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INSIDE THIS ISSUE

Industry, CDRH Officials Agree: Guidance Development Is in Need of Overhaul

The FDA's process for developing guidance documents needs a major revamp to speed efforts along and integrate feedback from stakeholders earlier, devicemakers and CDRH officials concluded during a Thursday public workshop.

Currently, a new guidance document must clear at least 21 separate hurdles between conception and final implementation, including reviews by multiple levels of center staff and, frequently, input from elsewhere in the FDA. The process takes more than two years even in a best-case scenario, said CDRH policy advisor Ruth Fischer — 14 to 15 months to prepare and clear a draft, three months for public comments, and then another year or so to review the comments and finalize the draft. It's "like watching a glacier go by," she said.

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High Court Hands Down Rulings In *Nautilus, Limelight* Patent Cases

The U.S. Supreme Court ruled Monday on two patent cases with potential ramifications for medical devicemakers.

In *Limelight Networks v. Akamai Technologies*, the court found that induced infringement is only possible if one party performs every step of a patent. The ruling overturns a Federal Circuit decision that said liability could apply to companies that only perform some of the steps.

"This decision makes inducement of infringement more difficult to prove, because it must be tied to the underlying direct infringement," Christine Lehman, an attorney with Finnegan, Henderson, Farabow, Garrett & Dunner, tells *D&DL*. "This case will likely have the biggest impact on method claim, particularly those that involve steps that are performed by different entities."

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AdvaMed Seeks to Increase Clout In China With On-Site Office

AdvaMed has hung up its shingle at an office in Shanghai, hoping to play a more proactive role in regulatory and reimbursement policies impacting devicemakers in China.

The office is AdvaMed's first physical location in China, in terms of a "bricks and mortar" facility, spokesman Jon Dobson told *D&DL*, adding that AdvaMed's efforts in China and its focus on the country are long-standing. "The office itself is a continuation of these efforts that further solidify our commitment to this important market."

The trade group aims to partner with Chinese authorities and other stakeholders to streamline regulations, ensure appropriate reimbursement for medical technologies and harmonize ethical business practices, AdvaMed President and CEO Stephen Ubl said in announcing the opening of the China office June 2.

"Our efforts in China will help ensure patient access to advanced medical technologies and will benefit both local Chinese companies and importers," he said.

Lynn Jiao, executive director of AdvaMed's China program, will head the new office, which will operate with a limited staff initially but could expand down the road, according to Dobson. Jiao has more than 20 years of experience working with the device industry and has been affiliated with AdvaMed since early 2013.

The Shanghai office is AdvaMed's latest foray into China. The group previously established a China Council comprised of member companies' senior representatives in the country and has shared a staff position with the American Chamber of Commerce in Beijing since 2009.
— Jonathon Shacat

Guidance Development, *from Page 1*

Assistant Commissioner for Policy Leslie Kux concurred, saying the guidance development process increasingly resembles rulemaking. To get advice out more quickly to devicemakers and other stakeholders, she suggested the agency consider developing less formal documents than FDA guidance, along the line of "recommendations" or "thinkings."

Still, it's difficult to shorten the guidance development timeline while still allowing for feedback, said Nancy Stade, CDRH deputy director for policy. Several stakeholders suggested that the FDA create an open docket before publishing a draft guidance to ensure that drafts reflect common industry concerns. But Stade said that soliciting comment before issuing a draft might not lead to actual time savings, given the time lag to get things into the *Federal Register*.

On the other hand, early industry input could help on highly technical device-specific guidances, said Angela Krueger, an associate director in the Office of Device Evaluation.

AdvaMed, which supports the open docket proposal, pressed CDRH officials to consider several other modifications to guidance development. Janet Trunzo, senior executive vice president of technology and regulatory affairs, said the FDA should establish a routine frequency for reviewing and revising guidance documents and note when a document is under review. She also recommended that guidance documents be more closely coordinated with international standards.

To ensure guidance documents don't languish in draft form forever, the FDA should be required to withdraw the draft or reopen the comment period after 30 months, said University of Minnesota law professor Ralph Hall. "If something is taking that long, there's a reason for it. A reopened comment period would either be an incentive to get things done, or help explain why there's a concern."

Stade said the agency will consider the various suggestions and may host further workshops on the topic in the future. — Elizabeth Orr

CDRH Funding Held to FY 2014 Levels Under House Measure

CDRH would see no funding boost for fiscal 2015 under the most recent FDA funding proposal to emerge from Congress.

The House Committee on Appropriations voted 31-18 late last month to approve a fiscal 2015 funding bill that includes $2.583 billion in discretionary funds for the FDA, a $23 million boost over current levels. The bill allocates $321 million for CDRH, which would match 2014 allocations, according to an analysis by the Alliance for a Stronger FDA.

In addition, the House anticipated CDRH would receive $128,282,000 in user fees in fiscal 2015.

Steve Grossman, executive director of the Alliance, expressed concern about the flat CDRH appropriations. "CDRH appropriation isn't growing as devices become more complicated. The FDA needs more resources, and that affects everybody in the space," he says.

However, he commends the committee for discussing the artificial pancreas development project in the bill — an effort the Alliance sees as a good example of the type of innovative research the FDA should be participating in.

In the funding measure, the FDA is praised for recently approving Medtronic's MiniMed 530G system with Threshold Suspend automation and encouraged to "continue collaboration with key stakeholders to ensure that artificial pancreas systems are further developed, rested and approved."

While many of the other congressional instructions to the FDA focus on the agency's food and drug programs, a few will affect CDRH. For example, the bill asks the FDA to:

- Quickly follow up on a November 2011 meeting of the National Mammography Quality Assurance Advisor Committee by reviewing data on how breast density affects the quality of mammograms;
- Work with the Department of Homeland Security and U.S. Customs Office to design a trusted trader program that will ensure that medical products from "highly compliant importers" can be cleared by FDA officials quickly and with minimal requests for additional data; and
- Report to Congress monthly on the amount collected in user fees, as well as on how those fees are being spent.

The FDA funding bill, part of a package for agricultural and nutritional programs, now heads to the House floor. In May, the Senate Appropriations Committee advanced its own funding package, which would give the agency a $36 million boost over fiscal 2014 discretionary levels. That measure provides CDRH with $318 million in funding.

To read the House bill report, visit www.fdanews.com/ext/resources/files/05/05-30-14-House-Report.pdf. — Robert King, Elizabeth Orr

India's CDSCO Issues Compensation Formula for Trial-Related Deaths

Manufacturers conducting clinical trials in India would be required to pay significant compensation for deaths of some subjects during a study, under a rule released last week by the Central Drugs Standard Control Organization. The rule, which must still be approved by the Supreme Court, lays out the conditions and amounts of payment.

The formula CDSCO has outlined considers the individual's age, risk factors including severity of the disease, the presence of coexisting medical conditions and the duration of the disease at the time of enrollment.

Payouts would range from nearly $7,000 to about $124,000 in most situations. In extreme cases where a patient has a 90 percent or greater chance of dying within 30 days, compensation

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Patents, *from Page 1*

Lehmen notes there are quite a few medical device-related patents with method claims, and these claims "could become more difficult to enforce. Certainly, proof of direct infringement is much more important now."

Lehman previously told *D&DL* that if the justices reverse *Limelight*, many patent claims will no longer be valuable. The case involved claims that two users are needed to operate the technology as described in the patent — e.g., a device in which the user performs the final assembly step.

The high court also ruled Monday in *Nautilus v. Biosig Instruments*, in which it was asked to decide whether certain technology was complex enough to be patented. The court vacated the judgment of the U.S. Court of Appeals for the Federal Circuit and remanded the case for further proceedings consistent with its opinion.

The decision in this case outlines a new test for when a patent will be held "indefinite" and thus invalid, Lehman says. The Supreme Court rejected the Federal Circuit's standard that patents are indefinite if they are "insolubly ambiguous," instead favoring a standard where a patent can be found indefinite if its claims would not reasonably inform someone skilled in the art about the scope of the invention.

Although the ruling doesn't have a direct impact on medical devices, "I expect that we will see more defendants challenging patents on the grounds of indefiniteness based on this decision," Lehman says.

In its complaint, Nautilus argued that the claim term "spaced relationship" was open to multiple interpretations. Biosig countered, claiming the term was clear if read in light of the specification accompanying drawings. The Supreme Court remanded the case so the Court of Appeals can reconsider it "under the proper standard," the ruling says — April Hollis

India, *from Page 3*

is set at roughly $3,500. The plan, however, does not guarantee compensation for all patients.

The formula was devised by an independent expert committee convened last year to examine trial-related serious adverse events and recommend compensation levels (*D&DL*, Jan. 24). Once the formula is implemented, the committee will be responsible for investigating patient deaths and submitting a report to CDSCO within 30 days of the event. CDSCO will then have 30 days to inform the trial sponsor of its decision, triggering a 30-day deadline for payment.

Vince Suneja, a founding partner at Two-Four Insight Group, an international research and advisory firm, says the formula is not necessarily new, as it mirrors a proposal that was recommended last August. The new development, however, is considered positive from an industry perspective as it creates certainty, which, in turn, helps establish models for use by insurance companies.

"If something happens in a clinical trial, you are not automatically awarded this money," he says, pointing to various factors that may determine payment. "Was there some kind of negligence, or was there something that was not appropriately implemented during the clinical trial?"

Suneja says it is difficult to say whether the amount of compensation is "enough" from the patient's perspective, as there is so much income disparity in India. Patients could range from a healthy volunteer to someone who is in a dire situation.

When it comes to nonpermanent injuries, the onus will be on sponsors to prove that the injury was not trial-related, according to a provision released last month. Compensation for such injuries would take into account the nature of the injury, transportation costs and any lost wages.

To view the formula, visit www.fdanews.com/ext/resources/files/06/06-14-compensation.pdf. — Jonathon Shacat

FDA: Some Cellulite Surgical Tools Move to Class II after De Novo Bid

Manufacturers of some cellulite-reduction devices may have an easier time bringing their products to market, thanks to an FDA reclassification order.

The final rule, published in Tuesday's *Federal Register*, assigns Class II status to devices known as "powered surgical instruments for improvement in the appearance of cellulite." These are surgical tools that slice through subcutaneous tissue, causing a short-term improvement in the appearance of body fat in the buttocks and thighs of adult women.

The decision stems from a petition for reclassification filed by Cabochon Aesthetics as part of the company's de novo application. Initially, in March 2011, FDA said the company's Cabochon System would have to be regulated as a Class III device because it was not substantially equivalent to any product then on the market. Cabochon responded the following October, asking that the system be moved to Class II under de novo rules. The FDA approved the device as Class II in July 2013 via the de novo process, and is now codifying that classification with publication of the final rule.

Potential risks of these devices include mechanical injury, infection, electrical shock, electromagnetic interference, adverse tissue reaction and use error, the rule notes. To mitigate the risks, manufacturers must follow certain special controls:

- Nonclinical testing to ensure the device meets design specifications and performance requirements, and to demonstrate its durability and mechanical integrity;
- In vivo evaluation to demonstrate device performance, including mechanical safety and blood loss at the treatment site;
- Biocompatibility, electrical safety and electromagnetic compatibility assessment;
- Labeling that includes a summary of in vivo evaluation data and any device-specific warnings; and
- Sterility and shelf-life testing of all device components that come into contact with patients.

The final rule does not exempt powered cellulite removal tools from premarket notification, so companies still must file a 510(k).

Cabochon was acquired in March by Ulthera, a Mesa, Ariz., maker of therapeutic ultrasound systems. The companies say patients' satisfaction with their appearance climbs from 0 percent before treatment with the Cabochon System, to 69 percent two weeks post-treatment and 94 percent at one year.

The final rule takes effect July 3. View the reclassification order at www.fdanews.com/ext/resources/files/06/06-09-14-cellulite.pdf.
— Elizabeth Orr

Steris Warned After Data Falsification

Steris Corporation was warned by the FDA for several violations related to employee data manipulation and falsification.

The company's Libertyville, Ill., facility opened an investigation in July 2013 to look into instances where product was overdosed but later made to appear within specification. However, the inspection fell short because it did not include a review of all potentially affected products, according to the May 22 warning letter posted recently online.

Steris also initiated local nonconformances for three instances of data manipulation at three separate facilities, but did not bump the issue to a corporate CAPA before the FDA's inspection, the letter says. This would have allowed the company to address the issue across all STERIS Isomedix gamma irradiation facilities.

And while the company identified about 89 runs as possibly affected, it did not inform all identified customers that testing of their products may have been subject to data falsification, the letter adds.

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Steris, *from Page 5*

The company, which sterilizes medical devices, did not adequately review its quality system in light of the data manipulation. The FDA notes that operators and material handlers were directly responsible for reading dosimeters that they placed on the product processing runs. "The analysis of the dosimeters is the primary quality control activity that determines the calculated dose for dosimeters in a gamma irradiation run and is the basis for product release," the warning letter says.

Operators and material handlers report through operations personnel, but this created a conflict of interest when an employee reported that a run was overdosed and an operations team leader "provided guidance on how to falsify the absorbance readings so that they would appear to be within specification," the letter says. "This reporting structure removes the Quality Unit from the ability to approve/reject irradiation runs based on dosimetry analysis and hinders the identification and correction of potential quality problems by the Quality Unit."

The FDA said it would conduct a follow-up inspection to verify that Steris has implemented a revised procedure requiring a reading by a second independent operator.

The Oct. 29, 2013 to Jan. 8 inspection also identified 2,900 records that were missing from the main table of the company's Dosimetry Measurement Application module between its installation at the facility on Nov. 4, 2011, and Nov. 6, 2013. "Each missing record represents an attempt at creating a dosimeter record," the letter says, adding that "of the 2,900 missing records, 1,623 records/dosimeters … contained dosimetry data and were intentionally deleted from the DMA module."

Other citations in the letter note that dosimeters are not routinely cleaned before analysis and an operator was seen putting an ungloved thumb on a dosimeter, thus introducing a fingerprint.

Steris has provided detailed responses to the FDA and is making improvements to the quality system at the Libertyville facility, spokesman Steve Norton told *D&DL*. The company does not believe the letter will have a material impact on financial results.

View the warning letter at www.fdanews.com/ext/resources/files/06/06-03-14-Steris.pdf. — April Hollis

HeartWare Lands Warning Letter For Validation, CAPA Concerns

Coronary device company HeartWare International said Wednesday that it received an FDA warning letter related to the company's Miami Lakes, Fla., manufacturing facility.

The June 3 letter, which followed a January FDA inspection, cites the plant for deviations related to validating device design, including device labeling, corrective and preventive action implementation procedures, maintaining records on investigations and validating computer software used in production and quality systems.

HeartWare said it will respond within the 15-day timeframe requested by the FDA, and will implement new and enhanced systems and procedures and take any additional steps required to settle the agency's concerns.

"HeartWare is committed to providing the highest quality products in compliance with FDA regulations to ensure the safety and welfare of patients who rely on our devices, and we are dedicating the resources necessary to address the items discussed in the letter," said HeartWare CEO Doug Godshall.

Leerink Partners analyst Danielle Antalffy called the warning letter "as benign as possible within the context of [warning letters]," because it won't take HeartWare's ventricular assist device off the market or halt ongoing clinical trial enrollments.

This is the second setback for HeartWare in the last several months. In April, the company recalled batteries used in the HeartWare VAD due to premature depletion (*D&DL*, May 2). There is no apparent connection between the recall and the warning letter, which has not yet been made public. — Elizabeth Orr

FDA Opens Some Drug Event Data; Device Reports to Follow Soon

The FDA is trying to encourage mobile app and web developers to give wide distribution to adverse events information by providing the data in an easy-to-use electronic format.

The agency kicked off the effort, called openFDA, on June 2. The initial database contains millions of reports of drug adverse events and medication errors that previously were available only through difficult-to-use reports or Freedom of Information Act requests.

Data on device adverse events will be added by the end of the summer, along with datasets on food incidents, product recalls and product labeling, says FDA spokeswoman Andrea Fischer.

Technology specialists, such as mobile application creators, web developers, data visualization artists and researchers, will be able to quickly search, query or pull massive amounts of information instantaneously and directly, the FDA says. Project goals include spurring innovation, advancing academic research, educating the public and protecting public health, says Walter Harris, the FDA's chief operating officer and acting chief information officer.

The program is being phased in using adverse drug event and medication error reports submitted to the FDA from 2004 to 2013.

The portal is designed to let web developers search text within the data and get results ranked as would happen with a standard search engine. "It's an easier way to get the data, and it's more usable," Fischer tells *D&DL*.

So far, the project won't require any new effort on the part of manufacturers, as the portal relies on existing reporting schemes. But at least one observer says that openFDA is "only partially open FDA."

Peter Pitts, president of the Center for Medicine in the Public Interest, says the more data that the FDA makes available, the better. But with openFDA, the agency is simply giving people easier access to information that is already available in some other form.

For example, the program does not explore any role the FDA might play in facilitating access to clinical trial data. Such information is not generally made public because it is considered "commercially confidential," but the agency could make redactions to studies and then release the appropriate material, Pitts says.

Clearly, the FDA wants to release more information, says Pitts, who served as FDA associate commissioner from 2001 to 2004. "My question is how many human resources the FDA is willing to put toward this project and over what period of time. It becomes a resource question, as well as 'the ability to want to do it' question."

Pitts suggests the FDA collaborate with industry so that the openFDA portal provides access to information available on manufacturers' websites. The FDA could also provide information to help people understand the risk/benefit factors within specific product approvals and answer questions such as why certain products are on the market or were withdrawn, he says.

Visit the site at http://open.fda.gov.
— Jonathon Shacat

Medtronic Payments to Infuse Docs Amounts to 'Racketeering,' Insurer Says

Payments made by Medtronic to physicians who supported use of the company's Infuse bone cement amount to illegal racketeering, a lawsuit filed by insurance giant Humana charges.

The lawsuit, filed March 30 in a Tennessee district court, says Medtronic has spent "hundreds of millions of dollars" on "a sophisticated and deeply deceptive marketing strategy" to encourage use of Infuse and a component of the device known as recombinant bone morphogenetic protein-2, or BMP. These

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Infuse, *from Page 7*

misrepresentations constitute racketeering under the Racketeer Influenced and Corrupt Organizations Act, Humana says.

The suit claims that Medtronic encouraged the publication of articles in scientific journals that falsely supported off-label use of Infuse and related products, and that Humana reimbursed for surgeries using Infuse and BMP based of those articles. Humana also alleges that Medtronic helped hospitals and physicians file fraudulent claims involving the use of Infuse.

According to the complaint, Medtronic paid a total of $210 million to "key opinion leaders" to encourage the off-label promotion of Infuse. One physician allegedly received $28.8 million from Medtronic between 1996 and 2010, when he wrote extensively on off-label use of Infuse. Another doctor, who received $34.2 million, wrote seven peer-reviewed articles on Medtronic spinal technology and presented on the topic at several medical conferences, the complaint says. That physician drew an annual salary of $400,000 from Medtronic, under a contract requiring only eight days of work per year.

The FDA approved Infuse in 2002 for use in spinal surgery using the so-called anterior approach. However, Medtronic has since encouraged the off-label "posterior" use of the product because most spinal surgeries are performed that way, Humana says. Medtronic sales staff told Humana that the "vast majority" of Infuse sales were for this off-label use, the complaint says.

The lawsuit contains 10 counts of wrongdoing, including fraud, off-label marketing, conspiracy, negligent misrepresentation, subrogation liability, violations of state consumer protection statutes, breach of warranty and unjust enrichment. It asks for unspecified compensatory and punitive damages, as well as court costs.

Medtronic called the claims "baseless," saying it will vigorously defend Infuse in court.

"Medtronic vigorously disagrees with any suggestion that the company improperly influenced peer-reviewed published manuscripts," said spokesman Eric Epperson. He added that the company "does not compensate physicians for the use or endorsement of our products, and disagrees with any suggestion to the contrary. The potential risks and benefits of Infuse Bone Graft have been described in the product labeling since 2002, and all payers had access to that information."

This is not the first time Medtronic has been accused of wrongfully promoting Infuse. A 2012 Senate report found the company was heavily involved in assembling studies published to support the use of Infuse and that those articles intentionally minimized adverse events (*D&DL*, Oct. 26, 2012). A 2013 *Annals of Internal Medicine* study found Infuse offered no benefits over traditional surgery (*D&DL*, June 21, 2013).
— Elizabeth Orr

Stryker Conflict Minerals Report Details Supply Chain Scrutiny

Stryker will use ongoing inquiries to continually assess its supplies for conflict minerals, according to a new supply chain policy outlined in the company's first conflict minerals disclosure report to the SEC.

At the same time, the company expects its suppliers to "take all reasonable efforts to source raw materials, components, and finished goods from socially responsible sub-tier suppliers," the report says. The report acknowledges that some necessary conflict minerals may have originated in the Democratic Republic of the Congo and its adjoining countries and might not have come from recycled or scrap sources.

The conflict mineral rule, which took effect in November 2012, requires devicemakers and other manufacturers to publicly disclose if their products include any tantalum, tin, gold or tungsten from the Democratic Republic of the Congo, Central African Republic, South Sudan, Zambia or Angola. The first conflict mineral reports were due May 31.

Stryker's due diligence policy calls for it to follow the Organisation for Economic Co-operation and Development's Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas. The company will encourage its suppliers to follow the guidance as well, the report says. Lawyers have advised medtech companies to follow this guidance and to include plenty of detail on their OECD compliance efforts in their conflict mineral reports (*D&DL*, May 16).

According to the SEC filing, Stryker has created structured internal management systems for its supply chain due diligence, as well as a cross-functional task force to oversee the process. Among the task force's duties is creating a transparency system to help identify Stryker's smelters and refiners. The system will also require suppliers of conflict minerals to identify the minerals' country of origin and describe how they were transported.

The task force has scrutinized Stryker's supply chain for suppliers that are more likely to work with conflict minerals. Suppliers suspected of dealing in conflict minerals were surveyed to identify smelters and refiners that provide the materials, the report says, adding the task force followed up on those that gave inconclusive information.

Compliance Hotline Installed

Stryker has also established a compliance hotline and plans to cooperate with downstream companies and other businesses that use the same suppliers.

While Stryker's due diligence efforts brought in sourcing information on smelters, the data have been inconclusive, according to the company's report. "Stryker is unable to determine whether the necessary conflict minerals in Stryker's products directly or indirectly financed or benefited armed groups in the covered countries," the SEC filing says. "Further, Stryker has been unable to determine the facilities used to process those necessary conflict minerals or their country of origin."

Going forward, Stryker says it will improve traceability by identifying conflict-free refiners and smelters through industry validation schemes, increasing outreach with such entities to learn about their due diligence practices and including provisions in supplier agreements on compliance with the conflict minerals policy and related audits.

The company also will support industry initiatives to assist smelters and refiners, such as conducting spot-checks at their facilities, and will ask smelters to obtain a "conflict free" designation from an industry program, the report says. And it will compare its RCOI results with those from independent conflict-free smelter validation programs, the report adds. — April Hollis

BRIEFS

Lawmakers Question ONC

Health IT regulations proposed by the Office of the National Coordinator for Health IT are getting some congressional pushback. GOP Reps. Fred Upton (Mich.), Joseph Pitts (Pa.), Marsha Blackburn (Tenn.) and Greg Walden (Ore.) sent a letter asking ONC chief Karen DeSalvo to explain the office's authority to regulate health IT, as well as how ONC plans to coordinate with the FDA on regulation of software in medical devices. The letter follows an April 2014 report recommending the creation of a Health IT Safety Center within ONC and an ONC budget proposal that suggested new user fees for Health IT vendors. View the June 3 letter at www.fdanews.com/ext/resources/files/06/06-09-14-ONC.pdf.

STENTYS Buys Deployment Technology

French medtech company STENTYS said Wednesday it is buying the assets of New Jersey-based Cappella Peel Away, including a novel stent delivery system. The catheter involved in the deal allows the SENTYS Self-Apposing stent to be released in the same manner as a conventional balloon-expandable stent. STENTYS plans to integrate the Capella technology into its next generation of stents, set to debut in 2015.

JAMA: ICDs Help Less Sick Patients

Implantable cardioverter defibrillators lead to improved survival in patients with a less severe level of heart failure than are normally recruited for clinical trials, a study published in Wednesday's *Journal of the American Medical Association* finds. The study by researchers at Duke University Medical Center found that after three years, about 51.4 percent of the patients who had been implanted with an ICD had died, compared with 55 percent of non-ICD patients. The 3.6 percent difference is similar to that found in other clinical trials of prophylactic ICDs, the researchers say.

Pregnancy Test Suit to Proceed

A New York federal judge ruled Tuesday that a false advertising case between two pregnancy test companies can proceed. Church & Dwight has charged that promotional material claiming Swiss Precision Diagnostics' Clearblue pregnancy test can estimate how many weeks a woman has been pregnant is inaccurate and violates the test's 510(k) clearance. SPD argues that the FDA is better suited to settle advertising disputes, not the courts. Judge Alison Nathan of the Southern District of New York found in Church & Dwight's favor, saying the court can evaluate the case without violating the FDA's authority.

Hospital to Pay $41M on False Claims

King's Daughters Medical Center has agreed to pay $40.9 million to resolve charges that it falsely billed federal programs for medically unnecessary coronary stents and diagnostic catheterizations. The Department of Justice says that between 2006 and 2011, the Ashland, Ky.-based hospital billed Medicare and Medicaid for numerous unnecessary stenting procedures that were supported by falsified documentation. KDMC allegedly also paid cardiologists unreasonably high salaries, violating the Stark Law. In addition to the financial settlement, KDMC will enter into a corporate integrity agreement with DOJ.

FDANEWS

Customer Service: Kim Williams
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

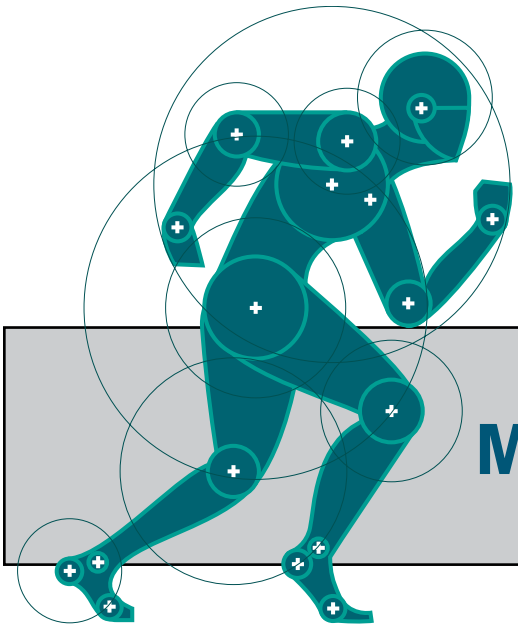
Editor: Elizabeth Orr
(703) 538-7652
eorr@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: April Hollis, Lena Freund, Robert King, Neal Learner, Kellen Owings, Bryan Koenig, Jonathan Shacat

President: Cynthia Carter; **Content Director:** Dan Landrigan; **Executive Editor:** Meg Bryant



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Ron Brown, Chief, Recall Branch, Division of Risk Management Operations, Office of Compliance, CDRH, FDA

Jay Jariwala, Quality System Specialist, Regulatory Compliance Officer, CDRH, FDA

Bill MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA (invited)

Isaac Chang, Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH, FDA (invited)

Sharon Kapsch, Branch Chief, Reporting Systems, Office of Surveillance and Biometrics, CDRH, FDA (invited)

Ann Ferriter, Director, Division of Risk Management Operations, CDRH, FDA (invited)

Jan Welch, Deputy Director for Regulatory Affairs, OC, CRDH, FDA (invited)

Tony Slater, Chief, Field Inspections Support Branch, Division of Analysis Program Operations, OC, CDRH (invited)

Expert Speakers —

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations (Co-chair)

Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA (Co-chair)

Jay Crowley, Vice President and Practice Lead – UDI, USDM Life Sciences; former Senior Advisor for Patient Safety, CDRH, FDA

Vinny Sastri, President, WINOVIA

Dan O'Leary, President, Ombu Enterprises LLC

Karl Vahey, Director of Compliance, International RA/QA, Covidien

Oluwole Edwin, Executive Director, Diagnostic Products, Quest Diagnostics

Patrick Caines, Director, Product Surveillance, GE Healthcare

Pamela Forrest, Partner, King & Spalding

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Heath Rushing, Principal Consultant Adsurgo LLC

Eleventh Annual Medica

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PRE-CONFERENCE WORKSHOP: TUESDAY, JUNE 24, 2014

8:30 a.m. – 9:00 a.m.
Registration and Continental Breakfast

9:00 a.m. – 12:00 p.m.
Harness the Power Text Mining the FDA's Recall Data to Handle Medical Device Recalls

Most pharmaceutical and medical device organizations are analyzing structured numerical (and categorical) data such clinical trials, R&D, process development, process monitoring, sales and marketing, product supply and commercial manufacturing. Structured numerical data is, well, numerous and used throughout most organizations. However, the majority of stored data is not numerical; it is in the form of unstructured text in reports and documents, such as nonconformance reports.

Nonconformance reports are written by different people in different areas of the organization; therefore, these reports often contain different words or phrases to report the same problem. The solution? Develop a document-term (word) matrix for the unstructured data. Use proven statistical tools and methods to "rank" words based on importance and frequency, then "translate" these ranked words and phrases into a "word cloud" that very often displays true root problems for systematic nonconformances. Drug and device companies can also use this information to "cluster" seeming unrelated nonconformance reports, providing a much more thorough analysis of nonconformances as part of a comprehensive CAPA program.

During this workshop, the instructor will use data taken directly from the FDA website to teach attendees how text mining can be used to determine how their products (and other products in their class) are being reported. The example used shows how analysis of recall reports from one medical device company established the words "ventilator," "infusion" and "simulator" as true root causes for one company's medical device recalls. Additionally, the instruction will show how analysis of this unstructured data may provide information on unknown trends and potential problems.

Attendees will:

- Understand how to analyze FDA recall data to narrow root causes down to key words
- Know how to develop and populate a matrix of raw data needed for text mining
- Understand how proven statistical tools and methodologies are used to perform text analytics

Your biggest data can be your best data if analyzed efficiently and correctly.

Heath Rushing, Principal Consultant, Adsurgo LLC

CONFERENCE AGENDA: TUESDAY – THURSDAY, JUNE 24-26, 2014

DAY ONE

12:00 p.m. – 1:00 p.m.
Registration

1:00 p.m. – 1:15 p.m.
Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

1:15 p.m. – 2:00 p.m.
KEYNOTE — FDA's Case for Quality Initiative Update

Reviewing and explaining often-cited 483 violations is not the only way to achieve device quality. Steven Silverman will present FDA device quality-related initiatives that move beyond the inspect-and-cite regulatory model.

Attendees will learn:

- How the Case for Quality Initiative works and how you can benefit from it
- Emerging FDA initiatives that similarly focus on device quality outcomes

Steven Silverman, Director, Office of Compliance, CDRH, FDA

2:00 p.m. – 3:30 p.m.
Panel Discussion: Best Practices in Implementing an Effective Risk Management System

As technologies and innovation push the boundaries for new medical devices, there is an increased emphasis and expectation that such devices shall be free from unacceptable risk to the patient and end user. In addition, many standards and guidance documents point to ISO 14971:2007 as the standard for medical device risk management. An effective risk management strategy, now more than ever, is a necessity for medical device manufacturers.

Attendees will learn:

- Organizational factors that lead to an effective risk management system
- How companies integrate their product life-cycle processes with risk management
- What constitutes an effective risk management file
- Methods companies use to review, validate and improve their risk management systems
- What companies need to do to address the latest in ISO 14971:2007 enforcement — including how devicemakers are struggling with EU compliance

Moderator:
Vinny Sastri, President, WINOVIA
Panelists:
Ann Ferriter, Director, Division of Risk Management Operations, CDRH, FDA (invited)
Jan Welch, Deputy Director for Regulatory Affairs, OC, CRDH, FDA (invited)
Bill MacFarland, Director, Division of Manufacturing and Quality, OC, CDRH, FDA (invited)
Karl Vahey, Director of Compliance, International RA/QA, Covidien

3:30 p.m. – 3:45 p.m.
Refreshment Break

3:45 p.m. – 5:00 p.m.
Panel Discussion: Managing Operations Effectively: Delivering Quality Devices and Always Being Audit Ready

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. In alignment with the recent reorganization of the Office of Compliance, CDRH, the FDA will be prepared to effectively follow up and act on potentially volatile situations to reassure the public that they are providing the public health protection they expect and deserve.

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Attendees will learn:

- 5 key elements to have in place to control your manufacturing processes
- How to create an effective listening system to know how your product is performing and the steps to take when something goes awry
- How to build an effective CAPA system to take corrective action quickly when a problem arises

Moderator:
Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA
Panelists:
Tony Slater, Chief, Field Inspections Support Branch, Division of Analysis Program **Operations,** OC, CDRH (invited)
Oluwole Edwin, Executive Director, Diagnostic Products, Quest Diagnostics

5:00 p.m. – 6:30 p.m.
Networking Reception

DAY TWO

8:30 a.m. – 9:00 a.m.
Continental Breakfast

9:00 a.m. – 9:15 a.m.
Welcome and Introduction by Co-chair Elaine Messa, Executive Vice President, NSF Health Sciences, former Director of the Los Angeles District, FDA

9:15 a.m. – 10:00 a.m.
KEYNOTE — Recalls: Communicating With FDA — What are the Regulatory Requirements and Expectations?
Getting devices off the market that pose a risk to patients is always your first priority. But effectively communicating with the FDA about it is a close second. In this presentation, the chief of the Recall Branch of CDRH will guide attendees though current recall policy. Plus, provide best practices for how to effectively communicate with the FDA. This session will give you a first-hand account of what the FDA expects of you.

Ronny Brown, Chief, Recall Branch, Division of Risk Management Operations, OC, CDRH, FDA

10:00 a.m. – 10:45 a.m.
Medical Device Recalls: Unique Challenges and Opportunities
What some devicemakers commonly call "product enhancements" the FDA might consider a recall. Recalls are defined in FDA regulations, a product enhancement is not. The FDA recently issued draft guidance that could impact your Part 806 recall efforts. The FDA was clear… devicemakers are required to file Part 806 forms if a recall, removal, correction or product enhancement was made "to reduce a risk to health posed by" the device. Even if the event was caused by user error.

Attendees will learn:

- What factors to consider to determine if you are effectively initiating a recall
- How to document the process you go through with product enhancements, servicing or removals to prove compliance
- How to create internal systems that assure you are in compliance at all times

Pamela Forrest, Partner, King & Spalding

10:45 a.m. – 11:00 a.m.
Refreshment Break

11:00 a.m. – 12:00 p.m.
Design Changes Impact Multiple Parts of Your QSR System — Are You Sure You Know All The Implications?
So your company has a procedure for handling design changes — that's good news. But when you make a design change are you documenting the impact of that change on multiple of parts of your QSR system? The bad news is most likely not. From nuanced requirements found in CFR preambles to 510K requirements to QSIT to UDI one improperly considered and document change can cause a cascade of problems. This session will help you understand how your design changes and controls procedures must always be in line with the other parts of your operations.

Attendees will learn:

- The reasoning behind these requirements
- Commonly confused or unknown considerations of production related to design output and design transfer
- The CDRH evaluation of 510(k) changes, its commitment to Congress, and the implications for design control
- Some side effects of the UDI rule that will impact your implementation strategy
- How evaluation design change impact your Risk Management File

Dan O'Leary, President, Ombu Enterprises LLC

12:00 p.m. – 1:00 p.m.
Lunch

1:00 p.m. – 1:45 p.m.
Closing the Loop on Corrective and Preventive Action (CAPA): A Call to Action
CAPA problems continue to be one of the most cited FDA Form 483 deficiencies, generating the single largest number of warning letter citations. A recent industry report breaks down the FDA's 2012 inspection findings into five categories: CAPA (30 percent), production and process controls (30 percent), design problems (15 percent), management issues (14 percent) and other (11 percent). Getting CAPA right remains incredibly important. This session will discuss the importance, requirements and elements of a best-in-class CAPA program, as well as describing how to use CAPA data to help mitigate risk and drive quality in a holistic manner.

Attendees will learn:

- New and updated regulatory requirements and expectations — and how to interpret the latest warning letter enforcement trends.
- How to implement a repeatable, standardized and complete process that can tackle CAPAs and ensure compliance
- The importance of developing closed-loop systems that detect existing potential quality problems and facilitate rapid problem resolution and closure

Jay Jariwala, Quality System Specialist, Regulatory Compliance Officer, CDRH, FDA

1:45 p.m. – 2:30 p.m.
Five MDR Traps That Doom Devicemaker Inspections
FDA inspectors evaluating the adverse event reporting programs at medical device companies are finding a lot of the same problems over and over again. Additionlly the FDA commonly finds weak or missing SOPs and procedure manuals. This presentation will provide you benchmarking data and intel to determine how your organization stacks up if you're ready to pass your next FDA inspection.

Attendees will learn:

- How the agency wants you to define "likely" when assessing whether a malfunction is likely to cause or contribute to a death or serious injury if it reoccurs.
- How to address FDA inspectors' questions during on-site visits when asked what constitutes a reportable event and what does not.

Five" Quality Concerns

ID

- Best practices for structuring appropriate time frames and deadlines into your adverse event reporting programs.
- Why training is key to successful MDR management — how all staff should be trained. This includes anyone answering the phone. They should know what to do if it's an adverse event call.

Patrick Caines, Director, Product Surveillance, GE Healthcare

2:30 p.m. – 2:45 p.m.
Refreshment Break

2:45 p.m. – 4:15 p.m.
PANEL DISCUSSION: Understanding UDI's True Impact Throughout Your Organization
It's no exaggeration to say that the FDA's UDI rule impacts every device company and applies to multiple parts of each organization's quality systems. This is not a rule that can be overlooked. Implementation is mandated in stages over the next few years, but truth be told, many companies are nowhere near compliance. If you're like most device manufacturers, you're working your way through the regs and adapting and changing your internal processes.

This panel will discuss:

- Top challenges industry is facing as they begin to implement the regulations —standardized date format, combo product/kit concerns and more
- When to assign new device identifier and when can you re-used existing ones
- How is GUDID coming along and best practices for inputting your data — what's working and what's not
- And much more…

Moderator:
Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations
Panelists:
Jay Crowley, Vice President and Practice Lead – UDI, USDM Life Sciences; former Senior Advisor for Patient Safety, CDRH, FDA
Dan O'Leary, President, Ombu Enterprises

4:15 p.m. – 4:30 p.m.
Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

SPECIAL FULL DAY TRAINING SESSION!

SUPPLIER QUALITY MANAGEMENT TRAINING

THURSDAY, JUNE 26, 2014

In December 2012, the FDA proposed the creation of a new Division of International Compliance Operations within CDRH's Office of Compliance as part of the center's increased international supply chain focus. Domestic — and overseas — inspections are also ramping up amid mushrooming international component sourcing and overseas contract manufacturing.

8:00 a.m. – 8:30 a.m.
Continental Breakfast

8:30 a.m. – 5:30 p.m.
Medical Device Supplier Qualification and Management — Practical Approaches to Cost-Effective Implementation
The development of extended supply chains raises major issues in risk management. While regulators are looking more closely at device supplier management issues, companies are recognizing the value of risk management in meeting the regulatory requirements.

In addition, risk management can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare by focusing on these important GHTF guidance documents:

- Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008)
- Risk Management Principles in a QMS (GHTF/SG3/N15R8)
- Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010)

These guidance documents provide the foundation, but lack practical details. This workshop gives you the tools and methods you need for a cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management — product risk, business risk, and recalls & liability risk
- How to conduct an on-site supplier audit applying risk management
- How to qualify suppliers that are virtual companies
- Understanding business issues in the supply chain and their risk challenges
- Medical device corrections & removals (recalls)
- How to select and apply supplier metrics and their role in the QMS
- Dealing with FDA record-keeping issues — sponsor vs. supplier

BONUS: Attendees will receive copies of implementation tools, including a process map, sample questionnaire, reevaluation form, audit checklist and more.

Expert Instructors:

John Avellanet, Managing Director & Principal, Cerulean Associates LLC

Dan O'Leary, President, Ombu Enterprises

5:30 p.m.
Training Adjournment

FDANEWS

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Managing the "Big Five" Quality Concerns

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Wright Medical Technology, Inc.

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KAREN KIRBY, Compliance Manager,
Baxter Healthcare

"It was great to have such knowledgeable personnel available for three days to ask questions and have discussions."

DIANE ADINOLFO, QA Project Compliance Manager,
DEKA Research and Development

WHO SHOULD ATTEND

- Quality Assurance/Quality Control
- Manufacturing and Contracting
- Supply Chain Management
- Risk Management and Product Lifecycle Management
- Executive Management
- Regulatory Affairs
- Research and Development
- Compliance Officers
- Consultants/Service Providers

ABOUT THE CONFERENCE CO-CHAIRS

STEVEN NIEDELMAN serves as lead quality systems and compliance consultant to the FDA & Life Sciences practice team at King & Spalding, specializing in regulatory, enforcement and policy matters involving industries regulated by the FDA. Mr. Niedelman retired from the Food and Drug Administration in 2006 after a 34-year distinguished career, where he served as the Deputy Associate Commissioner for Regulatory Affairs and as Chief Operating Officer of the Office of Regulatory Affairs.

ELAINE MESSA is Executive Vice President at Becker & Associates Consulting, Inc. She has more than 30 years of experience in FDA regulation of medical devices, having focused on the development and implementation of compliant Quality Systems for medical devices in the United States. Her most recent position was as the FDA's Director of the Los Angeles District, which is the district responsible for the largest import operations and medical device workload in the US. In total, Ms. Messa spent nearly 16 years in management positions within FDA district offices.

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **Eleventh Annual Medical Device Quality Congress** to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rate, and space is limited. The hotel may run out of rooms before the reservation cutoff date. The discounted rate is also available one night before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 24 hours of the date of arrival or "no-shows" will be charged for the first night's room rate plus tax.

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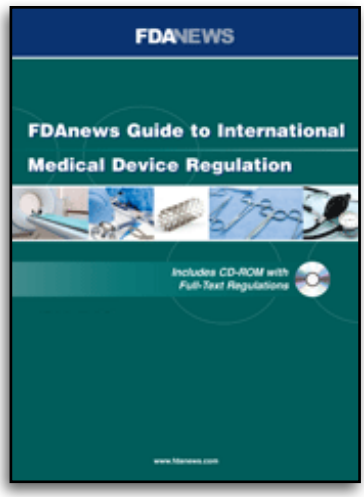

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