair, preventive maintenance, incoming inspection/acceptance testing, incident investigations, software update, modification, network configuration, and remote diagnostics.

The free template is available at www.aami.org/SLAT.

Guidance, *from Page 3*

the product undergoes a chemical reaction that allows it to bind to tissues, it does not cause a pharmacological response.

The guidance also lists implantable surgical barriers that biodegrade, temporary bone spacers, cryosurgery for wart removal and the use of gold nanoparticles in the treatment of cancer tumors in this category.

For products that meet the legal definitions of both a drug and a device under 21 USC 321, the FDA generally classifies those products as devices, the guidance said — unless it falls under a special category, such as the apparatuses used in preparing compounds for positron emission tomography scans.

Additionally, two products with exactly the same composition can be classified differently based on their proposed uses, the FDA said.

Sponsors can submit requests for formal declarations from the FDA's Office of Combination Products. Companies should recommend a classification in their request and justify its reasoning. Generally, the OCP plans to respond within 60 days — if not, the sponsor's recommendation is considered the official classification.

New determinations may be appropriate if there are changes in proposed indications or product components, but the guidance does not address agency re-evaluations of previous classifications, saying it will continue to address the issue on a case-by-case basis.

The FDA recommends that sponsors contact the OCP to confirm if any classification is unclear or in dispute.

The full final guidance is available here: www.fdanews.com/09-26-17-FDAClassificationGuidance.pdf. — Conor Hale

IMDRF Roundup: 3D Printing, Global Registries, SaMD

The International Medical Device Regulators Forum agreed to a new work item proposal to develop technical documents that support a harmonized approach to defining devices manufactured for individual patients.

Elizabeth McGrath, director of the Conformity Assessment Branch of Australia's Therapeutic Goods Administration, proposed the new work item to the management committee during the Sept. 19-21 meeting in Ottawa, Canada.

McGrath said it is now possible to mass produce individualized medical devices using 3D printing, and as individual regulators are now developing their own approaches, there is a risk of international divergence. She proposed that a task force:

- Address the differences between custom-made, customized and patient-specific devices and provide definitions for each;
- Address medical devices that are manufactured in a repeatable manner, especially those produced via additive manufacturing;
- Consider devices that are intended by the original manufacturer to be modified to suit an individual after the device is supplied; and
- Recognize that some devices are produced in a unique manner, and should continue to be eligible for existing custom-made exemptions.

International Registries

The IMDRF management committee also approved a proposed document, "Tools for Assessing the Usability of Registries in Support of Regulatory Decision Making," which the forum's Patient Registry Working Group will circulate for public consultation.

By coordinating internationally on methodologies for collecting and evaluating clinical data, international stakeholders can begin to develop a core dataset for evaluating device product life cycles to detect signals earlier. Registries could be used to apply comparative effectiveness data as well as for root cause analyses (*IDDM*, April 10).

The management committee also approved a final document that covers terminologies for categorized adverse event reporting that covers Annex B to D. Annex B discusses the type of investigation, such as testing of the device and trend analysis, while Annex C looks at investigation findings (whether the problem was biological, microbial, etc.); and Annex D considers the investigation conclusion and whether the cause of the problem is traced to device design, manufacturing or a quality control deficiency.

More information on this work group and final meeting items will be released shortly.

Software as a Medical Device

IMDRF also finalized a document outlining steps required to generate clinical evidence of effectiveness and safety of software as a medical device (SaMD). The document addresses standalone software designed to produce or extract data, including diagnostic information, in tandem with a medical device. SaMD is not part of a device, nor is it used to operate a device, and would run on general-purpose computing platforms.

Global Regulator Update

Erik Hansson, deputy head of the Health Technology and Cosmetics unit of the European Commission updated the IMDRF meeting on the EU's new medical device regulations that will be progressively implemented for medical devices by May 2020 and for IVDs by May 2022 (*IDDM*, March 13).

Getting EU notified bodies established remains a top priority as does setting up the Medical Device Coordination Group, which will be the main body supporting the Commission for implementing future regulations. The group comprises representatives from EU national authorities and is chaired by the EC.

Japan's Ministry of Health Labor and Welfare and its Pharmaceuticals and Medical Devices Agency noted that it has designated 14

(See **IMDRF***, Page 6)*

FDA Calls for Nominations To Join MDAC Panels

The FDA is calling for nominations from the medical device industry to join certain panels of CDRH's Medical Devices Advisory Committee.

Nominees should be full-time employees of a medical device organization or an organization in a similar field to qualify. Representatives can either self-nominate or nominate someone else.

The five panels are: the Circulatory System Device Panel; the Clinical Chemistry and Clinical Toxicology Devices Panel; the Gastroenterology and Urology Devices Panel; the General Hospital and Personal Use Devices Panel; and the Obstetrics and Gynecology Devices Panel.

The functions they serve include reviewing and evaluating data on the safety and effectiveness of marketed or investigational devices for use in the particular specialty area of the panel.

Panel members will also make recommendations for the classification or reclassification of devices as well as complexity categorization of in vitro diagnostics.

They will also advise the FDA on potential risks to health associated with a device use, on creating product development protocols, and on the need for a device to be banned. Other functions include reviewing premarket approval applications, guidelines and guidance documents.

Applicants have until Oct. 30 to submit a letter of interest to the FDA.

IMDRF, *from Page 5*

notified bodies to undertake medical device certification activities.

Japan is introducing conditional early approval schemes for innovative medical devices. The idea is to accelerate approval of devices that have high clinical needs by balancing pre- and postmarket requirements.

Meanwhile, Health Canada said it would use more real-world evidence in its regulations to improve device safety and effectiveness and to improve product lifecycle information.

The Canadian agency is also developing a targeted review process for digital health technology, as well as tools and processes to improve pre-submission meetings for devicemakers.

The next IMDRF meeting will be held in Shanghai in March 2018. The IMDRF management committee includes regulators from Australia, Brazil, Canada, China, the EU, Japan, the Russian Federation, Singapore, and the United States.

PEOPLE ON THE MOVE

TSO_3 appointed **Bradley J. Catalone** as its chief science officer. Catalone has extensive knowledge of medical devices and the sterilization industry. Previously, he served in leading roles at Olympus Corporation of the Americas, including as director of research. Most recently, he was vice president of laboratory services at Alcami Corporation with responsibility for drug development and analytical testing services.

Saranas appointed **Philippe Généreux** as its chief medical officer. Généreux is co-director of the structural heart disease program at Morristown Medical Center. Previously, Généreux was an interventional cardiologist at the Columbia Medical Center and the director of the angiographic core laboratory at the Cardiovascular Research Foundation. Saranas has developed a technology for early detection of bleeding complications associated with vascular access procedures.

OSF Ventures named **Garrett Vygantas** as managing director. Vygantas has two decades of healthcare experience as a physician, investor and entrepreneur. He has worked in biopharmaceuticals, medical technology and diagnostics. He was the founding CEO of NewBridge Pharmaceuticals and was also an entrepreneur-in-residence and investment director at a leading life science venture capital firm. Most recently, he led healthcare investments at Jump Capital.

483 Roundup: FDA Cites Five Firms for MDRs, Other Issues

The FDA flagged several U.S. and international facilities for a range of deviations including inadequate complaint procedures, MDR reporting, and recordkeeping.

Hand Biomechanics: The FDA issued a Form 483 to Hand Biomechanics, citing problems with its complaint process and failure to submit MDR reports.

The agency issued the form following a June/July inspection of the firm's Sacramento, Calif., facility. Investigators found the company did not submit an MDR report within 30 days of receiving information suggesting its devices may have contributed to injuries or deaths.

The FDA found that in handling complaints, the firm failed to include all information required in its own complaint procedures. Furthermore, the firm's process for package sealing was not properly validated and its processes were not revalidated in the wake of changes or process deviations.

The agency also faulted the company on its CAPA handling, finding 10 cases where it failed to prevent recurrences of quality problems.

Neuro-Fitness: The FDA dinged device manufacturer Neuro-Fitness for complaint handling and ensuring device conformance.

The agency hit the company with a Form 483 following a July inspection of its Fall City, Wash., facility. According to investigators, the firm currently used an unapproved version of its complaint form that was missing sections on complaint investigation requirements, responses to complainants and required corrective actions.

Lastly, the firm's procedure for purchasing controls required regular re-evaluation of suppliers for acceptability as well as for the company to keep an approved vendor list, but Neuro-Fitness failed to document re-evaluations or keep such a list.

Ever Corporation: An Ever Corporation facility in Kuroiso City, Japan drew a Form 483 following an FDA inspection in February for a range of deficiencies including a lack of written MDR procedures, and failure to establish procedures for device history records and records of acceptable suppliers.

The site inspection also revealed that several nonconformities that occurred while assembling products had not been documented or investigated.

AMD Medicom: The FDA cited AMD Medicom for lacking adequate procedures for CAPA actions, and for failing to maintain a device master record and to establish contamination prevention procedures.

The facility in Granby, Quebec had signed as completed, closed and/or verified as effective certain CAPA actions for customer complaints over issues such as "material falling apart" even though implementation of the actions had not been documented, the FDA investigator found.

In addition, the facility's device master record for ophthalmic sponges lacked device specifications, product process specifications, quality assurance specifications, and packaging and labeling specifications.

Diagnostic Grifols: The FDA flagged the Diagnostic Grifols manufacturing facility in Barcelona, Spain, for nonconformities relating to MDR reporting, and evaluations of potential suppliers, following an inspection carried out from Feb. 13-16.

It took the company 201 days to submit an MDR report from the day it became aware of the device malfunctioning incident with information that reasonably suggested the device could have contributed to a death or serious injury.

In addition, the firm failed to provide valid statistical justification for the sampling method used for inspecting incoming raw material, according to the Form 483.

Read the five Form 483s here: www.fdanews.com/09-28-17-FiveForm483s.pdf.

APPROVALS

Abbott Adds MRI-Compatibility To Ellipse Defibrillator

The FDA approved conditional labeling of magnetic resonance for Abbott's Ellipse implantable cardioverter defibrillator. The addition allows patients with the implants to undergo MRI scans.

Ellipse monitors heart rhythms and can deliver a shock to a patient's heart. The data captured by the device and wirelessly transferred allows for remote monitoring to help the patient's care provider determine whether intervention is needed.

FDA Clears Brainlabs' Radiosurgey Software Apps

Two software applications from device manufacturer Brainlab, Elements Spine SRS and Elements Cranial SRS, were cleared for marketing by the FDA. The software helps physicians craft plans for spine and brain radiosurgery treatments.

The Elements Cranial SRS can create a radiosurgery plan for several cranial indications and it uses an integrated algorithm that allows for organs at risk and healthy tissue to be spared from treatment.

The Elements Spine SRS takes into account spine curvature variations to help ensure that radiation doses are delivered to the tumor and not the spinal cord.

Endologix Snags CE Mark For Aneurysm System

Endologix received a CE mark for the Nellix EndoVascular aneurysm sealing system, an abdominal aortic aneurysm therapy that is the only device whose operating principle is centered around sealing the entire aneurysmal sac, according to the company.

The device is currently being studied in the U.S. for endovascular repairs.

Pentax Medical Wins CE Mark For DEC Duodenoscope

Hoya's Pentax Medical won CE Mark approval in the European Union for its DEC duodenoscope featuring a disposable elevator cup.

The device has advanced cleaning capabilities, high definition video quality and improved infection prevention controls.

The single-use, sterile, distal end cap was designed to reduce the likelihood of carbapenem-resistant Enterobacteriaceae infections which have been linked to duodenoscope devices.

Siemens Healthineers Receives CE Mark For Atellica Advanced Diagnostics System

Siemens Healthineers won a CE Mark for its Atellica Solution advanced diagnostic system. The system consists of scalable immunoassay and chemistry analyzers, and can run up to 440 tests per hour. It includes 170 assays and a 10-minute turnaround for certain cardiac, reproductive and thyroid tests.

The system is now available in Europe, the U.S., South America and Asia.

LivaNova Wins 510(k) Clearance For Optiflow Arterial Cannulae

LivaNova won 510(k) marketing clearance for its family of Optiflow Arterial Cannula.

The device has a "basket tip with large openings" to significantly reduce wall shear stress and turbulence.

The device provides improved hydrodynamics and includes a dispersive tip that boosts blood flow.

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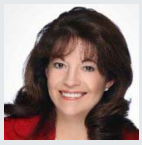
Senior Partner, Director Inspection Readiness Services, BioTeknica

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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