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MDISS Unveils First of Many Device Security Testing Labs

The Medical Device Innovation, Safety and Security Consortium has launched the first of its many device security testing labs planned for 2017 as part of its new World Health Information Security Testing Lab concept.

The first WHISTL lab has begun operations at the Sidney and Lois Eskenazi Hospital in Indianapolis, said Dale Nordenberg, executive director of MDISS, a public health physician, medical epidemiologist and medical informatics expert.

The second WHISTL lab is slated to open later this month at the University of Tampere in Finland. About a dozen more sites will follow by the end of the year, said Nordenberg. Those are planned for New York, Indiana, Tennessee, California as well as in the UK, Israel, and Singapore.

WHISTL facilities will comprise a federated network of medical device security testing labs, independently owned and operated by

(See **Labs**, *Page 2)*

Don't Give Up on 510(k) Clearance Process for PreCert Pilot, FDA Says

Companies already seeking traditional 510(k) clearance for marketing digital health devices should not abandon that effort to switch to a new pre-certification program the FDA is piloting, the agency said.

In answers in a Q&A on the new program posted online Aug. 8, the FDA said it could not estimate how long the PreCert process it is piloting will take to respond to applications.

The pilot program could allow lower-risk digital medical devices to enter the market without FDA premarket review and streamline the premarket review for higher-risk devices.

The agency plans to enroll nine companies in the pilot, and it is looking for a mix of companies — large and small, traditional and innovative – that offer products ranging from high-risk to low-risk (*IDDM*, July 28).

(See **Pilot**, *Page 2)*

Labs, *from Page 1*

MDISS-member organizations including healthcare delivery organizations, medical device manufacturers, universities and technology companies.

Nordenberg, former chief information officer at the National Centers for Disease Control's National Center for Infectious Diseases, said each WHISTL lab will operate under a shared set of standard operating procedures. The goal is to help organizations work together to more effectively address the public health challenges arising from cybersecurity issues in complex, multivendor networks of medical devices.

"One of the biggest risks we have in medical devices and cyber security is the lack of cyber security data about the device before its implementation and during its operation. This results in an incomplete understanding of the problem," said Nordenberg. "By improving the way we share information between manufacturers and health care systems, we can optimize the cyber security configuration of the medical device associated networks supporting our patient care delivery sites."

Those watching the field carefully are welcoming the new venture.

"Patient encounters with connected yet poorly secured medical devices are increasing exponentially, and nobody really has a handle on the risks we're facing," said Billy Rios, CEO at Whitescope, a security research and advisory firm. "We've got to integrate best practices from cybersecurity, public health and clinical engineering disciplines to better understand and mitigate these threats, and the new MDISS network of WHISTL device testing and data sharing facilities are a huge step in the right direction."

Enabling MDISS members to test devices in both physical and virtual environments, WHISTL labs plan to focus on finding and mitigating medical device vulnerabilities, sharing solutions and best practices, and device security education and awareness. Newly uncovered vulnerabilities will be reported to medical device manufacturers and to the NHISAC-MDISS Medical Device Vulnerability Program for Evaluation and Response (MDVIPER).

"WHISTL will provide much-needed insight from actual developers and users of medical devices, which will result in increased relevant and actionable information sharing and situational awareness for all stakeholders in healthcare," said Denise Anderson, president of the National Health Information Sharing and Analysis Center (NH-ISAC).

MDISS was established in 2010 as a nonprofit organization operating as public-private partnership. Together with NH-ISAC, MDISS has built a large national cyber information-sharing community to advance patient safety and privacy. Under a $1.8M contract from the Department of Homeland Security, MDISS built the medical device cyber risk assessment platform that helps health systems, device manufacturers, and technology firms collaborate to produce and share device risk assessments. — Suz Redfearn

Pilot, *from Page 1*

FDA Commissioner Scott Gottlieb announced the program in June as part of a broader effort within the agency to develop a framework for regulating digital health tools. As part of the pilot, Gottlieb said, the agency is exploring creating a third-party certification pathway for lower-risk devices that would help assess the quality and reliability of a company's software design, testing and maintenance.

Gottlieb framed this approach as part of a broader shift in how the FDA handles the review process, moving away from product-by-product review and toward a more company-based approach.

FDA officials believe a focus on real-world evidence will create a friendlier climate for investment in digital health technology and devices. This, in turn, would help developers adopt new or updated software more quickly and allow the FDA to focus its resources on top priorities, he said.

Granting more regulatory leeway to lower-risk devices has long been floated within the agency as a way to free up FDA resources and create a less burdensome environment for industry.

Read the Q&A here: www.fdanews.com/08-10-17-PrecertpilotQA.pdf. — Gregory Roberts

China Shortens Device Clinical Trial Authorization Timelines

China's Food and Drug Administration announced that device sponsors submitting clinical trial authorizations at the provincial and local level will no longer need to await approval before beginning the trials.

This means that once sponsors submit documentation to provincial FDAs, they can begin trials immediately. Applicants should file separately for each clinical site, the agency said.

Part of the reason for the switch is that China is implementing new medical device regulations to streamline the clinical trials process. The regulatory authority has reclassified many devices and exempted some from clinical trials.

The agency has revised its review process, so all imported devices will be reviewed by CFDA, as well as Class III domestic products. Class I and II devices from domestic manufacturers will be reviewed by provincial FDAs.

Under the new regulations, innovative medical devices are eligible for fast-track approval. Previously, the pathway was only open to domestic companies, but the government has opened the pathway for international devicemakers.

There are certain restrictions to qualify for the pathway. For example, the devicemaker must hold a patent in China, and the device must demonstrate significant clinical superiority over devices on the market, or fill an unmet clinical need (*IDDM*, Jan. 13).

The CFDA also clarified that a clinical trial should commence no later than one year after a registration test is completed.

CFDA's device review process is faster than that of the U.S., Dan Zhang, CEO of Beijing-based CRO Fountain Medical Development, told *IDDM*. Similar to the U.S. FDA's breakthrough pathway, the innovative pathway can shorten development time by 18 months.

Katherine Wang, Shanghai-based partner in the law firm Ropes & Gray, said the assessment of risk by China's regulators is usually more conservative than that of the U.S. FDA. For example, a product that is qualified for the 510(k) application pathway in the U.S. would be considered a Class III product in China.

There are significant delays in updating Chinese standards to reflect the latest ISO standards, so device makers seeking to introduce new technology to the Chinese market need to be sure the product complies with the Chinese standards.

"This requires companies to really think about the Chinese standards and its complications during the product development stage," Wang said (*IDDM*, April 7).

Brazil's ANVISA Proposes Extending Device Licenses to 10 Years

Brazil's National Agency for Sanitary Vigilance is seeking industry comments on a proposal that would extend licenses for medical devices from five years to 10 years.

The move would cut costs for industry and also reduce bureaucratic layers at the regulatory authority.

Brazil recently introduced a risk-based approach to inspections for manufacturers and distributors of medical devices, and has engaged in numerous international initiatives aimed at regulatory convergence.

Previously, Brazilian companies seeking licenses had to first request on-site inspections from local health authorities, undergo inspections, and obtain inspection reports before applying for the mandatory federal license. Under the new, risk-based system, low-risk facilities will be exempt from certain pre-licensing requirements. Companies importing or distributing medical devices need to comply.

(See **Brazil***, Page 4)*

Irish Notified Body Advises Embracing Global Standards as Brexit Looms

Ireland's national standards organization and notified body is advising devicemakers to become certified to global standards to get ahead of uncertainty surrounding Brexit.

The National Standards Authority of Ireland predicts the device sector will expand further with the introduction of the Medical Device Single Audit Program as the standardized, global approach to auditing and certification for medical device manufacturing.

Regulatory authorities in Australia, Brazil, Canada, Japan and the United States are concluding a three-year MDSAP pilot before the formal program gets underway. NSAI anticipates that the EU will join the MDSAP program during 2017, and Health Canada has said it will only accept MDSAP certificates, starting Jan. 1, 2019.

FDA Classifies Datascope Balloon Pump Recall as Class I

The FDA has deemed Datascope and Maquet's recall of their intra-aortic balloon pumps a Class I recall.

The recall will affect nearly 9,200 units, including every lot manufactured prior to June 30, 2013 and distributed between March 24, 2013 and December 11, 2013.

The companies announced the initial recall because of the risk of valve failures, which could hinder the balloons from deflating and inflating properly.

Brazil, *from Page 3*

Foreign companies need to have a local representative to manufacture or distribute medical devices in Brazil.

The new risk-based system also streamlines Brazil's rules for certifying good manufacturing practices. The system is similar to the European Medical Devices Directive 93/42/EEC, which assigns risk under four tiers. Low-risk Class I and II devices are exempt from certain pre-licensing requirements and require less technical data. High-risk devices have additional obligations prior to licensing, such as presentation of documents and records of previous inspections. Higher risk devicemakers need to provide a technical dossier that is based on the International Medical Device Regulators Forum standards.

Brazil also participates in the Medical Device Single Audit Program (MDSAP), which is on track for full implementation in 2019. MDSAP was devised to leverage regulatory resources into a single audit program so manufacturers do not face multiple inspections. The regulatory authorities currently participating in the MDSAP program are: Australia's Therapeutic Good Administration; Brazil's ANVISA; Health Canada; Japan's Ministry of Health, Labor and Welfare; and the U.S. FDA.

483 Roundup: FDA Finds Shortfalls At Four Device Facilities

The FDA found numerous GMP and other violations during inspections of four device manufacturing facilities.

Audina Hearing Instrument: Audina Hearing Instrument of Longwood, Florida drew the FDA's attention for various deficiencies observed during a May inspection, including inadequate procedures for responding to problems and complaints.

The agency said the company, Audina Hearing Instrument, of Longwood, did not include verification requirements to ensure corrective actions were effective in responding to problems and did not designate a specific unit in the company to handle complaints.

The agency also observed hearing-aid components stored in open anti-static bags, and employees working in an assembly area without wearing the wrist straps required by the company's written instructions.

Intra-Lock International: The FDA cited a Florida manufacturer of dental implants for numerous GMP and other deficiencies uncovered in a spring inspection.

The inspection of the Intra-Lock International facility in Boca Raton revealed problems with complaint evaluations, product standards, corrective actions, design changes, and assuring supplies received by the company were up to snuff.

The FDA pointed to the firm's failure to thoroughly follow up on a report from a member of its sales team that a wrong screw had been included in the packaging for one product.

The agency also observed a problem with package sealing, and the firm's failure to document and validate a change in cap size adopted in response to the issue.

Marlen: The FDA cited Marlen Manufacturing & Development for unclear CAPA procedures and inadequate complaint handling.

The agency issued a Form 483 to the device-maker following a March inspection of its Bedford, Ohio, facility. Investigators found the facility's CAPA procedure was incomplete. For example, it did not clearly specify when a CAPA is required, and did not establish what documentation is required for a preventive action. The procedure also failed to does not address verification/validation, effectiveness activities or actions needed to close a CAPA, the agency said.

The inspection further found that the facility complaint procedure does not explain how complaints are received, documented or assessed, or how the company documents why an investigation is not required. It also does not address the requirement to review and document complaints to determine whether an MDR is necessary.

The FDA also found the company's procedures for nonconformance controls does not detail how to document incoming and in-process non-conformances and when an investigation is necessary. Procedures for purchasing are also incomplete, with no documentation indicating the company is monitoring its 29 active suppliers.

Furthermore, the company has not incorporated the UDI labeling process, nor does its process control procedure define calibration activities or requirements. The company promised to correct all six observations.

ADProducts: The FDA cited ADProducts for problems with its complaints, MDRs and contractor agreements.

Following a June inspection of the device-maker's Spokane, Wash., facility, the agency issued a Form 483. According to investigators, the company did not define or implement complaint handling procedures. ADProducts documented one complaint for its AD Mirror System. The 2016 complaint did not document an evaluation for Medical Device Reporting, and a second complaint described to investigators was not documented.

(See **483s***, Page 6)*

FDA Guidance Aims to Smooth Path for New Devices

The FDA hopes to speed the development of new medical devices through newly issued guidance on the qualification of medical device development tools, published in the Aug. 10 *Federal Register*.

Under the Medical Device Development Tool program, the use of the monitor in a certain context could be qualified by the FDA, removing the need to confirm its suitability in each subsequent individual application for device approval. The FDA hopes device developers will make qualified tools available to other developers, through licensing or other arrangements.

The program could shorten review times for device-approval applications and increase the predictability of the process, the agency said.

Read the full MMDT guidance here: www.fdanews.com/08-09-17-MDDT.pdf.
— Gregory Roberts

483s, *from Page 5*

The company also had not defined or documented procedures covering MDR or finished device acceptance. The firm had no agreement with its contractors to notify ADProducts of changes in the product or service, and had no procedures governing the requirements for contract manufacturers.

The facility also lacked procedures for CAPA, quality audits or document control.

Read the Audina Form 483 here: www.fdanews.com/08-08-17-audinahearinginstrument483.pdf.

Read the Intra-Lock Form 483 here: www.fdanews.com/08-08-17-intralockinternational483.pdf.

Read the Marlen Form 483 here: www.fdanews.com/08-10-17-marlenmanudevelopco483.pdf.

Read the ADProducts Form 483 here: www.fdanews.com/08-10-17-adproductsllc483.pdf.
— Zack Budryk and Gregory Roberts

APPROVALS

FDA Grants 510(k) Clearance To Accuray Data Management System

Accuray secured 510(k) clearance from the FDA for its iDMS data management system.

The system will be used to integrate data from Accuray's technology platforms such as the TomoTherapy and CyberKnife systems. It allows users to store and manage patient data across numerous devices.

The approval comes shortly after the company published data showing a higher patient survival rate for its TomoTherapy radiation therapy system compared to Varian Medical's RapidArc radiotherapy system.

Laminate Gets IDE Approval For Study of VasQ Device

The FDA awarded an Investigational Device Exemption to Laminate Medical Technologies to evaluate its VasQ device's safety and efficacy.

The VasQ is an implanted blood vessel external support for patients needing arteriovenous fistula. Laminate's clinical trial will enroll 129 male and female patients from 18 to 80 years old and track their progress over two years.

The device is already CE Marked and used in European and Israeli hospitals.

Medtronic Gets CE Mark, FDA Approval for Aortic Surgical Valve

Medtronic announced CE Mark and FDA approval for its new aortic surgical valve.

The Avalus aortic surgical valve is indicated for treatment of aortic valve disease. The device is the only MRI-safe stented surgical aortic valve on the market, according to the company.

The valve features a design built around limiting central regurgitation, a single, one-cut release, and a more durable frame.

FDA Clears Standard Bariatrics Clamp

Standard Bariatrics has secured FDA clearance for its Standard Clamp surgical clamp device.

The disposable laparoscopic device can be used in performing laparoscopic sleeve gastrectomies. The clamps allow surgeons to plan and hold staple lines during laparoscopic sleeve gastrectomy procedures.

Standard has begun commercial U.S. distribution of the device.

FDA Clears Xavant Tech's Pain Relief Neuromod

Xavant Technology received FDA clearance for its Stimpod non-invasive pain relief neuromodulation device.

The device treats chronic, post-surgical and post-traumatic acute pain through a hybrid pulsed radio frequency waveform. The system uses nerve-locating technology and nerve mapping to track and assess treatment progress.

The South African company said it will use Bell Medical as its distributor for the device in the United States and Canada.

FDA Clears Teva's Breath-Actuated Inhaler

Teva Pharmaceuticals announced FDA approval for its QVAR RediHaler, a breath-actuated inhaler for asthma in children 4 years or older.

The device delivers a metered dose through breath-activation, leaving no need for hand-breath coordination. Teva's QVAR metered-distribution inhaler hit the market in 2014. As part of the launch of the RediHaler, the company will discontinue the older device.

The RediHaler is expected to be commercially available during the first quarter of next year.

GE's Signa Premier MRI Gets FDA Nod

GE Healthcare won FDA 510(k) clearance for its Sigma Premier MRI system.

The company developed the system as part of four-year collaboration with various research institutions and the National Football League to diagnose mild traumatic brain injury. It is the company's most powerful system for a wide bore MRI.

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

Malaysia Will Enforce Device Registration Requirements on Jan. 1

Malaysia's Medical Devices Authority said it will fully enforce new medical device registration requirements for importing, exporting, or placing medical devices on the market from Jan. 1, 2018.

From that date, only an establishment license and a device registration certificate will be acceptable as supporting documents in the procurement process, the agency said, adding that an acknowledgment of a receipt of an application for medical device registration will no longer be valid for use as a supporting document.

Establishments that have applied for registration but have yet to submit complete information should complete the application on or before Oct. 31, 2017, the agency said.

Approvals, *from Page 7*

The system features a digital transmit and receive capability that allows nearly 150 independent receiver channels to acquire patient data.

FDA Gives Nod to Mauna Kea Miniprobes

Mauna Kea announced the FDA granted 510(k) clearance to its CelioFlex confocal miniprobes, designed for use with its Cellvizio device.

The probes provide visualization during laparascopic, endoscopic and robotic-assisted procedures. The approval will enhance providers' ability to generate imaging for robotic-assisted procedures, according to company founder and CEO Sacha Loiseau.

Cellvizio applications have received clearance in more than 40 countries, including the U.S., Europe, Japan, China, Canada, Brazil and Mexico. Last month, the company released trial data supporting the use of the device in diagnosing pancreatic cysts.

FDA Clears AUM's Heart Sound Monitoring Devices

AUM Cardiovascular secured clearance from the FDA for its new non-invasive acoustic and ECG device.

The CADence device is designed to track pathological and physiological heart murmurs. It records sounds originating in the heart to determine patients' cardiovascular health.

The device is now available in the United States, and AUM is currently seeking clearance to market the device for detection of coronary artery disease.

Allergan IUD Gets FDA Nod For Extended Use

The FDA approved a supplemental NDA to extend the duration of use for Allergan's intrauterine device Liletta. Under the new approval, the levonorgestrel-releasing IUD's duration of use is extended up to four years. The device was first approved in February 2015.

FDA Clears In2Bones Foot Repair Systems

French devicemaker In2Bones secured FDA clearance for two of its orthopedic repair systems.

The agency cleared the 5MS Fracture repair and CoLag locking compression screw system. The repair system treats deformities and fractures of the fifth metatarsal bone while the CoLag system improves compression and helps heal fragments and fractures.

Fifth metatarsal fractures are the most common for athletes.

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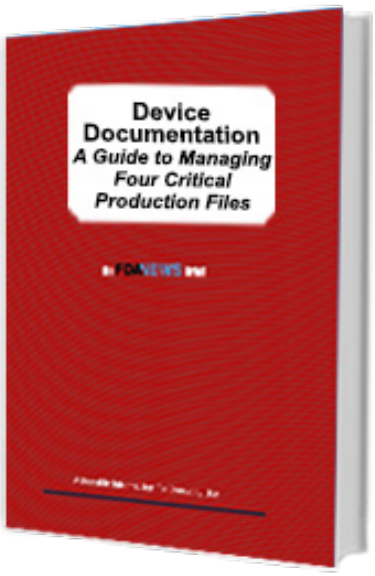

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