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IN THIS ISSUE

FDA to Require GCP Compliance for Device Trials That Rely on Foreign Clinical Data

Next year, the FDA will begin to require that data from medical device studies conducted outside the U.S. be gathered in accordance with good clinical practices, including review and approval from an independent ethics committee and well-documented informed consent.

The agency's final rule applies to data intended to support IDE applications, 510(k) submissions, and de novo classification requests, as well as applications for premarket approval, product development protocols and humanitarian device exemptions. It also applies to bench and in vitro diagnostic studies of de-identified specimens.

The FDA is also amending its regulations for IDE, 510(k) and HDE submissions based on domestic U.S. studies — to provide consistency in the agency's requirements for clinical data regardless of the type of application — adding requirements for statements of compliance with FDA regulations covering human subject protection and institutional review boards.

(See **GCP**, *Page 2)*

Health Canada to Provide Assistance For SMEs to Meet MDSAP Deadline

Health Canada is sticking to its compliance deadline of Jan. 1, 2019, for devicemakers selling products in Canada to transition to the Medical Device Single Audit Program, but is making adjustments to help small to medium-sized enterprises comply.

Holders of Class II, III and IV device licenses are expected to complete the transition before the deadline, and MDSAP certificates will be required to obtain or amend licenses.

However, Health Canada is shortening the audit or reducing fees for SMEs, according to Frédéric Hamelin, manager of the Quality Systems Section of the Medical Devices Bureau at Health Canada.

"We are making adjustments based on feedback from companies that audits are too expensive and take too long," Hamelin said

(See **Canada**, *Page 6)*

GCP, *from Page 1*

As the globalization of clinical trials continues, the agency is working to ensure that GCPs are followed in overseas studies by employing a more modernized approach, said FDA Commissioner Scott Gottlieb.

The updated regulations, included in 21 CFR 812.28, do not specify a particular GCP standard for sponsors to follow, but instead include a more flexible definition of principles that it describes as well-recognized and generally accepted. The rule defines GCP as standards for the "design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical investigations" that assure results are accurate and the rights and safety of subjects were protected. This includes initial and continuing ethics committee approval, and obtaining freely given informed consent.

This definition allows sponsors of clinical trials conducted outside the U.S. to determine their own appropriate standard, the FDA said.

ISO Standard

As an example of an applicable standard, the agency pointed to the ISO's GCPs for medical device clinical investigations, ISO 14155:2011, which was recognized by the FDA in 2012 and was developed with the participation of several countries and device companies. The ISO standard is also recognized by most of the members of the International Medical Device Regulators Forum, the agency said.

"Such standards help provide assurance not only that the research results are credible and accurate, but that the rights, safety and well-being of patients participating in these studies are protected," Gottlieb said, describing how the new regulations can also make product development more efficient, by helping device companies determine earlier in the process whether their global clinical trials can support an FDA marketing authorization.

The new mandates would replace the current premarket approval regulations that require clinical studies to conform to the Declaration of Helsinki or the law of the country where the research is conducted, whichever carries greater protection for human subjects, the FDA said. The rule does not apply to all clinical investigations performed overseas, but only sets criteria for FDA acceptance of data used to support device marketing applications or submissions.

In addition, sponsors must provide statements of compliance, the names of the investigators and their qualifications; a description of the research facilities and their addresses; the location of sites used for maintaining study records; and a detailed summary of the protocol and results of the investigation. Descriptions of the informed consent process, participation incentives, monitoring procedures, and GCP training should be provided as well.

Changes

Sponsors must also summarize the ethics committee's decision to modify or approve the investigation, and records describing the qualifications of committee members must be available for agency review upon request.

The final rule includes several changes to the version first proposed by the FDA in February 2013 — including the waiver provision, and different requirements for supporting information based on whether the device carries significant risk. Sponsors of non-significant risk devices need to submit their rationale for the categorization, and do not need to submit demonstrations that their data constitutes valid scientific evidence.

The FDA also published a frequently asked questions guidance on how to meet the agency's requirements, request waivers and provide the required information to support clinical data submissions.

The full final rule is available here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-03244.pdf.

The full FDA guidance is available here: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM597273.pdf.

Cybersecurity Researchers Find Medical Imaging Devices at Risk

Cyberattacks on medical imaging devices such as CT and MRI devices are poised to become a major challenge for device manufacturers, according to researchers at Ben Gurion University of the Negev, Israel.

The number of CT and MRI machines is increasing rapidly worldwide and by 2020, they estimate in a new study, there will be nearly 2000 CT/MRI devices for every one million inhabitants in the 34 member countries of the Organization for Economic Cooperation and Development (OECD) of which the United States is a member.

The machines are all connected to digital hospital networks, making them vulnerable to network-related cyber threats.

The study's lead author, Tom Mahler, a researcher at BGU's Cyber Security Research Center, says that while the machines have improved the ability to diagnose and treat diseases, their vulnerability to hackers means they could also be used to harm or even kill patients.

Remote Changes

In order to scan a patient, a CT device emits radiation, and an attacker could "remotely change the radiation levels, causing radiation burns to the patient, or even death," Mahler says. Hackers could also interfere with exam results. Manipulated results "could show a regular image of the brain without a tumor when the actual patient has a tumor," and the patient will not get the correct diagnosis or treatment, he says.

There is also a risk of a ransomware attack like the WannaCry attack of May 2017. Although this attack did not directly target medical imaging devices, it did find its way into hospitals (*IDDM*, May 22, 2017).

The process of development and regulation of medical devices makes them particularly susceptible to attack. The study's authors estimate that the time from concept to market for medical devices is three to seven years. In the rapidly-changing world of technology, the cyber threats directed toward the equipment when it finally goes to market will not be the same threats that the developers envisioned.

In addition, because of regulations regarding updates or changes to medical equipment, it is difficult to update device software, says Mahler. Hospitals cannot simply apply security patches to their computer systems when such patches are released. Instead, they must work with device manufacturers to test the patches and confirm that they will not affect the way the device works. This process takes time, during which the equipment remains vulnerable to hackers.

Dilemma for Regulators

"It's a really big dilemma for regulators," says Mahler, "because they need to make the regulation process quick enough to allow for regular software updates and security patches to be installed without compromising patient health and safety."

There is still no product that can effectively protect patients from such attacks, says Mahler, but "there are best practice methods." He cites the example of Israel's Clalit Health Services, which has created secure hospital networks that are separated from the internet.

The host control PC is the most vulnerable component in the CT's ecosystem, the researchers found, but common techniques for securing a computer, such as installing anti-virus protection, are insufficient for the prevention of cyber-attacks.

Mahler and colleagues are working on securing CT devices by using machine learning. The software would first learn the actual commands being sent to the CT's gantry and would then detect any anomalies, blocking malicious commands before they arrive to the device.
— Donna Scaramastra Gorman

Brazil Clarifies ANVISA Oversight Roles for Devices

Brazil's National Surveillance Agency released an order mapping out the specific oversight roles for federal, state and local ANVISA branches for medical devices.

Order RDC 215/2018 clarified that the federal ANVISA office will oversee device registration and Brazilian GMP inspections.

ANVISA audits all Class III and Class IV devices, and companies will need certification until they can market their devices in the country. Additional local requirements also may apply.

However, the agency said it would conduct risk assessments for international devices including reviews of technical documents rather than on-site GMP inspections, depending on the level of risk identified. The change will mean greater flexibility in determining risk for certain Class III or Class IV devices.

Backlog

ANVISA has made a lot of recent changes geared toward streamlining operations. The agency was earlier criticized for taking so long to approve products, which resulted in a backlog, said Marcelo do Ó, managing director and partner at L.E.K. Consulting, in São Paulo, Brazil.

In 2016, ANVISA took a number of steps in the direction of rationalization, better planning and listening to different stakeholders to improve processes, he said.

As part of this effort, the authority developed a regulatory agenda for the future that highlighted 15 macro topics and 127 themes to address from 2017 to 2020. The regulatory agenda has 11 topics relating to devices.

One of those changes was to extend the registration period for high-risk Class III and Class IV devices and in vitro diagnostics from five years to 10 years (*IDDM*, Feb. 5).

ANVISA made the decision to extend the license period on Jan. 16 after consulting with the ANVISA board of directors and industry. The authority had announced in August 2017 that it was considering doubling the registration period for devices and IVDs, saying the move would cut costs for industry and reduce bureaucratic layers.

"The first topic on the medical device agenda for 2017-2020 is registration and post-registration," do Ó said. "There will be a number of non-critical products that will not require a registration, but just a notification. Our expectation, though, is that critical products such as heart implants, hip implants and other orthopedic products, for example, will have higher quality standards on registration, post-registration, market monitoring, manufacturing quality certification and technovigilance."

Improved Access

Extending the medical device registration period for higher-risk devices to 10 years will substantially improve market access, BMI Research Analyst Karen Simpkins told *FDAnews*.

"For comparison, medical device registrations are valid for five years in Argentina and Mexico. The extended validity timeframe, along with other recent regulatory developments, will further enhance the attractiveness of the Brazilian market, which already has one of the lowest regulatory risks in the Latin American region," Simpkins said.

Brazil's device market is worth about $11 billion, and is growing at a rate of 5 percent to 7 percent, according to the Brazilian Association of High Technology Medical and Hospital Equipment, Products and Suppliers.

"ANVISA is the highest standard regulatory organization across Latin America, and often times used as a reference in the region," do Ó said.

Other regulatory developments in the works include regulation of software as a medical device, medical device traceability, a national implant registry and medical device marketing," do Ó said.

Pacific Hospital Supply Warned for Validation, Process Control Issues

The FDA hit Pacific Hospital Supply, a manufacturer of disposable medical supplies including catheters, cannulae, tubing, and aspirators, with a warning letter after an inspection at the firm's Miaoli, Taiwan facility revealed adulterated products.

During a February 2017 inspection, the agency found that the firm failed to ensure that when the results of a process could not be fully verified by subsequent inspection and test that the process was validated. One of the manufacturing processes the firm failed to validate was also flagged in a previous FDA inspection.

The facility failed to follow adequate process control procedures. For example, equipment in the facility was operating at temperature and speed settings that were outside defined limits. In addition, the firm had not resolved a Form 483 observation from its last inspection, failing to establish a required procedure.

Read the Pacific Hospital Supply warning letter here: www.fdanews.com/02-22-18-PacificHospitalSupply.pdf. — James Miessler

FDA Flags Seiler for Undocumented Changes, Lack of MDR Procedures

The FDA cited a St. Louis device manufacturer for inadequate CAPA procedures, failure to report all corrections and problems with complaint handling.

The agency conducted an inspection at Seiler Instrument and Manufacturing's St. Louis facility last October and issued a Form 483. According to investigators, the facility did not analyze service records or complaints to determine the cause of quality problems and non-conformances.

The investigator also found that the company responded to a customer complaint about its Alpha Air 6 ENT operating microscope unit toppling over by updating its medical presentation to warn of the potential hazard. It also updated the product's user's manual to note that users must use the handles mounted on the device when transporting it. But the company failed to notify the FDA that it was taking either action.

Seiler also lacked adequate procedures for quality audits. The facility did not require documentation of all complaints, review of them to determine the necessity of an investigation, or conduct an investigation to identify whether an MDR-reportable event had taken place.

Read the Seiler Form 483 here: www.fdanews.com/02-22-18-seilerinstrmfgcoinc483.pdf. — Zack Budryk

ZOLL Cited for Environmental Controls, Complaint Files

The FDA dinged ZOLL Circulation for problems with its complaint files and environmental controls observed in an October-November 2017 inspection at its facility in San Jose, California.

According to the FDA investigators, the device manufacturer did not maintain procedures to ensure all complaints were processed uniformly and on time. The investigators reviewed 6,975 complaints and found 829 were open while 6,146 were closed. Of the closed complaints, 4,923, or eight in 10, took longer than the company's goal for the time between opening and closure.

Investigators also found environmental deficiencies in the facility's clean room. The inspection found numerous personal fans creating multidirectional airflow in this area, which "nullifies any attempt to create a unidirectional air flow system," according to the Form 483.

The inspection also found the facility failed to submit an MDR within 30 days of being notified of information suggesting one of its products may have caused or contributed to death or serious injury. The FDA identified nine MDRs the firm filed late. The time it took the company to submit the reports ranged from 31 days to a full year.

Read the ZOLL Circulation Form 483 here: www.fdanews.com/02-22-18-zollcirculationinc483.pdf. — Zack Budryk

Canada, *from Page 1*

during a recent Health Canada webinar. "We're looking at other options for SMEs, particularly with small Canadian companies."

The regulator is working with other MDSAP regulatory agency partners to find ways to reduce audit times and fees, particularly for SMEs, while maintaining integrity of the program, he said.

Overall, the transition is progressing as expected, and more than 1,000 facilities have started the transition. Roughly 575 of them have had their first MDSAP audits, and as of Feb. 1, 100 MDSAP certificates have been received.

Those numbers are in line with agency expectations, with 5 percent to 10 percent of companies being early adopters, he said. The agency conducted a survey of devicemakers to gather feedback on transition progress, and 1,455 companies responded.

Generally, there is broad support for the concept of a single audit program that is accepted by multiple regulators, respondents said. However, stakeholders are concerned about the increase in audit time and costs associated with MDSAP, particularly for small companies. Canadian distributors are also concerned that foreign suppliers will abandon them.

Three out of four manufacturers said they plan to transition to MDSAP, and about 12 percent said they were undecided.

"Some companies reported challenges during MDSAP audits, but that was inconsistent from what Health Canada was hearing from Auditing Organizations (AOs)," Hamelin said.

"We want to make sure that device manufacturers don't lose access because auditing organizations can't get audits done in time," he said, assuring devicemakers that Health Canada won't let that happen and they won't be denied access because of that.

Manufacturers that don't intend to transition said that their sales in Canada didn't justify the expense of MDSAP, he said.

Health Canada is working with AOs and is monitoring the transition to proactively identify and mitigate the impact of potential auditor resource shortages. But most AOs are not seeing difficulty in meeting the MDSAP transition deadline. The biggest challenge is getting manufacturers to agree to schedule their MDSAP audits soon enough to complete the process before the transition time, Hamelin said.

He urged devicemakers to not delay in getting audits scheduled, stressing that "industry needs to do its part in supporting AOs to meet their deadlines."

The regulator is working on "options to help manufacturers that have begun the process but may not have completed the process by the deadline," Hamelin said, stressing, "we are committed to making MDSAP work."

MDSAP offers significant benefits to industry such as reduced inspections, Hamelin said. In 2016, FDA's Office of Compliance said that MDSAP audits are equivalent to U.S. FDA inspections, "so you won't be routinely inspected by the FDA if you have a MDSAP certificate," he said, noting that ANVISA also accepts MDSAP, so companies will get earlier market access to Brazil.

Mexico Reclassifies Medical Devices, Deregulates 2,200 Devices

Mexico is updating its medical device classification scheme, which will allow deregulation of more than 2,200 products considered low risk.

Mexico's Federal Commission for Protection against Sanitary Risks (COFEPRIS) said that by deregulating the lower-risk devices, it will be able to focus on enabling earlier access for innovative devices.

The announcement marks the third deregulatory listing for medical devices, following the deregulation of 1,669 in the first stage and 573 in the second stage, BMI Research said, noting that the revised device classification is a move toward harmonization with international standards.

Mexico is the leading exporter of medical devices in Latin America, and it ranks eighth internationally, according to COFEPRIS. U.S. exports to Mexico were roughly $3.4 billion, and U.S. imports from Mexico were roughly $7.6 billion, according to AdvaMed. The country is the third largest exporter of tubular sutures globally, and the fourth-largest exporter of surgical and dental instruments.

APPROVALS

FDA Clears First Blood Test For Concussion Detection

The FDA granted marketing clearance to Banyan Biomarkers' Brain Trauma Indicator — the first blood test for evaluating concussions.

The review and authorization, completed in less than six months, was expedited under the Breakthrough Devices Program in collaboration with the U.S. Defense Department.

The device measures neurologically released levels of proteins and provides test results in no more than four hours, allowing clinicians to determine whether to perform a CT scan.

The FDA said the test has the potential to rule out the need for a CT scan in at least one-third patients suspected of having mild traumatic brain injuries.

DreaMed Diabetes Gets CE Mark For Diabetes Management Platform

Israel-based devicemaker DreaMed Diabetes obtained a CE Mark for its Advisor Pro decision-support platform for management of Type 1 diabetes.

The cloud-based decision software uses the company's proprietary machine learning algorithms to analyze data collected from insulin pumps, continuous glucose monitors, among other connected medical devices, as well as food consumption data.

The analyses can be used to identify personalized insulin doses.

FDA Clears Quidel Influenza A+B Assay

San Diego-based developer of diagnostic testing solutions Quidel received FDA clearance for its QuickVue Influenza A+B assay.

The assay allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens, the company said.

It is designed to identify and differentiate between the two influenza viruses in about 10 minutes.

Arterys Wins FDA Clearance For Oncology Imaging Software

Arterys received 510(k) marketing clearance for the Arterys Oncology AI suite of software, covering all solid tumors.

The software automates the segmentation of lung nodules and liver lesions, with accuracy equal to segmentations performed manually. The initial focus will be for liver MRI and CT scans as well as for lung CT scans, the company said.

The cloud based system enables clinicians to get provide second opinions from within the hospital or from outside experts.

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

Approvals, *from Page 7*

Abiomed Snags New Indication For Impella Heart Pumps

Abiomed received expanded FDA premarket approval for a new indication on its Impella 2.5 and Impella CP heart pumps.

The pumps are the only percutaneous temporary ventricular support devices FDA-approved for high-risk percutaneous coronary interventions, including stenting and balloon angioplasties, the company said.

Edwards Lifesciences Earns CE Mark for CENTERA Valve

Edwards Lifesciences received a CE Mark for its self-expanding CENTERA valve for severe, symptomatic aortic stenosis patients at high risk of open-heart surgery.

The valve is repositionable and retrievable and can be delivered through a motorized delivery system.

The CE Mark was based on the trial results from a study of 203 high-risk patients at 23 centers in Europe, Australia and New Zealand.

Paragonix Technologies Receives CE Mark for Two Cardiac Transport Devices

Paragonix Technologies earned a CE Mark for its SherpaPak and SherpaPerfusion cardiac transport systems.

The SherpaPak is a single-use, disposable device for the hypothermic static preservation and transport of donor hearts. The SherpaPerfusion system is a single-use, disposable device for hypothermic oxygenated perfusion preservation and transport of donor hearts.

Following the commercial launch of SherpaPak in the United States, the company plans to introduce the devices to transplant centers across Europe.

FDA Clears Foot and Ankle Plating System

Centric Medical received 510(k) marketing clearance for its Centric foot and ankle plating system for use in stabilization and fixation of fractures or osteotomies, intra and extra articular fractures, joint depression, and multifragmentary fractures.

Centric Medical is a division of Life Spine focused on developing surgical implants for the treatment of distal extremity pathology.

FDA Grants Humanitarian Use Designation for Nativis System

The FDA granted the Nativis Voyager Pediatric system a Humanitarian Use Designation.

The device uses a proprietary ultra-low radio frequency energy (ulRFE) technology designed to treat medulloblastoma, a rare, high-grade glioma in children.

Corindus Receives FDA Clearance For CorPath GRX System

Corindus Vascular Robotics, a developer of precision vascular robotics, received 510(k) marketing clearance for use of its CorPath GRX System in peripheral vascular interventions.

The CorPath GRX system broadens the capabilities of the CorPath robotic technology platform from exclusively treating coronary artery disease to include peripheral artery disease. The system allows the cardiologist to sit at a radiation-shielded workstation to advance guide catheters, stents, and guidewires with millimeter-by-millimeter precision.

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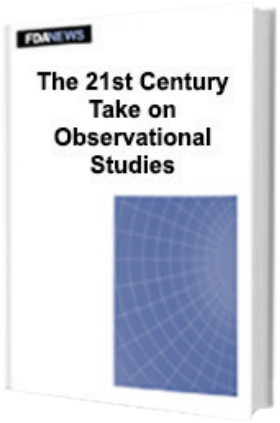

The 21st Century Take on Observational Studies: *Using Real-World Evidence in the New Millennium*

Passage of the 21st Century Cures Act reaffirmed Congress's and the FDA's commitment to using real-world evidence to supplement or even replace traditional clinical trials.

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- How drug- and devicemakers view observational research and how they are using it

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Using the MDSAP Model to Win International Device Approval

Are you one of the 75% of device manufacturers who conduct internal audits solely "because you have to — because the FDA and ISO regs say so?"

Instead of cringing at the idea of conducting an internal audit, consider implementing the Medical Device Single Audit Program (MDSAP) model. It's a single audit of your quality management system and satisfies medical device regulatory authorities.

Currently, Australia, Brazil, Canada, Japan and the United States are participating in the program. If you pass one MDSAP inspection then you will be ready to pursue marketing authorization in five separate countries.

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