INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Court Injunction Bars Qiagen From Marketing Its NGS System in U.S.

A federal district court has granted Illumina's request for a preliminary injunction to stop Qiagen from marketing its GeneReader NGS System in the U.S.

Illumina claims its '537 patent, which covers labeled nucleo-tides used in DNA sequencing technology, was infringed by Qiagen and its subsidiaries when it developed the GeneReader NGS System, which it planned to distribute later this year.

Illumina accused Qiagen of infringing four different claims with its GeneReader product. The '537 patent claims a method for labeling nucleotides using an "azido group" as the protecting group, rather than a phosphate group.

The U.S. District Court for the Northern District of California found that Illumina's "likelihood of success on the merits is a probability of fifty-one percent or more."

(See **Illumina**, *Page 2)*

Industry Skeptical of Reference Databases In FDA Draft Guidance for NGS-Based Diagnostics

Although industry overall commended the FDA for developing guidelines for next-generation sequencing technologies for infectious disease diagnostics, stakeholders questioned whether the agency's reference-grade databases would be sufficient to detect the vast majority of pathogens in the near future.

Microbiologics said in its comments that the reference databases listed in the draft guidance, such as the FDA-ARGOS and the NIST microbial standard reference materials, are not at a capacity to meet current diagnostics needs.

After extending the comment period from Aug. 11 to Sept. 12, the FDA received 10 comments on the draft guidance. Released May 13, the draft guidance spells out how the agency plans to regulate diagnostics that detect infectious disease organisms, antimicrobial resistance and virulence markers (*IDDM*, Aug. 22).

(See **Comments**, *Page 4)*

Illumina, *from Page 1*

Qiagen began marketing its GeneReader NGS system in April 2016, and it referred to Illumina's product in its marketing materials, stating that the GeneReader worked in the "same way as Illumina's machines, flooding the sample DNA with fluorescently labeled nucleotides and imaging the results."

"Although Illumina established a strong brand in the market for DNA sequencing products, Qiagen's GeneReader began to compete with several of Illumina's sequencing products, specifically in targeting clinical laboratories, where affordable desktop sequencing devices had just taken off," court documents said.

Illumina argued that Qiagen's GeneReader could interfere with Illumina's brand reputation and usurp its business opportunities.

The market for DNA sequencing is expected to grow substantially in the near future, and Qiagen has a foothold in the market due to its other product lines. Now, as the doors to the market have swung open, Qiagen seeks to usurp Illumina's position in the market with pirated technology, Illumina charged.

Qiagen said Illumina's four-year delay in seeking the injunction undermines its argument that it would suffer irreparable harm without the injunction.

The judge disagreed, holding that Qiagen's launch of the GeneReader was plagued by a series of false starts, delays, and reformulations, and the validity of the '537 patent hung in limbo until the Federal Circuit upheld a Patent Trial and Appeal Board decision on Intelligent Bio-Systems' IPR challenge just weeks before Illumina pressed for the injunction

"Illumina's motion is well-timed, seeking to halt Qiagen's assault on the market at its inception, before it can irreparably change the face of the market."

Qiagen argued that the motion should be denied because Illumina has not yet suffered irreparable harm. The court said that the purpose of an injunction is to prevent harm from occurring in the first place, not to remedy irreparable harm that has already occurred.

The court also said that "Illumina has demonstrated a real risk that Qiagen could capture and redefine the market with its pirated technology."

"Although Qiagen's invalidity arguments are not frivolous, this order finds that Illumina is likely to defeat them, particularly in light of Qiagen's burden to prove invalidity with clear and convincing evidence. Thus, this order finds Illumina is likely to succeed on the merits and now turns to the equitable considerations for a preliminary injunction." — Tamra Sami

Combination Products Added To FDA's 2016 Guidance Lineup

The FDA will provide advice on comparative analyses for drug-device combination generic products before the end of 2016.

The guidance added to the FDA's agenda is intended to shed light on how generics makers can conduct comparative analyses for the device component of a combination product.

The agency's announcement of the guidance follows increased concern over the FDA's review of generics for Mylan's EpiPen, which in less than a decade rose in price by about 400 percent.

Specifically, Reps. Fred Upton (R-Mich.), Joseph Pitts (R-Pa.) and Tim Murphy (R-Pa.) asked the FDA how ANDAs for combination products are reviewed and how many ANDAs the agency received and rejected for generics of the EpiPen (*IDDM*, Sept. 12).

The House Oversight and Government Reform Committee is summoning Mylan CEO Heather Bresch to explain the company's pricing practices for its EpiPen autoinjector device at a Sept. 21 hearing on Capitol Hill.

Read the revised agenda here: www.fdanews.com/09-13-16-GuidanceAgenda.pdf. — José Vasquez

Design Change, Validation Found Lacking at InterX Technologies

The FDA found deficiencies in design-change procedures, validation and design verification documentation during a June inspection of InterX Technologies.

The Richardson, Texas-based maker of handheld battery-operated neurostimulation devices for pain management received a five-item Form 483 at the conclusion of the inspection.

The FDA investigator found that a change in the liners was made to the firm's sterile, cutaneous gel electrodes without adequate documentation. As a result, the firm failed to understand how the release strength of the liner to the gel was characterized, but it still distributed the products to the market.

The inspector noted that due to the strong bond of the liner, the gel was pulling away from the carbon layer when the liner was removed.

Validation was also found lacking for the InterX1000 and InterX Personal Sport handheld devices. Standard operating procedures indicated that individuals with clinical expertise would validate the devices, but there was no evidence of expert validation.

Design verification results also were not documented in the firm's design history file, and conflicting data were observed for a software safety test for the InterX Personal device line, the 483 said.

"Although regression tests indicated all steps passed, I observed variances and/or deviation for certain test steps conducted in the initial test cases prior to regression testing," the inspector wrote. He also noted that fail results were not accounted for as variances and anomalies in the design verification test summary.

The 483 also pointed to inadequate procedures for design reviews and corrective and preventive actions.

For example, the firm's standard operating procedures note that for design reviews, at least one reviewer should be present who does not have responsibility for the design. But the FDA inspector observed design review records that documented the design transfer phase of the InterX Personal 1000 device that lacked an employee who was independent of the design stage.

Finally, the FDA cited the firm for failing to establish adequate CAPA procedures. Nine nonconformities were documented in 2014, and four in 2015, but five out of the nine and two of the four were still awaiting disposition at the time of the inspection.

The nonconformance investigations included critical suppliers and involved nonconformities such as brittle plastic caps, contaminated switches, bag mislabeling, missing plates for electrode caps, a missing LED and intermittent power issues.

Read the Form 483 here: www.fdanews.com/09-07-16-InterX483.pdf. — Tamra Sami

FDA Issues Final Guidance On COPD Biomarker

The FDA said that plasma fibrinogen can be used as a biomarker in interventional clinical trials examining patients at high risk for exacerbations or all-cause mortality in chronic obstructive pulmonary disease.

The biomarker can be used by drug developers in submissions of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker, the agency said in final guidance published Sept. 13. A draft version of the guidance was published in July; FDA said it received no public comments.

Fibrinogen, a protein produced by the liver, is a major factor in the formation of blood clots. Measured at baseline, the prognostic biomarker should be considered with other subject demographic and clinical characteristics, including a prior history of COPD exacerbations, as an enrichment factor in these trials, the FDA said.

The use of plasma fibrinogen levels in clinical trials was evaluated by CDER's Biomarker Qualification Program.

Fibrinogen was qualified using multiple assays, and an optimal enrichment threshold has not been determined, the guidance says. — Conor Hale

Comments, *from Page 1*

The Critical Path Institute said the regulatory-grade reference database requirements for microbial identification and antimicrobial resistance are undefined and quite different, and it suggested the two concepts be separated out.

Oxford Nanopore said that an "overly prescriptive approach to individual performance metrics (which will vary widely between pathogens, sample types and sequencing technologies) may fail to capture the benefits of newer technologies." It suggested instead focusing on the properties and performance of technologies overall in the intended-use cases.

Roche Diagnostics echoed that sentiment and was critical of the FDA's approach to regulating NGS in vitro diagnostics for infectious disease via a systems approach. Such an approach would limit innovative tools, because manufacturers often specialize in areas such as target enrichment, instrumentation and bioinformatics pipelines.

"This approach is diametrically opposed to FDA's expressed policies and precedent," Roche said.

It urged the agency to adopt a more flexible regulatory pathway that enables developers of NGS assays or bioinformatics pipelines to develop and evaluate their products using existing and innovative NGS instrument platforms.

The Critical Path Institute said the draft guidance appears to be specific to whole genome sequencing, but it asserted that targeted sequencing "may make more sense for diagnostic applications." It suggested that the agency develop a section devoted to targeted sequencing.

The institute also said the guidance does not contain a discussion on subpopulation analysis for antimicrobial resistance.

Exempt from Premarket Notification?

Roche said the agency should consider exempting Class II infectious disease NGS-based tests from premarket notification requirements under certain circumstances. It explained that the agency took this approach for NGS-based germline guidance, and it should follow the same pathway since the risks associated with such tests would be similar.

Oxford Nanopore said the guidelines appear focused on centralized clinical laboratory-delivered testing based on traditional, short-read technologies and don't take into account newer, portable, real-time, long-read DNA sequencing technologies, including those based on nanopore sensing.

The company stressed that a "point-of-care device with a rapid workflow" has the potential to deliver rapid results, which would provide numerous benefits.

The guidance was drawn from stakeholder input during an April 13, 2015, meeting that stressed the need for more advanced testing to better detect and identify infectious disease organisms. Stakeholders stressed that next-generation sequencing can replace previous methods with a single approach (*IDDM*, May 16).

The comments can be read here: www.fdanews.com/09-15-16-Comments.pdf.— Tamra Sami

Appeals Court Strikes Down Treble Damage Award in Stryker Lawsuit

A federal appeals court struck down a treble damage award to Stryker in its lawsuit against Zimmer Biomet for infringement of three patents associated with its pulsed lavage devices.

The U.S. Court of Appeals for the Federal Circuit affirmed a jury's findings on patent infringement, but it reversed the jury's "exceptional" finding and vacated the treble damage award and attorney's fees.

The appeals court was reconsidering the case after it was vacated and remanded in June by the U.S. Supreme Court, which rejected the Federal Circuit's review framework for damage awards.

The case dates back to 2010, when Stryker charged that Zimmer's Pulsavac Plus devices infringed various claims of three patents (329, 807 and 383). The U.S. District Court for Western Michigan ruled in favor of Stryker, finding infringement of patents 807 and 383.

The question of the third patent went to trial, and a jury awarded $70 million in lost profits and found that Zimmer willfully infringed all three patents.

In August 2013, the district court affirmed the jury's verdict and awarded $70 million to Stryker in damages plus royalties.

The court also found the case "exceptional" and awarded attorney's fees to Stryker and imposed a permanent injunction. The total award came to $228 million.

The Sept. 12 federal appeals court decision upheld the willfulness determination but said that it did not necessarily follow that the violations were exceptional. The court vacated and remanded the district court's exceptional finding, and with it the treble damages award.

Read the federal appeals court ruling here: www.fdanews.com/09-14-16-StrykervZimmer.pdf. — Tamra Sami

Australia's TGA Issues Guidance on Registering Class IV In Vitro Diagnostics

Australia's Therapeutic Goods Administration released guidance on its website to help sponsors through the process of registering Class IV in vitro diagnostics in the Australian Register of Therapeutic Goods.

Sponsors need to first submit manufacturer evidence, and the TGA needs to approve it before applications can be submitted.

The agency accepts the following certificates as manufacturer's evidence:

- A Conformity Assessment Certificate issued by the TGA for Schedule 3 Part 1 (full quality assurance) or Schedule 3 Part 4 (production quality assurance);
- An EC certificate issued by an EU Notified Body for Annex IV.3 (full quality assurance) or Annex VII (production quality assurance) of the EU IVDD 98/79/EC; or
- An ISO 13485 medical devices quality management system certificate. A compliance certificate can be issued by a certification body that is also a Notified Body for the purposes of the IVDD 98/79/EC, a Canadian Medical Devices Conformity Assessment System recognized registrar or a certification body that is accredited by a signatory of the International Accreditation Forum Multilateral Recognition Arrangement to perform ISO 13485 certification.

The module walks sponsors through the process for working with the agency's business services using the on-line portal to submit an application.

Sponsors will need to submit an evidence number, unique device identifiers and other supporting information.

Read the TGA guidance here: www.fdanews.com/09-15-16-TGAguidance.pdf. — Tamra Sami

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Holes in Packaging Compromise Sterility of Ecolab Klerpack Syringes

The UK's Medicines and Healthcare products Regulatory Agency is warning that sterility may be compromised in Ecolab's Klerpack BD syringe multi-pack due to small holes in the packaging.

If holes are present, there is a risk that the syringe may no longer be sterile. The holes cannot be detected visually, and there is a high likelihood of syringe packaging being compromised, Ecolab said.

The company alerted users to quarantine affected stock and perform a risk assessment for unexpired products using the affected batches of syringes.

The risk assessment should take into account the specific use of the syringe; the nature of the product (such as expiry period; susceptibility to microbiological proliferation); route of administration and patient population; likelihood of product shortage; and the impact of that shortage on patients.

Read the recall notice here: www.fdanews.com/09-15-16-MHRAsafetynotice.pdf.

NICE Recommends IUD For Emergency Contraception

The UK's price watchdog says women should be advised that a copper intrauterine device is more effective than the morning-after pill for emergency contraception.

The National Institute for Health and Care Excellence said the IUD, or coil, can be used as an emergency method of contraception for up to five days after unprotected sex.

NICE said that in 2014, 95 percent of emergency contraception issued by reproductive health services was for the morning-after pill.

In response, the agency developed a new quality standard that sets out key areas where advice to women on contraception needs to improve.

"We know that the coil is the most effective method of emergency contraception available, so we must all continue to ensure that ease of access to this method is increased and maintained across services from a variety of providers," said Sue Burchill, head of nursing at Brook, a UK provider of sexual health services for young people.

"The advantage of the coil, on top of being more effective, is that it can be retained as long-term contraception. Some can even be left in place for 10 years," said Jan Wake, a general practitioner and member of the guideline development group.

The quality standard includes advice on contraceptive information and methods, emergency contraception, contraception after abortion and contraception after childbirth.

Read the quality standard here: www.fdanews.com/09-15-16-NICE.pdf. — Tamra Sami

Australia Warning for Smith & Nephew Tandem Bipolar Hip System

Australia's Therapeutic Goods Administration is warning of the potential need for revision surgery due to parts becoming detached in Smith & Nephew's Tandem Bipolar Hip System.

The firm discovered that a number of devices were manufactured with a retainer groove that is out-of-specification. The nonconformance could lead to three potential failures, including the device not assembling properly and the head being too tight and not moving freely. Both of these failures would be identified during preparation before the implantation surgery.

The other potential failure is parts detaching after implantation surgery, even though the device may appear to be assembled properly during surgery.

If this failure occurs, it could result in adverse events and require additional surgery.

See the affected lot numbers here: www.fdanews.com/09-15-16-TGAalert.pdf. — Tamra Sami

BRIEFS

FDA Approves Obalon Balloon System

Obalon Therapeutics received approval from the FDA for its Obalon Balloon System, which is a non-surgical and fully reversible device for weight loss.

The Obalon Balloon System consists of a balloon folded inside a capsule that is swallowed by the patient, with no sedation or anesthesia required.

In clinical trials, roughly 65 percent of patients who received the device experienced clinically meaningful weight loss of at least 5 percent of their total body weight.

The Obalon Balloon System is expected to be available in early 2017.

Japan Approves Medtronic Cardiac Monitor

Japan's Ministry of Health, Labour and Welfare approved Medtronic's Reveal LINQ Insertable Cardiac Monitor.

The country's pricing body also agreed to reimburse the insertable cardiac monitoring system.

Designed to help physicians diagnose irregular heartbeats, the device is one-third the size of a AAA battery and is placed beneath the skin through an incision in the upper left side of the chest.

In Japan, the cardiac monitor will be used to diagnose unexplained fainting and cryptogenic stroke.

Medtronic Drug-Coated Balloon Cleared for ISR

The FDA approved Medtronic's IN.PACT Admiral drug-coated balloon for treating in-stent restenosis in patients with peripheral artery disease.

The expanded indication for the device marks the first approval in the U.S. for a drug-coated balloon (DCB) to treat ISR. The agency approved the device in 2014 to treat superficial femoral and popliteal arteries.

ISR occurs when a stent is placed in the artery to restore blood flow but over time plaque can form in and around the stent. This condition is estimated to occur in up to 40 percent of all stents placed in the superficial femoral artery, according to Medtronic.

VisuMax Femtosecond Laser Approved

Carl Zeiss Meditec's VisuMax Femtosecond laser was approved for the small incision lenticule extraction (SMILE) procedure to reduce or eliminate nearsightedness in patients 22 years of age or older.

The VisuMax Femtosecond laser removes a small amount of eye tissue to permanently reshape the cornea. A femtosecond laser makes cuts within the cornea, creating a disc-shaped piece of tissue that is removed through a small incision in the surface of the cornea.

Ossix Volumax Receives FDA 510(k)

Datum Dental's Ossix Volumax dental regenerative has received FDA 510(k) clearance.

The product is designed to restore lost volume in guided bone regeneration, guided tissue regeneration and soft tissue augmentation cases.

SyntheticMR's MAGiC Gains 510(k)

SyntheticMR's partner, GE Healthcare, has received 510(k) clearance for MAGiC, a customized version of SyntheticMR's SyMRI Image software marketed by GE Healthcare.

MAGiC (Magnetic Resonance Image Compilation) is the industry's first multi-contrast magnetic resonance (MR) technique to be cleared by the FDA.

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2016 SUMMIT HIGHLIGHTS

4 panels featuring current and former FDA officials, including:

- **New for 2016** - FDA Inspections – A New, Modern Record Review Technique
- **New for 2016** - After the Election: A Look Ahead to What a New Administration Could Bring and the Impact on the FDA
- Effective Management of Front and Back Inspection Rooms – Secrets You've Never Heard and Answers to Questions You've Always Wanted to Ask
- A Day in the Life of an FDA Field Investigator – How Inspectors Prepare and Approach Assigned Inspections

How the FDA's Realignment Program Impacts You

The Latest on the FDA's Re-organization of the Inspectional Corps and How Could it Impact Your Daily Operations and Your Upcoming Inspection

Measuring the Real Business Impact of Quality Metrics

Plus twin tracks for drug/biologics and device manufacturers and 2 pre-conference workshops, focusing on drugs and devices.

FEATURED EXPERT SPEAKERS:

MARC-HENRI WINTER, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA (invited)

ARMANDO ZAMORA, Deputy Director, Office of Enforcement and Import Operations, Office of Global Regulatory Operations and Policy, ORA, FDA (invited)

DAVID CHESNEY, Principal and General Manager, DL Chesney Consulting, LLC

BRYAN J. COLEMAN, Senior Director Pharmaceutical & device Consulting Services, EAS Consulting Group

TERESA GORECKI, VP Global Business Quality, Janssen Pharmaceuticals

STEVEN GROSSMAN, President of HPS Group, LLC, former Deputy Assistant Secretary for Health, HHS, former Health Staff Director, Senate HELP Committee

KAY HOLCOMBE, Senior Vice President, Science Policy, Bio

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JOHN TAYLOR, Principal, Compliance and Regulatory Affairs, Greenleaf Health LLC

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Pre-conference Workshops Agenda

WEDNESDAY, NOVEMBER 2

DRUGS & BIOLOGICS TRACK

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

FDA warning letters begin with a summary of the failed inspection, and then quickly dismiss a firm's effort to respond. In a very public way, FDA categorizes one company after another as "inadequate," "insufficient," "lacking" and worse.

Handling an inspection successfully requires a strategy designed to get the FDA investigator in and out as quickly as possible. The longer an FDA investigator is on site, the worse your chances are of avoiding a FDA 483.

And when the 483 arrives, do you know how to respond in less than 15 days to avoid a warning letter?

A defensible response can be hard to assemble – and get through internal review – with enough time to beat the enforcement clock at FDA.

This workshop gives you proven, practical techniques for fast, flexible and flawless inspection handling and responses that exceed FDA expectations and support your side. You'll learn how to prepare for an inspection, how to encourage the investigator to see you in a "state-of-control," and how – if the worst happens – to go from 483 observation to FDA's coveted untitled letter – and avoid the warning letter publicity.

Attendees Will Learn:

- Critical inspection preparation techniques to take – even if you get surprised by FDA
- Hidden tactics FDA investigators use to test your controls
- How to speed the inspection to minimize the risk of 483 findings
- Key elements of a realistic regulatory inspection handling SOPs
- How to write an inspection response designed to reduce warning letter likelihood
- Red flags FDA looks for in your inspection response

Attendees Will Receive:

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

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

MEDICAL DEVICES TRACK

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

ISO 13485:2016 – Understand the Concepts of Risk and Their Applications

The new QMS standard, published in March, alerts manufacturers to the presence of risk in almost all operations—from design control to supplier management to software validation and more. While it does not specifically address the concept of risk management (you'll find that in ISO 14971:2007), ISO 13485:2016 makes it clear that manufacturers must be aware of the opportunity for risk in all they do.

This workshop examines the concept of risk as presented in the new standard and explains how to apply it in the quality management systems. Through examples that illustrate ISO 13485:2016's requirements, interactive exercises that help solidify understanding, and a unique set of checklists that cover all the QMS bases, attendees will learn:

- How the QMS standard integrates with the risk management standard in ISO 14971:2007
- How the implementation timeline may differ from country to country
- How inclusion in MDSAP could impact inspections of U.S. manufacturers
- How the European version differs from the international version

Quality systems expert Dan O'Leary explains ISO 13485:2016's concept of risk in clear terms that will prepare you for the changes ahead.

Dan O'Leary, President, Ombu Enterprises

What Past Attendees Have Said About the FDA Inspections Summit:

"This Summit is in the top 3 meetings I have attended. Looking forward to next year."

"I loved the ease to interact with FDA investigators and others involved in the conference."

"I really enjoyed having the opportunity to ask FDA investigators questions in a long open session."

Day 1 Agenda

THURSDAY, NOVEMBER 3

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

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson John Avellanet, Managing Director & Principal, Cerulean Associates LLC

8:45 a.m. – 9:30 a.m.

FDA Realignment Program Is In Effect: How That Impacts You

Under its recent organizational changes, FDA is developing specific action plans to align its centers and the Office of Regulatory Affairs with new strategic goals and increased demands. The plans include critical actions to fulfill the agency's mandate in training; compliance and enforcement; imports; and information technology, all of which will affect all areas of medical products inspection and poses these vexing questions:

- What impact will the transition to a commodity-based and vertically integrated regulatory program have on inspections?
- What will be the major changes in MDSAP?
- How will new training and certification requirement impact medical product inspections?

9:30 a.m. – 11:00 a.m.

FDA Inspections – A New, Modern Record Review Technique: A Panel Discussion

It is becoming more common for investigators to review your documents and data maintained in your QMS in real time. An investigator may request electronic copies of your records on a memory stick. Or request the ability to browse through your complaint management system to review documentation. Are you prepared?

This panel will discuss:

- FDAs new ability to analyze your data – by sorting it and spotting trends which they can then link to potential issues in other quality management systems.
- The lack of SME preparation – as you don't know what they will look at you can't rehearse each document and be ready when questioned.
- Increased document challenges – some documents don't stand on their own without significant explanation.

(cont.)

- The importance of writing plain, simple English – all documents need to convey what you need without interpretation. Writing clearly and consistently has never been more important.

11:00 a.m. – 11:20 a.m. | BREAK

11:20 a.m. – 3:30 p.m.

Two Concurrent Breakout Tracks

Track 1 — Drugs & Biologics

Track 2 — Medical Devices

3:30 p.m. – 3:50 p.m. | BREAK

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

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

DRUGS & BIOLOGICS TRACK

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

11:30 a.m. – 12:15 p.m.

Understanding OPQ's New Inspection and Reporting Plan and Organizational Structure

This session will discuss how CDER's new "super" Office of Pharmaceutical Quality plans to divvy up inspections among its three offices, and how it will incorporate pre-approval inspections into the OPQ team review to standardize quality assessments.

Attendees will learn about OPQ's new inspection protocol that will focus on expert investigator-developed questions and assessment practices and how mobile technology will be incorporated to support investigators during inspections

12:15 p.m. – 1:00 p.m.

Quality-Driven Data Integrity Approach In the EU and US Inspections

Data integrity requirements have been strongly enforced in recent years by almost every regulated agency in the pharmaceutical environment: the expectations have been clarified in a number of guidances issued by MHRA, WHO and most recently by the FDA. Therefore, the requirements for data integrity are now considered a fundamental expectation and strictly connected to the relevant predicate rules.

This presentation will provide real life case studies and examples you can use to base your control measures upon the potential impact of data on product quality and patient safety.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

How to Deal with Difficult Inspections

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

3:30 p.m. – 3:50 p.m. | BREAK

MEDICAL DEVICES TRACK

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

11:30 a.m. – 12:15 p.m.

Update from the Office of Compliance at CDRH: Priorities for 2017

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

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

12:15 p.m. – 1:00 p.m.

Medical Device Single Audit Program Pilot (MDSAP) In Full Swing

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the U.S., Canada, Australia, Brazil, the EU and Japan.

So far, one audit has been conducted and others are in the pipeline, and responses from participants have been positive.

One big advantage to the MDSAP is that because audits aren't performed by the U.S. government, their results aren't public record — and there's no Form 483 that can be requested via the Freedom of Information Act.

Attendees will hear first-hand progress on the program from the FDA's Marc-Henri Winter, who will share lessons learned from the pilot program. Devicemakers will learn what to expect from an audit and how multiple sites should be audited.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask: A Panel Discussion

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms
- Handling data requests, particularly for electronic records — best practices from inspectional veterans

(cont.)

- Being a SME in your job doesn't make you an inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

A Day in the Life of FDA's Field Investigators — Current Field Investigators Explain What They Look For and Why: A Panel Discussion

Ever wonder what an investigator is thinking when she receives the next inspection assignment? Investigators typically create inspection plans based on a company's previous Form 483s, warning letters, responses to warning letters, consumer complaints and recalls. But they also study a company's website, including literature, products manufactured and recent press releases.

This presentation will give you a glimpse into the inner workings of an investigator's mindset before, during and after your inspections.

Attendees will learn:

- What does an investigator's prep package contain?
- What research – both internal and external – do they use to prepare themselves for your company, plant and products?
- What do they look for once inside your plant?
- How they apply QSIT and other inspectional techniques to the QSR
- Why they include items in the EIR and Form 483 and how they take into account your comments

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

8:00 a.m. – 8:30 a.m. | BREAKFAST

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson

8:45 a.m. – 9:30 a.m.

FDA's Office of Regulatory Affairs: Enforcement Update

This presentation will focus on ORA's Office of Enforcement priorities for 2017, and how the office approaches the enforcement process. This session will educate attendees on how they can more proactively prepare for FDA investigators before they arrive.

Attendees will learn:

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

9:30 a.m. – 10:15 a.m.

The Regulatory Intelligence Platform

Being prepared for inspections means that you understand both the internal and external data that affect your products. Now more than ever there is an expectation that companies are analyzing and acting on this data

In this session, you'll learn:

- What is regulatory intelligence and how does it affect your business
- How to leverage regulatory intelligence as integral part of inspection readiness
- What data is available through open systems and what you should be looking at
- What should be included in your regulatory intelligence platform

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

After the Election: A Look Ahead To What a New Administration Could Bring and the Impact on the FDA

In this election year, if almost anyone tells you that they know who the next president is going to be or exactly what's going to happen at FDA in 2017 and beyond is probably just whistling in the wind. But these panelists bring incredible inside knowledge and decades of experience in the nitty-gritty of Washington politics to provide an educated analysis of FDA operations. Here's what you'll hear discussed at this lively, interactive session about the future of FDA:

- Will there be increased efforts at global regulatory harmonization or more country-by-country compliance
- Will there be increased agency enforcement or more reliance on voluntary industry compliance
- Will there be increased legislation or rollbacks in regulation

12:00 p.m. | CONFERENCE ADJOURNS

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

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

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The FDA Inspections Summit — now in its 11th year — has fast become the "go-to" event for regulatory, compliance and quality assurance professionals and the one place to discover the tools and techniques to improve your inspectional readiness.

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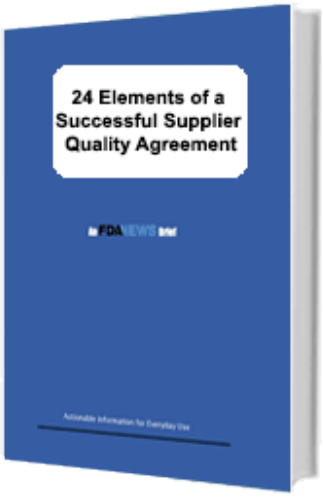

24 Elements of a Successful Supplier Quality Agreement

Supplier quality is a fundamental topic of perennial importance.

Your agreements with suppliers must be written and executed to cover every possible contingency and ensure that the materials that go into your products are exactly what you require and are available when you need them.

Today's minor mistake by your supplier could easily turn into tomorrow's major recall. And if you don't catch all the oversights in your quality agreement, odds are the FDA will.

In this FDANews Brief, 20-year industry veteran Steven Sharf, explains the elements that need to go into your quality agreement:

1. Calibration and Maintenance
2. Batch Documentation
3. Change Control
4. Deviations / OOSs
5. Field Alerts / Recalls
6. Material Inspection / Testing / Release
7. Labeling Controls
8. Rejected Materials
9. Complaint Handling
10. APR / PQR Inputs
11. Audits / Inspections
12. Specifications
13. Subcontracting
14. Dispute Resolution
15. Warehousing and Distribution
16. Technical Transfer
17. Validation / Qualification
18. Record Retention
19. Sample Retention
20. Reprocessing / Reworking
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22. Stability Programs
23. Contact List
24. Responsibility Matrix

Use this 24-point plan to make sure you've covered all your bases and keep your suppliers well in hand. Order your copy today.

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