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IN THIS ISSUE

Canada Issues Draft Guidance On 3D Printing for Implantable Devices

Health Canada issued draft guidance for devicemakers on preparing applications for 3D-printed implantable devices.

The guidance covers the evidence required to support pre-market Class III and Class IV licenses applications for implantable devices manufactured by 3D printing under ISO 13485. The guidance covers design and manufacturing processes, material controls, device testing and labeling of 3D devices.

Class III and IV medical devices by additive manufacturing are subject to the Medical Device Regulations and "require a review of submitted evidence of safety and effectiveness before a license can be issued," the agency said.

The same data requirements apply to 3D-printed devices as those for conventional devices in terms of their characterization and evidence of safety and effectiveness, including physical and mechanical bench testing, biocompatibility testing, software and

(See **Canada***, Page 2)*

IMDRF Posts Three Final Guidances Following Beijing Meeting

The International Medical Device Regulators Forum (IMDRF) has released final guidances on optimizing standards for regulatory use, essential principles of safety and performance, and definitions for personalized devices.

Following up on the forum's Sept. 18-20 meeting in Beijing, the Standards Working Group issued guidance on optimizing standards for regulatory use, noting that optimizing standards will help to streamline regulatory processes as medical devices grow in complexity and international markets expand.

Most IMDRF regions have developed programs for consensus standards, and they have more in common than differences, which sets the stage for future harmonization, the working group said.

(See **IMDRF***, Page 4)*

FDA Warns US Vascular On Complaints, MDRs

The FDA issued a warning letter to US Vascular for failing to correct deficiencies in its complaint reviews and to fix problems with medical device reporting, among other violations.

The agency issued the warning letter following the company's response to a Form 483 issued after a March 2018 inspection of Vascular's Beaverton, Oregon facility.

In its response, the devicemaker promised to review design procedures, lack of procedures governing complaint handling, CAPA procedures, lack of procedures to ensure that all receiveds product and services conformed to specified requirements, failure to maintain device master records, and failure to document quality audit procedures. The company failed to provide objective evidence of its corrections or timeframes in its response.

The FDA also found that the devicemaker's response to findings that it failed to review complaints for medical device reporting to beinadeqaute. The company promised to correct the problem but the agency has not yet received adequate corrections, according to the warning letter.

Read the warning letter here: www.fdanews.com/11-15-18-USVascularWL.pdf. — Zack Budryk

Canada, *from Page 1*

clinical evidence. Additional requirements may also apply to 3D-printed devices.

The guidance does not cover third-party software, custom-made devices, patient-specific anatomical models, devices manufactured at point-of-care or devices with biological components.

The guidance adopts definitions developed by the International Medical Device Regulators Form (IMDRF) with respect to personalized medical devices. Health Canada said it is actively working with international counterparts to "keep pace with the research and development of 3D printing."

For the device description, manufacturers should include the starting material, a description of the 3D printing method and an overview of the manufacturing process, the agency said. The description should clarify whether the entire device or only a component of the device is 3D printed.

Additional characterization of the starting material should include parameters measured prior to polymerization/fusion, including if the material is in solid phase, liquid phase or is a polymer or monomer mixture.

The following evidence should be provided on the printer:

- A summary of cleaning and maintenance processes for the printer;
- Validation of the consistency of the printer performance, including analysis of worst case parameters and recommended in-process parameters;
- Validation of the printer and material combination with consideration of build direction, variations between sizes to determine the degree to which the build orientation and location may affect the mechanical properties of the finished device;
- If multiple build paths are used, each build path should be documented and validated;
- If multiple devices or components are printed simultaneously in the same build location, quality assurance should consider repeatability with a cycle and across lots; and
- With respect to patient-specific devices, evidence to support the accuracy of device reproduction from patient images is required.

Preclinical performance testing should be conducted on the final, finished device subjected to all post-processing, cleaning and sterilization steps, Health Canada said. A detailed summary is required for each test.

The guidance also lists additional considerations for device performance and shelf life, software verification and validation, biocompatibility tests and clinical studies.

Health Canada is seeking feedback on the technical considerations in the guidance by Jan. 8, 2019.

Read the guidance here: www.fdanews.com/11-15-18-Canada.pdf.

Sen. Grassley Presses FDA For Action on Cybersecurity

In a letter last week to FDA Commissioner Scott Gottlieb, Sen. Chuck Grassley (R-Iowa) asked what the agency is doing to deal with cybersecurity issues highlighted in a recent HHS Office of Inspector General (OIG) report.

Grassley called the OIG report, released in November, of particular concern due to its revelations about lack of preparedness for a cybersecurity event directed at medical devices. The report noted inadequate testing of the agency's capacity to respond to potential medical device cybersecurity emergencies, with two district offices maintaining no written standard operating procedures for recalls of vulnerable devices.

The FDA, Grassley noted, disagreed with OIG's conclusions that the lack of a formal arrangement with federal partners hurts information flow about cybersecurity, as well as its conclusion that the FDA had not properly addressed device cybersecurity at the component level.

Grassley expressed particular concern over the potential for foreign actors to exploit the vulnerabilities. "For example, I recently wrote a letter to NIH raising concerns about foreign governments effectively installing foreign agents in U.S. based research institutions to steal intellectual property produced by taxpayer funded studies," the letter states. "Medical devices could be exploited by those same foreign actors to not only interfere with normal device operation, which could cause harm to patients, but also to steal personal medical information. I think you can agree, action must be taken to reduce and eliminate these threats."

Grassley called on Gottlieb to provide a written summary of how the agency is addressing the four recommendations in the OIG report, as well as information on what the FDA has done to address the threat from foreign governments or entities. He also asked how the FDA is using medical device report data to improve device cybersecurity. The senator requested a briefing for the staff of the Senate Judiciary Committee, which he chairs, on cybersecurity threats to devices. — Zack Budryk

FDA Issues Alert Over Misuse Of Implantable Pumps

The FDA issued an alert on the possibility of implantable pump failure or dosage errors from using pain medications not approved for use with pumps that deliver drugs into the spinal fluid.

FDA-approved Instructions for Use for implantable pumps list pain medicines that have been evaluated by the agency for compatibility with the pump, including Infumorph and Prialt. But not all pumps are approved for use with Prialt.

The agency has learned that patients are sometimes being treated with medications that are not approved for use with an intrathecal implanted pump — including compounded medicines as well as hydromorphone, bupivacaine, fentanyl and clonidine.

The agency found that implantable intrathecal pump failure is more frequent with the use of medicines not approved for use with the pump. For example, some medicines or fluids may contain preservatives or other characteristics that can damage the pump tubing or lead to corrosion of the pumping mechanism. This may cause the implanted pump to perform in unexpected ways, including motor stalls, which ultimately stop the medication delivery, leading to potential opioid withdrawal. When a pump fails, patients must undergo surgery to remove or replace it.

Dosage errors may also occur when medicines that are not approved for intrathecal administration are nonetheless used in these pumps. Programmable implanted pumps have dose calculation software that provides options for users to select pre-programmed medicines and concentrations identified in the approved pump labeling to help prevent unintended dosing errors.

The accuracy of the software calculations depends on using the approved medicine, medicine concentration and medicine characteristics. For example, if there is more than one medicine in the pump reservoir, the pump software can only calculate the dose based on the infusion rate of a single medicine.

IMDRF, *from Page 1*

The guidance includes recommendations for regulators, standards developing organizations (SDOs) and other stakeholders for improving standards globally.

The working group is conducting a survey among regulators to better understand policy differences and to lay the groundwork for future best practices guidance. It plans to:

- Publish recommendations for developing "regulatory-ready" standards;
- Enhance regulator participation in the standards development process;
- Advance IMDRF relationships with ISO and IEC; and
- Analyze regulators' approaches to the use of standards in regulatory review.

Standards optimized for regulatory use will lead to greater confidence in their utility among regulatory authorities and in conformity assessment, the guidance says. Optimized standards will streamline the device review process, improve the efficiency of regulation and establish productive dialog among regulators, manufacturers, conformity assessment organizations, clinicians and the public.

Although regulatory processes differ among IMDRF regions, international consensus standards generally "reflect the best experience of industry, researchers, consumers, regulators and other experts worldwide," it said. Globally accepted consensus standards are best, but regional, national and consortia standards may be equally useful, especially for emerging technologies for which SDOs "may be able to react quickly to changes in the state of the art" (*IDDM*, Oct. 26, 2018).

Harmonized Essential Principles

IMDRF's Good Regulatory Review Practices Group released final guidance on the Essential Principles of Safety and Performance of Medical Devices and IVDs, with harmonized principles for designing and manufacturing devices to ensure they are safe and perform as intended.

The document is for regulatory authorities, conformity assessment bodies, industry and other stakeholders. Essential principles of safety and performance provide broad, high-level criteria for design, production and post-production throughout the device lifecycle.

IMDRF says standards being considered as part of regulatory compliance can benefit from the essential principles of safety and performance.

The essential principles cover clinical evaluation; chemical, physical and biological properties; sterilization and microbial contamination; environmental considerations and conditions of use; protection against electrical, mechanical and thermal risks; medical devices that incorporate software or are software as a medical device; devices and IVDs with a diagnostic or measuring function; labeling; and protection against radiation.

Definitions for Personalized Medical Devices

IMDRF's Personalized Medical Devices Working Group released definitions for devices intended for a particular individual.

Many regulators already define the term custom-made medical device and have exempted them from certain regulations. But technology has made custom-made devices, including implantable devices for particular patients possible, so this approach means that patients are receiving higher risk devices that may be exempted from regulation.

The guidance distinguishes between personalized medical devices and custom-made medical devices. Personalized devices describe devices intended for a particular individual, but custom-made devices are not patient-matched, the guidance says.

It also defines patient-matched devices and adaptable medical devices and provides specific examples and recommendations for interpreting the guidance.

Read the guidance on optimizing standards here: www.fdanews.com/11-15-18-IMDRFOptimizingStandards.pdf.

Read the guidance on safety and performance here: www.fdanews.com/11-15-18-IMDRFSafetyPerformance.pdf.

Read the guidance on personalized medical devices here: www.fdanews.com/11-15-18-IMDRFPMD.pdf.

China's Copious International Stumbles on MDRs, Complaints

China's Copious International fell short on submitting medical device reports and tracking complaints, as well as validation procedures, a Feb. 5 to Feb. 8 inspection of the firm's Guang Dong, China facility revealed.

The Chinese firm's MDR procedures didn't define time frames for submitting reports to the FDA, and it didn't record complaints related to products on the U.S. market, according to the seven-item Form 483.

The firm's CAPA procedures didn't include adequate requirements for investigating the cause of nonconformities relating to products, processes or the quality system, or for implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

Validation was found to be lacking for equipment management control procedures for revalidating equipment, and not all test results were available for certain test operators.

In addition, document control procedures were sloppy in that document changes weren't validated by appropriate personnel, and not all changes were recorded correctly.

In-process product inspection control procedures fell short when it came to ensuring that sampling plans were based on a valid statistical rationale.

For example, the sampling methods didn't adequately define the sampling rate for tightened or reduced sampling levels.

Read the Copious International Form 483 here: www.fdanews.com/11-15-18-copiousintlinc483.pdf.

Equipment Adjustment and Calibration

Equipment adjustment is an important part of QSR-compliant operation. Under §820.70(g)(3), "Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments."

This requirement can be covered by including this information in procedures and work instructions, documents that should be readily available to employees performing these tasks.

Companies need to determine which pieces of equipment have an inherent limitation or an allowable tolerance and what that limitation or tolerance is. Then they must determine, for each piece of equipment, whether that information needs to be available to staff and how it should be presented. Documentation showing that these determinations were made and their justification should be maintained.

It's also important that devicemakers then audit this as part of their overall equipment audit program. In the course of this audit, companies need to verify that the equipment has an inherent limitation or allowable tolerance, and that the information is either visibly posted or readily available. They should confirm that the information is contained in a controlled document and record the document number and revision so that it is clear to FDA investigators. They also need to trace to the document's review and approval in the document control system under §820.40.

Calibration is another important factor in the operation of equipment that includes any sort of measuring function. Under §820.72(a), devicemakers are required to "establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained." The FDA expects to see a rational schedule established for calibration activities as well as documented evidence of adherence to that schedule. Calibration is often paired with other routine maintenance for convenience.

ISO standard 13485:2016 includes similar requirements. It states, "As necessary to ensure valid results, measuring equipment shall be calibrated or verified, or both, at specified intervals, or prior to use."

Excerpted from the FDAnews management report: *Three Phases of QSR-Compliant Equipment Control*.

Validation Issues Uncovered At Dannoritzer Medizintechnik

Germany's Dannoritzer Medizintechnik received a six-item Form 483 following a Feb. 5 to Feb. 8 inspection of its Baden-Wuttemberg facility for inadequate validation and process control procedures for its surgical equipment.

The FDA said the firm couldn't provide evidence that some of its processes were validated. For example, the instructions for use for one device specified that cleaning be performed by machine or manual methods, but manual cleaning was not challenged during the validation. The 483 said that usability of the Instructions for Use by the intended population also was not validated.

Procedures for monitoring and controlling process parameters for a validated process were also found to be inadequate and parameter settings used during production were not routinely documented in the device history record.

The FDA also cited the firm for failing to establish schedules for adjustment, cleaning and maintenance of equipment. For example, there was no documentation for equipment calibration.

Read the Dannoritzer Medizintechnik Form 483 here: www.fdanews.com/11-15-18-dannoritzermedizintechnik483.pdf.

Risk Analysis Missing At Chinese Medical Laser Maker

Risk analysis, validation procedures and appropriate test methods were found to be inadequate at China's Beijing ADSS Development during a Feb. 5 to Feb 8 FDA inspection of the firm's Beijing facility.

The company makes a number of aesthetic and medical laser products, including lasers for hair removal, face and body contouring, acne scars and other treatments.

Design validation was not performed under defined operating conditions on initial production units, and the company didn't "adequately ensure the device conforms to user needs," the FDA Form 483 said. The risk analysis also didn't adequately consider risk for at least one of the devices.

The Chinese company's design and development control procedures were not documented to ensure adequate evaluation of conformance against design inputs, the agency said. For example, the design outputs documented in the company's design and development output list for an unnamed device, which included a list of schematics, work instructions and procedures, didn't include the related design inputs.

The firm's validation procedures didn't include complete testing to evaluate quality attributes, and "the only documented test was a visual inspection," the agency said.

"The Quality Assistant mentioned the only test related to electronic product radiation safety is checking the energy output of the finished device prior to release," the FDA said.

Read the Beijing ADSS Development Form 483 here: www.fdanews.com/11-15-18-beijingadssdevelopmentcoltd483.pdf.

FDA Issues Emergency Use Authorization for Ebola Test

The FDA granted an emergency use authorization (EUA) for a single-use, rapid fingerstick test for the Ebola virus, only the second test of its kind made available under an EUA.

The EUA authorization — which has been declared in the midst of the deadly pathogen's outbreak in the Democratic Republic of the Congo — allows unapproved medical products to be used in emergency situations when there are no approved alternatives available.

Chembio's Dual Path Platform Ebola Antigen System detects the virus in blood samples from patients that exhibit symptoms of the disease and other risk factors, such as excessive exposure to areas with large numbers of Ebola cases. Chembio's device includes a portable reader and can be used in locations where healthcare providers don't have access to PCR testing.

"It takes a sustained, robust and globally coordinated effort to protect our nation and the global community from various infectious disease threats," said FDA Commissioner Scott Gottlieb. "By authorizing the first fingerstick test with a portable reader, we hope to better arm health care providers in the field to more quickly detect the virus in patients and improve patient outcomes."

With this EUA authorization, the agency has now issued a total of 11 authorizations to help with the Ebola crisis, including nine nucleic acid tests. — James Miessler

APPROVALS

MaxQ AI's Intracranial Hemorrhage Platform Cleared by FDA

The FDA granted 510(k) clearance to MaxQ AI's Accipio Ix intracranial hemorrhage platform.

The device is designed to detect intracranial hemorrhage (ICH), commonly known as brain bleed, in adult non-contrast head computed tomography.

Accipio Ix, which received the CE Mark earlier in the year, uses AI algorithms to identify and mark potential regions of interest related to acute ICH.

FDA Grants 510(k) Clearance For Siemens' Mobile C-Arm

The FDA has cleared Siemens Healthineers' Cios Spin, a mobile C-arm that produces 3D images for improved quality assurance during surgical procedures.

The device is used to provide 3D imaging similar to computed tomography (CT) for orthopedic, spinal and traumatic surgery.

The 3D images the Cios Spin produces can remove the need for CT after the procedure and can help reduce the number of needed revisions.

Teleflex Gains Japanese Approval for Urolift System

NeoTract, a Teleflex subsidiary, received approval from Japan's Ministry of Health, Labor and Welfare for its Urolift system intended for benign prostatic hyperplasia treatment.

In the common and treatable urinary condition, also known as prostate gland enlargement, the prostate enlarges and surrounds part of the urethra.

Teleflex's system uses a minimally invasive procedure that places tiny devices in the urethra to reopen the lower urinary tract by moving tissue blockage away from the enlarged prostate.

Lumendi Cleared for Endolumenal Interventional Platform

The FDA granted 510(k) clearance for Lumendi's endolumenal interventional platform used to improve tissue retraction during therapeutic endoscopies.

The device's suture loops help to facilitate tissue manipulation and simplify dissection and removal of stomach polyps without surgical intervention.

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

Approvals, *from Page 7*

The single-use, close-fitting non-sterile sleeve covers a standard endoscope to stabilize it inside the large intestine and can shift many gastrointestinal surgeries to endolumenal procedures.

Atlantic Therapeutics' Transcutaneous Electrical Stimulator Cleared

The FDA issued de novo clearance to Atlantic Therapeutics' INNOVO therapy device, used to treat stress urinary incontinence.

The company's transcutaneous electrical stimulator is the first device of its kind to be granted FDA approval.

INNOVO is a non-invasive, novel wearable device for women with stress urinary incontinence and is designed to be used at home.

Mesa Biotech Obtains CE Mark For Respiratory Syncytial Virus Test

The EU granted Mesa Biotech's respiratory syncytial virus (RSV) point-of-care test the CE Mark.

The test, which diagnoses the highly contagious RNA virus, is designed for use with the devicemaker's polymerase chain reaction testing platform.

The RNA virus affects nearly all children by the time they are two years old and is severe in children with underlying diseases.

BioFire Diagnostics' Pneumonia Panels Cleared by FDA

The FDA granted 510(k) clearance for BioMérieux affiliate BioFire Diagnostics' panel assay for detecting lower respiratory tract infections.

The PCR-based panels are able to distinguish between 33 common pathogens that cause pneumonia. A version of the panel featuring an extra target has also received the CE Mark.

The panels, which give test results in approximately one hour, have been cleared for use with sputum and bronchoalveolar lavage samples.

Medtronic Receives CE Mark For Thoracic Stent Graft

Medtronic received a CE Mark for its Valiant Navion thoracic stent graft, used to repair lesions in the descending aorta.

The stent graft is intended for use in minimally invasive therapies to treat a variety of aortic conditions, including thoracic aortic aneurysms, blunt traumatic aortic injuries, intramural hematomas and type B aortic dissections.

The device is a low-profile version of the company's Captivia thoracic stent system and allows patients with small iliac arteries to undergo thoracic endovascular aneurysm repairs.

Diabeloop Receives CE Mark For Blood Sugar Monitoring Technology

Diabeloop's DBLG1 technology for monitoring and maintaining blood sugar levels has earned the CE Mark.

The self-learning, customizable system can mimic the pancreas' insulin-dispensing functions and adapt to the patient.

The DBLG1 links to a continuous blood glucose monitoring system and an insulin patch pump to predict glucose levels and optimally control the pump.

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Complaint Management for Devicemakers: *From Receiving and Investigating to Analyzing Trends*

Complaint management is essential to a functioning quality management system.

Understanding the FDA's Quality System Regulation isn't enough — you must also master ISO 13485:2016 and the new EU MDR. They all require devicemakers to conduct trending in some form or another. But none of them tell you HOW.

This new edition of the best-selling **Medical Device Complaint Management** fills in that gap for you.

In addition to teaching the principles of successful complaint management …

- Receiving, documenting and investigating complaints
- Determining when complaints are reportable
- Using complaints to update risk management data …

… the new report teaches you how to analyze trends in your complaint files to spot opportunities for product and program improvement.

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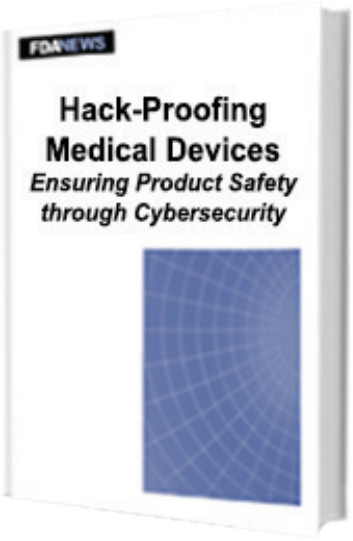

Hack-Proofing Medical Devices: *Ensuring Product Safety through Cybersecurity*

How does the FDA expect you to fight cyber incursions?

With the recent release of the final guidance on postmarket management of cybersecurity, you now have advice from the agency.

The key is awareness — of product vulnerabilities, current threats, developments in cybersecurity protection, how to defend your company from disastrous liability litigation… and the list goes on.

Hack-Proofing Medical Devices will show you how to get — and keep — control of your devices' networked operations. The management report covers:

- Six environmental stressors that contribute to cybersecurity problems
- The overwhelming magnitude of the problem — 68,000 medical devices were found to be freely accessible through the Internet in 2015
- How the FDA and international regulators are handling issues involving software as a medical device (SaMD)
- Types of cybersecurity threats, including ransomware and device piggybacking
- And much more!

BONUS — the report also provides a variety of tools including:

- A checklist for verifying a device's cybersecurity controls status
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