INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

President Signs Device User Fee Renewal Bill

A bill reauthorizing the FDA's drug and medical device user fees for the next five years became law Aug.18 when President Trump signed it.

The bill, given near-unanimous approval by Congress, was the culmination of two years of work and negotiations with industry.

The FDA Reauthorization Act of 2017 (FDARA) is expected to bring in $1.42 billion in fees — about a quarter of the agency's budget, over the next fiscal year — including a 45.2 percent increase in medical device fees over the $126 million anticipated from MDUFA this fiscal year.

Title VII of FDARA contains specific provisions relating to device inspection, including a pilot program allowing the FDA to certify and audit conformance testing laboratories. It also directs the HHS to ensure the uniformity of inspection processes and

(See **User Fee**, *Page 2)*

Singapore Launches Device Priority Reviews, Pre-Market Consultations

Singapore is introducing a pre-market consultation scheme and a priority review mechanism for medical devices.

The move is part of an effort to attract more devicemakers and bring more novel devices to market.

The Medical Devices Branch of Singapore's Health Sciences Authority began accepting priority review applications for medical devices Aug 1. Class A devices and those incorporating medicinal products are not eligible for the priority review scheme.

Devices can qualify for the priority review pathway if they:

- Address priority healthcare areas in cancer, diabetes, ophthalmic disease, cardiovascular disease or infectious disease; or

(See **Reviews**, *Page 4)*

User Fee, *from Page 1*

standards, as well as notify establishments of a pending inspection "within a reasonable time" before it occurs.

CDRH Director Jeffrey Shuren, in a blog post last week, said FDARA supports the agency's efforts to establish a "flexible and more efficient path to market for certain new medical device accessories, to enable new and innovative accessories to come to market more rapidly and enable accessories to be used with a wide range of devices – creating important options for patients."

The bill funds the individual programs that cover inspections and reviews of medical devices, drugs, generics, biologics and biosimilars, as well as more than a third of the agency's approximately 14,000 employees — and includes provisions for hiring 230 additional staff in the next five years.

The Senate voted 94-1 Aug. 4 for the measure that had passed the House with a voice vote in July, H.R. 2430, as a way to expedite the process instead of considering its own, separate version.

The newly authorized user fees will apply to applications received by the FDA on or after Oct. 1. — Ana Mulero and Conor Hale

FDA Reports Uptick In Pediatric Device Approvals

The FDA approved a total of 13 premarket approval applications (PMA) and humanitarian device exemption (HDE) applications for pediatric use in 2016 — up from 11 approvals in 2015, the agency reported, in a newly released annual report to Congress.

The FDA approved more of such applications last year than it has since 2011.

The majority of approvals (68) were for PMAs, with only 3 being HDEs. The number of applications for treating, diagnosing, or curing a disease or condition within a subpopulation of pediatric patients totaled 65, according to the report.

Among the only two applications that were intended solely for pediatric use and exempted from user fees was the first wearable defibrillator, the LifeVest Wearable Defibrillator, manufactured by ZOLL Manufacturing Corporation. The device alerts patients prior to delivering a treatment shock if it detects a life-threatening rhythm through dry, non-adhesive sensing electrodes.

Read the full report here: www.fdanews.com/08-24-17-PediatricDevices.pdf.

Cybersecurity Bill Draws Support From Stakeholders

A recently introduced cybersecurity bill for medical devices is attracting some support — at least from the medical community.

The Medical Device Cybersecurity Act of 2017 (S. 1656), introduced last month by Sen. Richard Blumenthal (D-Conn.), aims to address the problem of device manufacturers who "knowingly or unknowingly" sell devices that fail to safeguard patient records and health.

Among other provisions, the bill calls for an annual "cyber report card" for devices and mandated testing prior to sale. The report card would include a cybersecurity risk assessment conducted by the manufacturer or a third party, explaining the risks and clinical hazards.

The cyber report card would include:

- A description of any cybersecurity evaluation conducted on the device, including any testing of the device, who conducted the evaluation, and the results.
- An indication of whether the device is capable of being remotely accessed.
- A description of any manufacturer controls that address known common vulnerabilities.

The WannaCry ransomware attack "shined a bright light on the vulnerabilities in the healthcare sector and more specifically with medical devices," said Deborah Stevens, chief security officer at Tufts HealthPlan and chairperson of the board at the Association for Executives in Healthcare Information Security, which supports passage the bill.

"Initially, I actually liked the FDA's approach of building collaboration and allowing manufacturers to develop their own path forward," said Axel Wirth, technical architect for Symantec Corporation. However, too many manufacturers do not see themselves as security partners to healthcare providers and "think there is still 'no business case' in investing in security. So, looking at the entire spectrum, I have to admit that we probably need the legislative pressure in order to move forward."

Devicemakers are unequipped to develop and maintain appropriate cybersecurity controls for their products, according to the Healthcare Industry Cybersecurity Task Force's Report on Improving Cybersecurity in the Healthcare Industry. No company within the industry is able to "provide a comprehensive information sharing solution to the entire industry," the task force found.

The Chertoff Group, a security and risk management advisory firm, noted that "many industry providers are small or medium-sized businesses with little to no cybersecurity expertise or ability to process significant amounts of information," which means manufacturers would need to outsource their cybersecurity needs in order to meet the requirements of the act. The group projects that the use of connected devices or remote patient monitoring will grow at an annual rate of 47.9 percent.

Read the text of the bill here: www.fdanews.com/08-23-17-CybersecurityBill.pdf.
— Donna Scaramastra Gorman

FDA Recognizes UL 2900 Cybersecurity Standard

The FDA added the UL 2900 cybersecurity standard for medical devices to its list of recognized standards. The standard covers assessments of network-connectable devices for malware, software limitations and vulnerabilities.

Medical device applicants may now include their conformity with the standard as part of their registration in the U.S. market.

The standard reflects consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements, the agency said, in an Aug. 21 *Federal Register* notice.

The notice includes several updates and corrections made to the list of existing recognized standards, which the agency will continue to modify at least once a year.

Read the full list here: www.fdanews.com/08-24-17-UL2900Standard.pdf.

Reviews, *from Page 1*

- Are designed and validated to meet unmet clinical needs such that there is no existing alternative treatment or means of diagnosis; or they represent a breakthrough technology that provides a clinically meaningful advantage over existing technology on the market.

Devices that meet both criteria would see a 25 percent reduction in the number of working days for approval by mid-2018, and a 35 percent in the number of working days by the end of 2019, the HSA said.

For example, Class B devices would see a 120-day review compared to 160 days for the normal review; Class C devices under the priority review would see a 165-day review compared to the normal 220 days, and Class D devices would see a 235-day review instead of a 310-day review.

Fees Increased

Fees would increase 15 percent over the current fee for devices that meet the first criteria. Class B devices would pay S$4,100 (U.S. $3,010), Class C devices would pay S$6,600 (U.S. $4,845), and Class D devices would pay S$13,200 (U.S. $9,690).

Devices that meet the second criteria would pay 50 percent more compared to the current fee. Class B devices would pay S$5,300 (U.S. $3,891), Class C devices would pay S$8,600 (U.S. $6,313), and Class D devices would pay S$17,100 (U.S. $12,553) under the priority review pathway.

The application process is a simple "opt-in" selection under the current pre-market application process. The application will be reviewed, and if the agency requests further information or clarification, the devicemaker must respond within two weeks or it will be dumped into the normal route under the non-priority process.

The HSA is also offering pre-market consultations to allow devicemakers to seek regulatory advice during the development stage.

The HSA will offer clarification on regulatory requirements, including regulatory strategy, device claims, safety/performance studies, sterility, biocompatibility, risk management and clinical trials. Devicemakers may request a meeting at any time during the device development process, and the consultation can apply to one specific device or a group of devices to be used together.

The agency said the consultation is not intended to be an endorsement of any validation plans, test protocols or results discussed in the meeting – and it does not guarantee approval.

A second pre-submission meeting is suggested so devicemakers can get feedback on their dossiers and supporting documents before they submit their applications to the HSA.

There are fees associated with face-to-face meetings with the HSA team. For development consultations, which can last up to two hours, devicemakers would pay S$500 (U.S. $367) per device. For pre-submission consultations, which last about an hour, devicemakers would pay S$200 (U.S. 147) per application.

Appointments should be arranged five months before the suggested appointment date, and documents should be submitted 30 days before the appointment.

Read the HSA notice here: www.fdanews.com/08-24-17-Singapore.pdf.

PEOPLE ON THE MOVE

Insulet Corporation appointed **Michael R. Minogue** and **James C. Mullen** to the company's board. Minogue is CEO, president and chairman of Abiomed. He previously served with GE Healthcare, where he holds three patents and spent 11 years in sales, marketing, product development, information technologies and software/service operations. He currently serves on the board of AdvaMed and as chairman of the Medical Device Innovation Consortium. Mullen is CEO of Patheon, which recently announced an agreement to be acquired by Thermo Fisher Scientific.

Australia Reports More Infections Associated with Heater-Cooler Devices

Australia's Therapeutic Good Administration issued an update on its product review investigation of heater-cooler devices after more patients were found to be infected with *Mycobacterium chimaera* infections following heart surgery.

The TGA has narrowed the investigation to heater-cooler devices intended to be used for cardiac bypass surgery, where blood is circulated outside the body and infused with oxygen and returned to the patient. The devices are used to control blood temperature during surgery.

Initial product safety reviews suggest the water tanks could become contaminated with bacteria, and patients were likely infected when bacteria in the water tank became airborne. The water is not intended to come in contact with patients.

The six confirmed cases in Australia were associated with Stockert Heater-Cooler 3T heater-cooler units manufactured before September 2014.

The following heater-cooler devices were withdrawn from the Australian market: Zoll Circulation's Coolgard; Chalice Medical's Paratherm; Medos Medizintechnik's DeltaStream; and Sorin Group's Stockert Heater-Cooler 3T and Stockert Heater Cooler 1T (*IDDM*, May 19).

The Australian Commission on Safety and Quality in Health Care issued a notice to health care facilities in October 2016 on the proper cleaning and disinfection procedures to mitigate risk of infection. It instructed hospitals to keep records and perform routine maintenance on the heater-cooler devices. At the time, roughly 50 individuals worldwide had become infected following surgery.

The UK's Medicine's and Healthcare Products Regulatory Agency also issued guidance calling on users to ensure that a full local risk assessment is conducted and a local quality assurance program is implemented for the use of heater-cooler units. The agency requested that HCUs be monitored for harmful bacteria, and that suitable cleaning and disinfection regimes are implemented (*IDDM*, Feb. 24).

The TGA said in its recent update that more than 100 individuals have been severely infected globally since 2013. In fact, more than one-third of the devices used to control blood and organ temperatures during open heart surgery may be contaminated.

LivaNova, which manufactures one of the most commonly used heater-cooler units, responded to the research by developing a three-part plan to resolve the issue. The company said it would modify the device design to include internal sealing and a vacuum system, implement a no-charge deep disinfection service and loan users a new device at no charge (*IDDM*, June 19).

Read the TGA update here: www.fdanews.com/08-22-17-Australia.pdf.

DHS Flags Hacking Risk in Philips' Radiation Monitoring App

The Department of Homeland Security issued an advisory over major software vulnerabilities in two versions of Philips Healthcare's web application DoseWise Portal (DWP) that can give hackers access to protected electronic patient health information.

The software is used in the U.S., Australia, Japan and Europe for simplifying the analysis of collected radiation exposure doses. Philips was made aware of the vulnerabilities after receiving a complaint and vulnerability report from a user.

The DHS said the app can be exploited remotely by an attacker with low skill. But the company, in a separate advisory, said "elevated privileges" are required for an attacker to access the system files.

The company plans on releasing an update version of DWP 2.1.1.3069 with a new authentication method and without any password vulnerabilities. User passwords for version 1.1.7.333 will be changed and encrypted with Philips' support.

The DHS advised using defensive measures with the current DWP versions to lower the risk of hacking, such as reducing network exposure and isolating all medical and remote devices located behind firewalls from business networks.

Japan Builds Ties With International Regulators

Japan's Pharmaceuticals and Medical Devices Agency has been ramping up its regulatory training activities with overseas regulators, and it inviting international regulators to a medical device seminar in Tokyo, Nov. 6-10.

The seminar is intended for medical device and in vitro diagnostic reviewers from overseas regulatory authorities. The event will cover topics ranging from regulations and safety measures to consultations and product reviews. The agency also plans small group discussions among participants.

The agency said 28 regulators from 11 countries participated in a previous seminar in June at the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs in Tokyo. Participants included regulators from Brazil, China, Chinese Taipei, Hong Kong, Malaysia, Myanmar, Philippines, Saudi Arabia, Singapore, Thailand and Vietnam. The program included a site visit to observe a patch manufacturing facility and its quality control measures.

Meanwhile, China and Japan have been in active discussions over device regulations. Officials from the China FDA met with Ministry of Health Labor and Welfare officials in mid-July to discuss how the two countries could strengthen cooperation.

Work Begins on New Medical Device Manufacturing Zone in India

India is moving ahead with a plan to boost its medical device manufacturing sector, and work has begun on a 270-acre state-of-the-art park in Andhra Pradesh dedicated to medical device manufacturing.

The zone will include several scientific facilities like gamma irradiation, electric safety testing, biomaterials testing, 3-D design and printing labs in close proximity to more than 200 manufacturing units. Contracts for all the scientific facilities have already been signed with the respective service providers and the first model factory is expected to be ready by mid-October.

The zone will include an expo hall, convention center, and warehouse space to "provide a holistic ecosystem for growth of the medical device manufacturing industry in India."

483 Roundup: FDA Cites Three Firms For Quality, Documentation Failures

The FDA issued Form 483 reports to three devicemakers over inadequate quality procedures and documentation.

Hebei Pukang Medical Instruments: The FDA cited Hebei Pukang Medical in Hebei, China for its design control and quality processes.

The agency issued a Form 483 following a January inspection of the electric hospital bed manufacturer's facility.

The company's Class II AC-powered adjustable hospital beds did not go through the design control process, and the firm had not established design control procedures, according to the Form 483.

The firm has been shipping the AC-Powered Adjustable Hospital Beds to the U.S. for 10 years.

The agency also cited the firm for lack of CAPA procedures or device history records. Investigators found several cases of beds manufactured for the U.S. market with no device history records to show compliance with the device master records.

Other deficiencies included damaged pumps on wheeled stretchers, an infant hospital bed with the wrong frame and rust on a hydraulic bed. The firm also conducted no quality audits to ensure its quality system was compliant and effective.

Invacare: The FDA faulted Invacare on its supplier controls and quality documentation.

The agency issued the devicemaker a Form 483 following a May/June inspection of its Elyria, Ohio, facility. The inspector found Invacare's supplier controls procedure failed to define levels of control or quality requirements for affiliates, with the documentation stating the only affiliate requirement was to be listed on the Approved Supplier List.

The supplier files were also insufficient, lacking required documentation such as completed supplier agreements, and procedures did not define how a supplier is moved from "approved" to "conditionally approved" or "restricted" status.

Invacare Way failed to adequately control all of its suppliers, the FDA stated in a report that resulted from a recent inspection of the medical device manufacturer's procedures.

The agency outlined specific examples of Invacare's flawed and outdated control procedures, including the lack of "all necessary quality documentation" in its supplier files and the use of an expired protocol.

Investigators also found the company's motor supplier has been listed on "restricted" approval status since 2012 and currently uses a protocol that expired in 2013. The manufacturer promised to address the issues.

The Metz Dental Laboratory: The Metz Dental Laboratory in Columbus, Ohio drew a Form 483 for problems observed in a May 16-22 inspection, including a lack of design validation procedures.

The facility failed to verify that the design output met design input requirements, the agency said.

The company also lacked a design history file and a device master record for the Metz Appliance device.

The FDA also noted the company's device history records did not include all of the labeling applied to each device. The agency also found inadequat4 document control procedures

The facility's device history records did not include all of the labeling applied to each device. For example, the usage and home care instruction and seating instructions for the Metz Appliance were not included in the device history files.

In addition, not all the firm's quality documents were processed in accordance with the firm's document control procedure. For example, the design plan, design control traceability matrix, preliminary hazard analysis, design specifications, and bill of materials were not identified and added to the quality document master index.

Read the three Form 483s here: www.fdanews.com/08-25-17-ThreeForm483s.pdf.

APPROVALS

Globus Scores 510(k) Approval For GPS Guidance System

Globus Medical secured 510(k) approval from the FDA for its GPS robotic guidance and navigation system.

The device, the Excelsius, works with three different imaging technologies to integrate implants and instruments. It is compatible with pre-operative, intra-operative and post-operative CT and fluoroscopic imaging.

The company plans a worldwide launch and is increasing investment in R&D, technology acquisition and distribution channels following the approval.

FDA Clears Dictum Health Portable Spirometry System

Dictum Health received 510(k) approval for the last stage of its IDM100 Medical Tablet.

The last step, spirometry, completes the tablet's cardiopulmonary capabilities.

The portable device is intended for use with pediatric and adult patients with supervision by healthcare professionals. It has the same accuracy as in-hospital exams, improving outcomes and cutting readmission risk, according to the company.

Creo Gets FDA 510(k) Nod On Speedboat RS2 Device

Creo Medical Group has secured FDA 510(k) clearance for its Speedboat RS2 device and CROMA platform.

The Speedboat RS2, which enables minimally invasive endoscopic removal of cancerous and precancerous lesions, was cleared ahead of schedule, according to the firm.

Creo CEO Craig Gulliford said the early approval gives the company confidence to move forward with the devices it has in development.

Medtronic Gets CE Mark for CRT Leads

Medtronic received a CE Mark for its Attain Stability quad cardiac resynchronization therapy leads.

The leads are MRI safe and designed for CRT defibrillators and pacemakers. They are cleared for use with 1.5T and three Tesla scans. They include a side-helix that can be affixed in veins of several sizes.

Medtronic has begun a limited European launch, with the first commercial implants performed at the Haukeland University Hospital in Bergen, Norway. The company has launched a global clinical study to determine the lead's safety and effectiveness in heart failure patients.

Bioventrix Scores IDE Nod for Revivent TC

BioVentrix announced the FDA granted it investigational device exemption approval for its Revivent TC transcatheter ventricular enhancement system.

The company has launched a safety and efficacy trial for the system, which is designed to treat ischemic cardiomyopathy. The system eliminates the need for cardiopulmonary bypass or heart incisions, according to BioVentrix.

BioVentrix enrolled the first patient in its trial, with the first procedure performed at Papworth Hospital in the United Kingdom. The company will enroll 120 patients at 20 sites across the U.S. and the UK.

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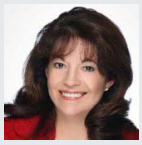
Principal and General Manager, DL Chesney Consulting, LLC

JULIE LARSEN
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)

DANA CORRIGAN, J.D.
Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)

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., Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)

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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