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IN THIS ISSUE

FDA Urges Industry to Collaborate To Counter Cybersecurity Threats

The FDA is pressing forward with efforts to combat cybersecurity threats, with the agency releasing draft guidance providing recommendations for monitoring, identifying and addressing vulnerabilities in medical devices once they have entered the market.

In draft guidance issued Jan. 15, the FDA says manufacturers should implement a structured and systematic comprehensive cybersecurity risk management program and respond in a timely fashion to identified vulnerabilities.

In the majority of cases, manufacturers conducting routine updates or patches currently are not required to give the agency advance notification, additional premarket review or reporting. But the FDA would require devicemakers to notify the agency for a small subset of vulnerabilities and exploits that may compromise the essential clinical performance of a device and present a reasonable probability of serious adverse health consequences or death.

(See **Cybersecurity**, *Page 2)*

Exclusive: Trautman Leaves FDA, Moves on to NSF Health Sciences

Following what she calls a "wonderful" 25-year career at the FDA, including serving as the agency's main cheerleader for the International Medical Device Regulators Forum, Kim Trautman has announced that she has taken on a new opportunity at NSF Health Sciences.

Trautman will serve as NSF Health Sciences' executive vice president, medical device international services, where she says she will be able to pursue her passion of training.

"It was an excellent opportunity at the right time," Trautman tells *IDDM*. "The missions of FDA and NSF Health Sciences are very much aligned. NSF Health Sciences is looking to develop a stronger training program, and I am coming on board to expand that."

(See **Trautman**, *Page 2)*

Cybersecurity, *from Page 1*

The FDA does not intend to enforce urgent reporting of the vulnerability to the agency as long as there are no serious adverse events or deaths, the manufacturer notifies users and implements changes to reduce the risk within 30 days, and the manufacturer is a participating member of an information-sharing analysis organization, the draft guidance says.

ISAOs are collaborative groups in which public- and private-sector members can share cybersecurity information.

The draft guidance on postmarket devices follows final guidance issued in October 2014 that contains recommendations for incorporating premarket management of cybersecurity during the design stage of device development. The agency held a workshop with stakeholders Jan. 20 and 21 to discuss the draft guidance and the complex challenges in ensuring device cybersecurity.

The agency is encouraging collaboration. Stephen Ostroff, the FDA's acting commissioner, stressed the need to ensure that medical device systems are protected from intrusions and exploitations, as the devices become increasingly sophisticated, more interconnected and more interoperable.

"We know, for instance, that the risk that the entire healthcare network could be compromised has grown exponentially over time. We also know that it takes work, and it is hard to build cybersecurity into medical devices and systems that are not self-contained at the time that they are actually developed," he said. "As hard as that is, it is probably even harder to maintain cybersecurity after the devices are on the market, because we know that the risks and vulnerabilities and capabilities only increase over time," he said during the workshop.

Beau Woods, a core contributor to a grassroots initiative called I Am the Cavalry, explained there are many pathways to fix a cybersecurity problem, including maintaining a device, eliminating the device from a network, or turning it on only when needed. Ultimately, the solution requires collaboration from the community.

"It is a shared responsibility among everybody in the chain of care delivered. As long as you keep that in mind, I think the option to eliminate risk or remediate risk is down to a controllable level, and the possibility is much greater to succeed," he said.

Comments on the draft document are due by April 21. Read the draft guidance here: www.fdanews.com/01-16-FDA-Cybersecurity.pdf. — Jonathon Shacat

Trautman, *from Page 1*

Specifically, Trautman will be conducting training courses for industry and manufacturers, as well as those to help build competency for auditors and reviewers. She adds that while there already are strong training programs in the U.S. and EU, she will be working to expand training beyond those realms.

Trautman left her footprint at the FDA with her work on IMDRF, which was established in 2011 to accelerate international medical device regulatory harmonization and convergence.

"IMDRF is 'firmly established,'" Trautman says. "It has really gotten its feet on the ground."

She also served as chair of the Medical Device Single Audit Program Regulatory Authority Council, where she will be succeeded by the vice chair from Brazil's ANVISA.

Since MDSAP's inception, the IMDRF has produced nine documents intended to implement the concept of a single audit program. N3, for example, was produced to explain requirements for auditing organizations and individuals performing regulatory audits.

"They are strong fundamental building blocks for any regulator," Trautman says.

Trautman acknowledges that the program will face some challenges, but that is true of any new program. She notes that industry will have to get on board with what regulators will be doing going forward — a process that may take some time. Trautman adds that she will be a "very strong supporter" of MDSAP in the future. — Michael Cipriano

FDA Sets Deadline for Surgical Gown Manufacturers to Submit a 510(k)

Manufacturers of certain surgical gowns must file a 510(k) early next month, with performance testing data to support liquid barrier claims, according to FDA guidance.

A gown that is not intended for use as a surgical gown is a Class I exempt device that is not subject to premarket notification requirements. However, a gown that is intended for use as a "surgical gown" is a Class II device subject to premarket notification, the final guidance says.

Class I gowns must be labeled as a gown other than a surgical gown. Further, if it has statements related to barrier protection, they are for minimal- or low-barrier protection. Class II surgical gowns must be labeled as such, have statements related to moderate- or high-level barrier protection and/or have statements that they are intended for use during surgical procedures.

Manufacturers planning to market Class II gowns should submit a 510(k) by Feb. 7, have the submission accepted by Feb. 22 and obtain clearance by June 6.

The final guidance is largely similar to draft guidance issued last summer (*IDDM*, July 2, 2015). Several comments submitted during the consultation period raised concerns over the Feb. 7 deadline, but the FDA didn't budge.

"We continue to believe this timeframe for submission is appropriate since submitters should already have conducted the testing to support their particular liquid barrier claims," the FDA says.

Read the final guidance here: www.fdanews.com/01-16-FDA-Gowns.pdf. — Jonathon Shacat

MDSAP Implementation On Target for 2017, FDA Says

The International Medical Device Regulators Forum's single-audit program remains on schedule for full implementation in 2017, officials say.

Applications for participation in the Medical Device Single Audit Program have been received from 12 of 13 eligible auditing organizations. Five organizations currently are authorized to conduct MDSAP audits, CDRH spokesman Eric Pahon tells *IDDM*.

MDSAP was developed so that a single audit, performed by an authorized organization, meets the quality management system requirements of multiple regulatory agencies, derived from ISO 13485:2003. In December, the FDA announced it will terminate its ISO 13485:2003 Voluntary Audit Report Pilot program effective March 31, to help manufacturers transition over to the MDSAP (*IDDM*, Dec. 31, 2015).

Meanwhile, Brazil's ANVISA published a resolution earlier this month listing TÜV SÜD America as an authorized company to perform auditing reports.

ANVISA will accept the MDSAP audit reports as a substitute for routine agency inspections. The validity of ANVISA's authorization expires on Dec. 31, explains Roberto Rodrigues, an attorney with Licks Advogados in Rio de Janeiro. In December, ANVISA recognized BSI Group as an accredited auditor under MDSAP.

Canada still is planning to implement MDSAP as the sole mechanism for manufacturers to demonstrate compliance with QMS requirements.

MDSAP will replace the current Canadian Medical Devices Conformity Assessment System program, even in situations when a manufacturer intends to sell only in Canada, according to a notice issued by Health Canada in December.

Effective Jan. 1, 2017, Health Canada will accept certificates issued under both CMDCAS and MDSAP. However, only MDSAP certificates will be accepted starting in 2019.

MDSAP pilot full members are the U.S., Australia, Brazil, Canada and Japan.

Read ANVISA's resolution here: www.fdanews.com/01-16-Anvisa-RE80.pdf. Health Canada's notice is here: www.fdanews.com/01-16-Canada-Notice.pdf. — Jonathon Shacat

Domestic Indian Device Companies Welcome Duty Hike on Imports

Indian medical device manufacturers are praising the country's government for its recent decisions to hike the duty on imported devices, reimpose the special additional duty on the imports and reduce taxes on raw material imports.

"The move is the first big boost to unshackle India from perilous import dependency in a critical sector. It will catalyze domestic manufacturing of medical devices and will go a long way in ensuring [the] big success of [Prime Minister Narendra] Modi's 'Make in India' mission," says Rajiv Nath, forum coordinator of the Association of Indian Medical Device Industry.

Last week, the Ministry of Finance announced that the rate of basic customs duty on certain specified medical devices increased from 5 percent to 7.5 percent. Also, the exemption from special additional duty on the devices was withdrawn, and the SAD of 4 percent was reimposed.

"Further, to give fillip to domestic manufacturing, basic customs duty is being reduced to 2.5 [percent] along with full exemption from SAD on raw materials, parts and accessories for [the] manufacture of medical devices," the ministry says in a Jan. 19 statement.

Nath says the previous system had made imports far cheaper than domestically produced goods, as the taxation burden on domestic manufacturers was far higher. The taxation regime — which was heavily biased towards imports — had resulted in significant cost differential between domestically manufactured goods and imports, making imports far cheaper, he explains.

The net impact was serial closure of domestic units, making India dangerously import dependent, Nath says. India has general import dependency of more than 70 percent in medical devices and up to 90 percent in the niche and electronic medical device segment.

— Jonathon Shacat

Australia Calls Attention to Safety of Device Batteries

Australia's Therapeutic Goods Administration is stressing the need for protocols and procedures to help minimize the risks of using medical devices that run on batteries.

The TGA has received more than 50 adverse event reports over the past 10 years involving deaths or serious injuries in which a battery-related problem was listed as a potential contributing factor, the agency says.

Active implantable medical devices dominated the list, with 345 battery-related reports from January 2013 to October 2015.

The batteries in AIMDs are generally non-rechargeable, and replacement would require surgery. Investigations usually reveal battery depletion is due to excess current drain, such as low circuit impedances and high output settings, and generally not battery failure, the TGA says.

Other battery failure reports involved infusion and insulin pumps, patient monitors and vision systems. The most common type of battery failures are for rechargeable batteries that fail to charge, fail to hold a charge or are not inserted correctly.

The TGA says protocols should consider factors, such as using the best quality battery cells available, ensuring charging regimes suit each battery type and setting up routine battery testing timetables.

Read the safety update here: www.fdanews.com/01-22-16-TGA.pdf. — Jonathon Shacat

FDA Schedules Inspection With Singapore Device Company Cited in Import Alert

The FDA says it has scheduled an inspection with Singapore-based Biosensors International, following an import alert that banned the company's medical devices.

Biosensors International manufactures interventional cardiology products, such as drug-eluting stents, bare metal stents and angioplasty catheters. It also manufactures critical care products, including vascular catheters, pressure monitoring kits, arterial blood sampling kits and blood pressure transducers, according to its website.

The interventional cardiology products are not approved by the FDA, and are not available for prescription or use in the U.S., the company's website says.

The FDA issued the Jan. 15 import alert stating that Biosensors International barred an inspection by agency officials. However, CDRH spokesman Eric Pahon says the company actually did not refuse an inspection. Biosensors International was added to the import alert due to a delay in responding to a proposed inspection notice over the holidays, he says.

"FDA has now scheduled an inspection and is working to remove the company from the import alert," he tells *IDDM*.

The company could not be reached for comment by press time.

Read the import alert here: www.fdanews.com/01-16-FDA-ImportAlert.pdf. — Jonathon Shacat

Brainlab Recalls Cranial Image-Guided Surgery System

Brainlab is recalling its cranial image-guided surgery system due to potential inaccuracies in the display compared with a patient's anatomy.

The recall — designated as Class 1 by the FDA — involves 1,021 units distributed from May 1996 to May 2015, according to an FDA recall notice. The affected product was distributed in eight states.

The problem could lead to inaccurate, ineffective medical procedures, as well as serious life-threatening injuries or death, the FDA says.

Brainlab notified customers of the issue on April 22, 2013, and issued an update on May 29, 2015.

The company advised customers to adhere to the instructions for use supplement document "Measures to Improve Cranial Navigation Accuracy" when using the affected product.

Brainlab says affected customers' software is being updated with an additional safety feature.

(See **Brainlab**, *Page 6)*

Senate Committee to Examine Biomedical Innovation Bills

It's back to the drawing board for Congress and its biomedical innovation legislation efforts.

Senate HELP Committee Chairman Sen. Lamar Alexander (R-Tenn.) has announced that the committee plans to hold three markups — the first being Feb. 9 — to consider a number of proposed bills.

With its multiple pieces of proposed legislation, the Senate appears to be taking an incremental approach to innovation. That's in stark contrast to the House's overwhelming passage of the 21st Century Cures Act (H.R. 6) last July.

The committee also will consider legislation regarding FDA regulation of duodenoscopes, as well as the FDA Device Accountability Act of 2015 (S. 1622), Alexander said.

The committee also scheduled a March 9 markup, during which it will consider a series of bills with the aim of "modernizing" the FDA and NIH, as well as providing congressional support for the President's Precision Medicine Initiative, including the Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077).

A final markup will take place on April 6.

AdvaMed commended the initiative, as it includes measures that would require the FDA to take steps so that medical technology reviews are done in the most efficient and expeditious manner possible; allow device clinical trial sponsors to use a central Institutional Review Board to facilitate the conduct of multi-center trials; and improve the Clinical Laboratory Improvement Amendments-waiver process to accelerate the availability of rapid point-of-care diagnostic information. — Michael Cipriano

Brainlab, *from Page 5*

The update is nearing completion, and the company is expediting the process.

There have been no serious injuries related to this recall reported to Brainlab by any hospital, company spokeswoman Ann Marie LaCasha tells *IDDM*.

Read the recall notice here: www.fdanews.com/01-16-Brainlab-Recall.pdf. — Jonathon Shacat

Expert: Prepare for Investigators On Software Verification, Validation

The FDA has hired a team of tough new investigators to crack down on medical device-makers whose software doesn't measure up in terms of verification and validation (V&V).

John Lincoln, principal of J.E. Lincoln and Associates, offered advice during a recent FDAnews webinar to help prepare for these inspectors' visits.

IDDM: *Today, we're seeing a significant amount of software of unknown pedigree (SOUP), middleware, standard libraries, and event build tools. Can you speak to the issue of commercial off-the-shelf/SOUP and its verification, validation and management?*

Lincoln: The above would be addressed in integrated systems black box tests. The selection process for such SOUP should include appropriate verification, particularly if the more its origin, development or use is unknown, has a poor history or appears to have extraneous code.

IDDM: *What would you recommend when existing software has not been code-reviewed or unit-tested?*

Lincoln: If it passed a system level V&V, that may be sufficient. When in doubt, perform additional verifications — for example, white box code review and unit testing.

IDDM: *Is ISO 14971 compliance absolutely necessary for 510(k) submission?*

Lincoln: Hazard analysis — which is only one part of ISO 14971 — is mandatory for a 510(k) submission involving software. However, having a complete ISO 14971 file or report will assist in the justification of amount of test cases, scripts or sample sizes used for each requirement. The FDA lists ISO 14971 as one of its recognized standards, so it presents a safe choice.

IDDM: *How have FDA requirements for V&V evolved — specifically, what are 2016 differences in guidance versus recent past?*

Lincoln: There have not been any 2016 differences in guidance for software. A review of the FDA's inspectional observations database by fiscal year and industry will show that 483 observations (and warning letters) are for basics, nothing esoteric. Check with your notified body for EU / ISO et al concerns, since each NB has a slightly different take on some issues.

IDDM: *In an agile development environment, would it be required to update documentation at each phase of development or would a final production document suffice for approval?*

Lincoln: To satisfy the FDA, your documentation would have to meet the 820.30 requirements for design control, and the other CGMPs for general documentation, which has to be in place / approved prior to implementation / release of product.

J&J Restructuring Projected to Save Up to $1B Per Year by 2018

Johnson & Johnson is restructuring its cardiovascular, orthopedics and surgical businesses, with an eye toward streamlining operations and speeding up the pace of innovation.

Plans call for eliminating 4 percent to 6 percent of the company's medical device segment's global workforce over the next two years. J&J expects the restructuring program to save $800 million to $1 billion in annual costs by 2018.

The restructuring should be a positive step towards growing the business and enhancing profitability at J&J. The device business has been one of the weaker performing areas in recent years, says Lawrence Biegelsen, a senior analyst with Wells Fargo Securities.

J&J says the savings will provide added flexibility and resources to fund investment in new growth opportunities. The restructuring does not reduce the likelihood of mergers and acquisitions, adds Biegelsen.

The company's vision care and diabetes care businesses are not affected by the restructuring. — Jonathon Shacat

BRIEFS

Medtronic Nabs Clearance for OsteoCool

The FDA has blessed Medtronic with 510(k) clearance for its OsteoCool RF ablation system. Featuring cooled radiofrequency ablation technology, the system uses targeted high-frequency energy to destroy cancer cells. According to Medtronic, the device offers simultaneous, dual-probe capabilities, providing procedural flexibility, as well as predictable, customized treatment. The devicemaker has launched the system in the U.S.

Philips to Introduce Service in Indonesia

Royal Philips has announced the full-scale commercial implementation of its mobile obstetrics monitoring service in West Sumatra, Indonesia, following an agreement with the Sijunjung Regency. A smartphone-based digital health service, the solution aims to identify expectant mothers who are at high risk of pregnancy-related complications. The goal is to reduce maternal mortality rates, Philips says. The solution will be introduced in other regions in Indonesia, India and Africa later this year.

PMAs on Ad Com Meeting Agenda

The FDA's Circulatory System Devices Panel of the Medical Devices Advisory Committee will vote March 15 on the premarket approval application for Abbott Vascular's Absorb GT1 bioresorbable vascular scaffold system on March 15. The panel will vote on the PMA application for Angel Medical Systems' implantable cardiac monitor AngelMed Guardian System the following day. Read the notice here: www.fdanews.com/01-16-FDA-CSDP.pdf.

FDA Postpones Warfarin Monitoring Workshop

The FDA has postponed a workshop on potential solutions to address the scientific and regulatory challenges for a certain type of point of care in vitro diagnostic that monitors warfarin, due to the inclement weather that was forecasted for the Jan. 22-24 weekend. The event, originally scheduled for Jan. 25, will now take place on March 18. The workshop will cover topics associated with prothrombin time/international normalized ratio tests, such as their benefit-risk balance, the current process for clearance and the advantages and limitations of the technology in different devices (*IDDM*, Dec. 31, 2015).

Japan Gives Thumbs Up to AtriClip Products

Patients in Japan with left atrial appendage occlusion will have new treatment options, thanks to a decision by that country's Ministry of Health, Labor and Welfare in favor of AtriCure's AtriClip products. The approval includes the AtriClip Standard and AtriClip Pro devices, which will be distributed by Century Medical. The exclusive distribution agreement runs through 2019, according to AtriCure.

Svelte Launches Stent in Europe

New Providence, N.J.-based Svelte Medical Systems has announced the European launch of its SLENDER sirolimus-eluting coronary stent-on-a-wire integrated delivery system to certain accounts specializing in transradial intervention. The system aims to reduce the catheter size and number of steps necessary to perform percutaneous coronary intervention. It consolidates the guide wire, delivery balloon stent and drug coating technologies into a single, fixed-wire system.

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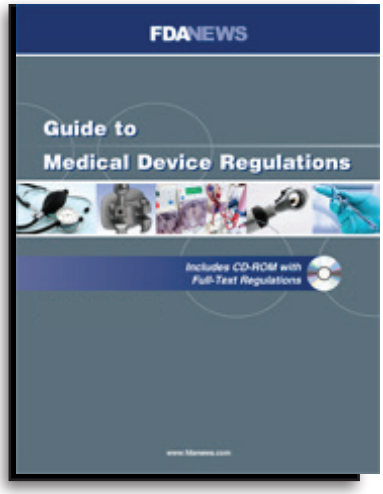

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Whether you need to help your company convince the FDA to accept a predicate device in a simple 510(k) filing or you're responsible for implementing UDI across a family of high-risk implantable devices, there's one thing all regulatory professionals need. The most up-to-date, latest FDA regulations available.

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Medical Device Complaint Management

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