International Devices & Diagnostics Monitor

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IN THIS ISSUE

Separate UK Regulations Are Bad For Business, Stakeholders Warn

Creating two distinctive regulatory frameworks would disrupt innovation and growth for the EU and the UK's medtech industry and hinder access to needed medical devices, said medtech stakeholders concerned about the effect of the impending exit of the UK from the European Union.

A transitional period to implement secondary legislation for devices and in vitro diagnostics is needed to maintain parity of regulation with the EU, stakeholders said in a letter to Michel Barnier, the EU's chief negotiator, and UK Member of Parliament David Davis, the UK's secretary of state for the Department for Exiting the European Union.

Signed by leaders of MedTech Europe, the Association of British Healthcare Industries and the British In Vitro Diagnostics Association, the Sept. 12 letter stressed the need for sector-specific measures to be implemented during the ongoing Brexit negotiations.

(See **Regulations**, *Page 2)*

Preservation Solutions Draws FDA Warning for GMP Violations

Preservation Solutions, a Wisconsin-based provider of organ preservation and transplant solutions, was hit with an FDA warning letter for GMP nonconformities.

The agency sent the warning letter after it found the company's response to observations in a Form 483 report — issued after a facility inspection conducted from April 21 through May 19 — to be inadequate.

The FDA investigator noted that the required validations of media fills, stability, equipment, clean room and processes were either not being done or were inadequate. For example, the firm's procedure for cleaning its cleanrooms was not validated to prove the method was adequate or acceptable.

The agency also noted problems with complaint handling, saying the company had not followed a necessary procedure for any of

(See **Violations**, *Page 2)*

Regulations, *from Page 1*

They noted the UK device industry has benefitted from the single European-wide CE marking system, and has seen a significant growth in employment in recent years. The majority of device companies in the UK and the EU are small to medium enterprises, and they may stagnate due to uncertainty surrounding regulations in the UK post Brexit.

The letter urges the leaders to adopt the EU's new regulations covering medical devices and IVDs to encourage global harmonization and to keep EU-wide networks strong.

"Any regulatory divergence will increase both bureaucracy and cost," the letter says. "Creating two distinctive regulatory frameworks would disrupt innovation and growth in the industry, and hinder patient access to medical technologies."

Stakeholders pointed to five critical factors to ensuring regulatory stability:

- The UK should remain an active part of the EU regulatory framework for medical devices and IVDs under a full implementation of the new regulations;
- UK notified bodies should remain European designated notified bodies;
- Legal entities such as authorized representatives in the UK should be considered "European-based" under the new regulations;
- MHRA should participate formally in the European Commission's new Medical Devices Coordination Group; and
- The UK should continue to have full access to and reliance on the newly set European Database for Medical Devices (Eudamed), which includes EU-wide pre- and postmarket data, registration of economic operators, and details of clinical investigations among other data.

Stakeholders also urged the leaders to "limit regulatory and administrative barriers for products being moved between the EU and the UK."

Lord James O'Shaughnessy, secretary of state for England's Department of Health, tried to calm jittery nerves in a Sept. 14 speech, suggesting that Brexit "offers a major opportunity to build on our existing strengths."

He stressed the importance of the medtech sector in the UK, and said patients in the UK and the EU would not be put at a disadvantage, and that the UK would continue to play a leading role promoting and ensuring public health in the EU and globally. He also promised that devicemakers would be able to get their products into the UK market as quickly as they do now.

O'Shaughnessy noted that the UK's five notified bodies assess a "disproportionate number of medical devices," with the British Standards Institution alone having a 30 percent share of the EU market. He estimated that UK notified bodies oversee between 50 percent to 60 percent of "all the highest-risk devices on the EU market."

In addition, he said, the UK wants to see zero tariffs on trade in the medtech sector, and it plans to have a new customs agreement with the EU to support these objectives. The UK will also continue to support global initiatives such as the Medical Device Single Audit Program.

Violations, *from Page 1*

the four complaints it had received since Jan. 1. The complaints had not been entered into a CAPA system, and they were all classified as complaints with "no allegation of a defect noted" even though at least one of them did involve an alleged defect.

Another Form 483 observation was for inadequate procedures for controlling environmental conditions. The clean rooms, for example, were not being monitored for humidity.

Lastly, the agency was not satisfied with the company's response to a noted lack of adequate procedures for CAPA actions because it did not "describe or commit to any systemic corrective actions or retrospective review" of its CAPA system.

Read the warning letter here: www.fdanews.com/09-20-17-PreservationSolutions.pdf.
— Ana Mulero

Claims for Dynavision D2 Exceeded Approved Indications, FDA Says

An Ohio company violated federal regulations for medical devices by making claims for its product that were not approved by the FDA, the agency said in a warning letter.

The company, Dynavision International, of West Chester, had received FDA approval for its Dynavision 2000 product as a device that measured reaction time. But it ran afoul of the regulations when it introduced an updated model, the Dynavision D2, and made claims on the company web site that went beyond the approved indication, the letter said.

The expanded claims concerned the ability of the Dynavision D2 to measure cognitive, visual and physical impairment related to stroke, Parkinson's disease, traumatic brain injury and other conditions and to assist in concussion management and in "return to play" decisions for athletes, the FDA said.

The warning letter also faulted the company for its failure to comply with quality procedures required for medical device manufacturing.

To read the warning letter, click here: www.fdanews.com/09-15-17-DynavisionWL.pdf.
— Gregory Roberts

Court Agrees to New Trial Over Negligence Claims Against DePuy

The Cook County Circuit Court will revive a 2013 lawsuit against DePuy Orthopaedics and Premier Orthopaedics Sales alleging negligence in designing a hip replacement device.

The plaintiff's argument is centered on DePuy's alleged failure to initiate a timely recall of its DePuy Articular Surface Replacement XL hip replacement device due to the risk of a premature failure that could potentially cause excessive wear.

The Illinois court granted a request for a new trial after it found the 2013 decision to exclude testimony from a Newcastle University orthopedic surgeon denied a fair trial. The testimony, from Dr. David J. Langton, consisted of a volumetric wear analysis of the device.

"As a result of the Court precluding Dr. Langton from testifying at trial, the question becomes was the Plaintiff denied a fair trial," the Cook County order states. "In resolving the question, the Court must look at the entire trial and the answer is yes, Plaintiff was precluded from giving the jury evidence of the amount of wear on the explanted ASR that was vital to her case."

MHRA Unveils Guidance On Human Factors in Device Design

The UK's Medicines and Healthcare products Regulatory Agency published new guidance on human factors and usability engineering for medical device manufacturers — pulling back the curtain on the UK's regulatory structure, and showing how various usability engineering strategies stack up against each other.

The document also delves into the stages of a usability engineering process, post-market surveillance, and various concerns during the medical device lifecycle.

Aimed at manufacturers of all device classes and drug-device combination products, as well as notified bodies responsible for assuring the quality of those devices, the guidance focuses on ways human factors can be applied so products are optimized for the intended users.

MHRA said those involved in procurement and risk management of activities involving medical devices, as well as physicians and other stakeholders may also find the guidance relevant to their roles.

As devices become increasingly diverse in their capabilities and the environments in which they are used becomes busier, with new distractions and requirements for specialized training, the potential for user error also increases,

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

Guidance, *from Page 3*

the agency said, adding that as healthcare evolves and patient care is transferred to the home or public environment, "less skilled or even unskilled users, including patients and carers, must be able to use quite complex medical devices safely."

Devices such as infusion pumps, ventilators, automatic electronic defibrillators and drug-device combination products (such as auto-injectors) are recognized as potentially having use-related design issues that can result in problems such as overdoses, incorrect therapy and dangerous delays or difficulties with delivery of medication, says the document.

Human factors take into account features of the intended user population, such as age, size, strength, cognitive ability and training. Also considered are factors such as potential competing distractions, lighting level, or urgency of use.

"This will very much depend on the design of that technology, what education and training that person has, and the environment in which they will be using the technology," says the guidance.

The MHRA guidance is intended to be consistent with FDA guidance and other international standards. Although it aims to clarify regulatory expectations of medical devices marketed in the UK, it does not represent a compliance requirement. Alternative approaches to demonstrating safe and effective use could be proposed by applicants. The agency said the guidance applies to the design of future products and changes in user interfaces of existing products, rather than those already approved for the UK and EU market.

In addition, MHRA clarifies that usability engineering is an iterative process involving design, testing and validation of design stages. The agency calls for attention to the post-market phase, since "evidence may come to light while a device is being used in clinical practice that the design requires further improvement."

MDSAP Participants, Regulators Consider the Program's Future

MDSAP participants identified actions for improving the program at 2017 RAPS Convergence.

Although the program will not become fully operational until Jan. 1, 2019, participating manufacturers and auditing organizations have begun to prepare for how MDSAP regulatory authorities will use program outcomes differently across different countries.

For example, Health Canada will use MDSAP certificates to decide on whether to issue device licenses, while program audit reports submitted to the CDRH will be accepted as substitutes for routine FDA inspections, Nancy Shadeed, special advisor at Health Canada's International Programs Division, explained during the session at the conference.

Despite reported concerns over a potential increase in audit frequency, more and more manufacturers are embracing MDSAP, Shadeed said. The total number of participating manufacturer sites has substantially increased — from seven in the third quarter of 2014 to 417 as of the second quarter of 2017. At least 266 have been added this year alone, she said.

Patricia Murphy, global head of the MDSAP program at BSI said issuing guidance on how to conduct an electronic audit records review, and improving regulatory training on jurisdictional requirements, are actions that will help to improve MDSAP.

Other identified opportunities for growth include expanding the use of MDSAP audit reports, adding more regulatory authorities, and increasing harmonization among regulators.

FDA Hits Medex Cardio-Pulmonary on Complaints, Control Records, Sterility

The FDA cited an Illinois device manufacturer over its investigation of discrepancies, control records and complaint handling.

The agency issued a Form 483 to Medex Cardio-Pulmonary after a June/July inspection found the firm's quality unit failed to investigate out-of-specification test results in several cases. The facility's batch production and control records were incomplete, lacking full documentation of aseptic filling operations to ensure they were performed according to procedure, the agency said.

The facility's aseptic processing areas were also inadequate, with investigators noting an employee performing sanitization procedures for the fill system enclosure wearing non-sterile gloves. The company also failed to perform dynamic smoke studies to validate the sterilization process.

The FDA faulted the company on its record-keeping for drug complaints, noting it did not always include the results of investigations. Furthermore, the company did not perform routine inspection and checking of electronic equipment according to a program designed to ensure adequate performance. The air supply for the production area lacked an appropriate air filtration system, and as of June, the firm had not opened a formal CAPA since 2014.

Document control procedures also lacked several required elements, including document numbers, current revisions and document titles. Company records for out-of-specification products did not include the machine technician responsible for the deviation. Investigators also reported that management failed to make sure all employees understood, implemented and maintained the company's quality policies.

Read the Medex Form 483 here: www.fdanews.com/09-21-17-Medex483.pdf. — Zack Budryk

FDA Clears First Duodenoscope With Disposable Distal Cap

Following deadly superbug outbreaks linked to contaminated duodenoscopes, the FDA has cleared the first duodenoscope with a disposable distal cap to improve access for cleaning.

Flexible duodenoscopes provide access to upper gastrointestinal tracts to treat bile duct disorders. However, they must be thoroughly

(See **Scope***, Page 6)*

MHRA Plans Guidance on Co-Developing Medicines and IVDs

The UK's Medicines and Healthcare products Regulatory Agency plans on issuing guidance on co-developing medicines and IVDs in the near future.

Big changes are in the pipeline for how companion diagnostics are regulated in the EU following the entry into force of the new medical device regulations, according to Stephen Lee of the UK Medicines and Healthcare products Regulatory Agency's Devices Division, who discussed companion diagnostics during a July 14 joint meeting in London sponsored by MHRA and the UK BioIndustry Association.

The new rules-based risk classification for IVDs means more work for notified bodies as 80 to 90 percent of devices will have to go through them. Reference laboratories and expert panels will be created with the goal of helping notified bodies develop more expertise, he said.

Lee highlighted the EU regulations' inclusion of a definition and assessment route for a companion diagnostic — "a device which is essential for the safe and effective use of a corresponding medicinal product, to identify before and/or during treatment [for] patients who are most likely to benefit from the drug in question, or to identify patients at risk of a serious adverse event."

According to his interpretation of the rules, following an analytical study, the clinical performance of a proposed companion diagnostic could be tested during Phase II/III trials.

The medicines regulator will give an opinion on the suitability of the test for use with the corresponding drug to feed into the notified body's review, Lee said.

National medicines regulators and notified bodies will work together on conformity assessments with the goal of approving a medicine and its companion diagnostic around the same time, he said.

Scope, *from Page 5*

cleaned and disinfected to prevent contaminated tissue or fluid from being trapped in the adhesive, the agency said.

CDRH acting director William Maisel called the clearance of Pentax of America's ED34-i10T a major step toward lowering the risk of future infections associated with the devices.

An earlier version of a Pentax duodenoscope had a design flaw that could allow leaks of contaminated tissue or fluid into the device. The problem prompted the FDA to issue a safety alert in January. Olympus and Fujifilm are among the manufacturers of duodenoscopes that have been flagged by the FDA for design issues.

Earlier this year, the FDA began requiring the inclusion of cleaning, disinfection, and sterilization validation data in 510(k)s for these and other specified reusable devices (*IDDM*, June 12).

PEOPLE ON THE MOVE

Surgical implant manufacturer **RTI Surgical** named **Julius Aviza** as vice president of quality assurance. Aviza was previously vice president of global quality at American Medical Systems. The company also appointed **Jonathon Singer** as chief financial and administrative officer, and **Olivier Visa** as president of OEM, donor services and sports. Singer is a member of RTI's board of directors. Visa was formerly vice president of global compounding at Baxter.

Paul Hermes has been appointed to the board of directors at regenerative medicine company **Biorex**, which manufactures bioresorbable scaffold technology. Hermes, currently entrepreneur in residence at Medtronic, will serve as an independent director on the Biorex board.

Relievant MedSystems has named **Kevin Hykes** as its new president and CEO. Outgoing CEO Alex DiNello will remain as COO. Hykes was previously chairman and CEO at medical device manufacturer Metavention.

APPROVALS

C4 Imaging Wins Additional FDA 510(k) Clearance for Sirius MRI Marker

C4 Imaging won an additional 510(k) marketing clearance for its Sirius MRI marker used during the treatment of prostate cancer with brachytherapy.

The additional clearance is for sterilization with ethylene oxide. Previously only gamma sterilization was available.

The company said it is assessing plans to supply Sirius for prostate cancer patients outside the U.S.

Douglas Medical Products Receives 510(k) Clearance for IV Administration Set

Douglas Medical Products won 510(k) clearance for its Tubetech IV administration sets for use in peristaltic IV infusion pumps.

The device controls the flow in the IV tubes. It is available for use in hospitals, alternative site settings and long-term care facilities.

Douglas Medical, a contract manufacturer of IV administration sets, said it will begin commercialization of the product immediately.

FDA Clears Agilent's GenetiSure Dx Postnatal Assay

Agilent Technologies received 510(k) marketing clearance for the GenetiSure Dx Postnatal Assay, the company's first comparative genomic hybridization assay for diagnostic use.

The device enables clinical geneticists to detect genetic aberrations associated with developmental delay, intellectual disabilities, congenital irregularities, and unexplained dysmorphic features.

The device is intended for use on the Agilent SureScan Dx microarray scanner system, a Class II exempt medical device.

FDA Approves Two Ortho Hepatitis B Assays

Ortho Clinical Diagnostics received FDA approval for its Vitros HBeAg and Anti-HBe assays for use with the company's Vitros 5600 and 3600 systems.

Both assays are currently available on the Vitros ECi/ECiQ immunodiagnostic systems.

The assays are used to diagnose individuals with acute or chronic hepatitis B or in recovery from hepatitis B infection.

FDA Approves GlaxoSmithKilne's Triple Trelega Ellipta Inhaler

The FDA has approved the triple inhaler developed by GlaxoSmithKline and Innoviva to treat chronic obstructive pulmonary disease.

The Trelega Ellipta dry powder inhaler uses fluticasone furoate, umeclidinium and vilanterol to help adults with COPD manage the condition. The device is the first once-daily product approved in the U.S. that combines three active molecules in a single inhaler for COPD patients.

An EMA panel recently recommended approval for the Trelegy Ellipta triple-combination inhaler.

Medtronic Receives FDA Approval of Spinal Cord Stimulator

Medtronic received FDA approval of the Intellis platform for the management of certain types of chronic pain.

The device is placed under a patient's skin to deliver mild electrical impulses through a lead implanted in the epidural space to block pain signals from going to the brain.

The device tracks and records patient activity 24/7 and is managed on the Samsung Galaxy Tab S2 tablet interface, enabling physicians to monitor progress and make modifications to suit their patients' therapy needs.

App for Substance Abuse Treatment Wins FDA Marketing Clearance

The FDA approved marketing of a prescription smartphone app to help patients with substance abuse issues. The app, reSET, from Pear Therapeutics, is the first approved mobile medical application for treatment of substance use disorder.

(See **Approvals**, *Page 8)*

Approvals, *from Page 7*

The app is designed for use in outpatient therapy for abuse of alcohol, cocaine, marijuana and stimulants. It is not intended for treatment of opioid dependence.

The app delivers cognitive behavior therapy that teaches skills for increasing abstinence. In clinical trials of a desktop-based version, it achieved better results than those experienced by patients who engaged in conventional face-to-face therapy alone.

SurModics Wins 510k Clearance and CE Mark for Balloon Dilation Catheter

SurModics won both a 510(k) clearance from the FDA and a CE Mark in the European Union for its 0.014″ low-profile percutaneous transluminal angioplasty balloon dilation catheter.

The device includes the company's Serene hydrophilic coating for low friction and particulates.

SurModics said it plans to launch the device in the coming months.

Mazor Robotics Snags CE Mark for Surgical Platform

Mazor Robotics, a Caesarea, Israel-based manufacturer of surgical robotic systems, announced it has received CE Mark approval for its Mazor X Surgical Assurance Platform.

The platform, which received 510(k) clearance as a Class II device in 2015, is a guidance system for spine surgery with 3-D planning tools, precision mechanics pre-op analytics software, and intraoperative surgical arm verification.

Mazor X will be marketed and sold in Europe by the company's commercial partner Medtronic.

FDA Blesses Heart Pump For Right Heart Failure

The FDA approved Abiomed's PMA for its new Impella RP heart pump.

The device is designed to deliver flow and pressure without the need for surgical insertion. It stabilizes a patient's hemodynamics by providing more than four liters of blood per minute.

It is the only percutaneous temporary ventricular support device for treating acute right heart failure that has received the agency's approval, according to Abiomed.

Arkis Wins FDA Clearance For CerebroFlo Catheter

Arkis Biosciences' new catheter intended for external ventricular drainage of cerebrospinal fluid has received FDA marketing clearance.

CerebroFlo is the first neuro catheter to incorporate Endexo, a catheter technology for reducing protein adhesions and activation with demonstrated success in in vitro studies.

Arkis was awarded an exclusive license of the Endexo technology from Interface Biologics for neurological cerebrospinal fluid applications.

Stryker Wins FDA Clearance For 3D-Printed Fusion Cage

Stryker has obtained 510(k) clearance for its Tritanium C 3D-printed interbody fusion cage.

The new implant, intended for treating cervical spine cell attachment and proliferation in patients with degenerative disc diseases, is designed to reduce stiffness, minimize subsidence and contain bone graft.

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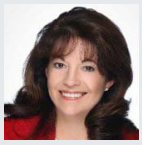
FDA SPEAKERS:

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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