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IN THIS ISSUE

Brazil Introduces Firsts Unique Device Identifier Requirements

Brazil released its first requirements for unique device identifiers for high-risk medical devices that are slated to go into effect in 2020.

The regulation specifically refers to coronary artery stents, drug-eluting stents and artificial hip and knee implants.

The new UDI requirements were based on guidance from the International Medical Device Regulators Forum and they conform to internationally accepted practice. The device labels will need to include the device identifier, the date of validity and the batch or serial number.

The resolution by Brazil's National Agency for Sanitary Vigilance (ANVISA) "identifies two bar coding agencies — GS1 and Health Industry Business Communications (HIBCC) — as meeting

(See **Brazil**, *Page 2)*

China Releases New Draft Regulations for Medical Devices

China's Ministry of Justice is seeking comments on revisions to its medical device regulations that will significantly change the environment for devicemakers.

The June 25 draft amendment updated a previous amendment issued in October by the former China Food and Drug Administration — now the National Drug Administration of China (CNDA).

Several of the regulatory reforms from the October draft were included, such as providing for compassionate use of devices that treat life-threatening diseases as well as conditional approvals for similar devices, according to Ropes & Gray attorney Katherine Wang. However, the new draft includes some noteworthy changes that are aimed at encouraging innovation and reforming the approval and inspection process.

One bit of good news for devicemakers in China is that foreign clinical trial data will be accepted rather than companies having to

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BRIEFS

India's CDSCO Expands List Of Devices Requiring Registration

India's Central Drugs Standard Control Organization (CDSCO) is expanding its list of devices that require registration for market authorization, including all implantable devices and "other high end equipment."

The list includes all implantable medical devices, CT scan and MRI equipment, defibrillators, dialysis machines, PET equipment, X-ray machines and bone marrow cell separators.

The full list will be published in the official Gazette and will go into effect 12 months after the date of publication.

MHRA Streamlines Online Services for Devicemakers

The UK's Medicines and Healthcare products Regulatory Agency issued an update on a new service that aims to provide access to medical device registration and certificates of free sale services through an online portal.

The program provides enhanced customer service through a single account with the agency. It also allows MHRA staff to interact more efficiently with customers, enabling staff to more quickly access and provide information to customers.

The agency aims to have all customers on the system by the end of the year. Customers that use the device registration service or apply for certificates of free sale will automatically be incorporated into the new system.

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the relevant standards of the regulation, but also states that ANVISA may recognize other agencies for bar coding," said Karen Simpkins, medical devices market analyst for BMI Research.

"Manufacturers will need to make available a minimum of three copies of the label, one for the clinical file, one for the document to be given to the patient and one for the financial document," she said.

Brazil defines the device identifier as a numeric or alphanumeric code that allows unique and unambiguous identification of each reference, version, business model or component of the medical device.

A National Registry of Implants is being introduced that will store records of surgical procedures involving stents for coronary arteries, and hip and knee implants.

During the IMDRF conference in Shanghai in March, Brazilian officials noted they were conducting a public consultation on a proposal to include UDI codes on patient implant cards for cardiovascular stents, and hip and knee implants.

IMDRF's Unique Device Identifier Applications Guide Working Group is developing a globally harmonized approach to applying a UDI system. A preliminary draft is currently under review, covering responsibilities for establishing and maintaining a UDI, placement of UDI on all packaging and labeling, use of UDI in forms and databases, and general principles for implementing a UDI system and database.

The working group expects to publish a final document that could be available by December (*IDDM*, April 30).

Read the ANVISA notice (in Portuguese) here: www.fdanews.com/07-03-18-BrazilUDI.pdf.

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WEBINAR

FDA's NEST Program and Real World Evidence: *Evaluating Benefit & Risk: What Devicemakers Need to Know*
July 17, 2018 • 1:30 p.m. - 3:00 p.m. ET
www.fdanews.com/nestprogramrwe

TGA Rolls Out New Platform For Device Advertising Complaints

Australia's Therapeutic Goods Administration has introduced a single platform for online complaints relating to medical device advertising.

As of July, the agency has taken over the advertising complaint handling system, revamping the previous system to improve compliance with both drug and device regulations. Under the new system, the complaint form will be consolidated to give the TGA sole responsibility for handling complaints about device and drug advertising directed at the public.

The agency will continue requiring pre-approvals for advertisements through July 1, 2020, with the date on a pre-approval determining the serial number used for the applications. The TGA will continue to issue recommendations to advertisers during the transition from the existing 2015 code to when the new code takes effect on Jan. 1, 2019.

Consumers, meanwhile, will be able to use the platform for further education on device advertising regulations. This will include fact sheets on topics such as common red flags.

Advertisers can learn how to prepare compliant advertisements through e-learning modules. The first module on the basics of therapeutic goods advertising regulation is now available, with future modules planned for the coming months. The agency said advertisers can also check whether a particular therapeutic good can be advertised to the public by using a simple online decision tool. — Zack Budryk

Stakeholders Respond to RFI From Congress on Device Cybersecurity

Stakeholders called for additional guidance on medical device security and funding to help resolve cybersecurity flaws in responses to a request for information by the House Energy and Commerce Committee.

AdvaMed noted that the committee's RFI did not directly acknowledge that "medical devices cannot support updates beyond the useful life of the underlying technology, which for common off-the-shelf components can be as short as 3-4 years."

The American Hospital Association said hospitals' efforts to improve cybersecurity for medical devices often run up against unsecured legacy systems and the patching necessary to resolve the security flaws often impede the device's function.

"Replacing these technologies is not financially feasible, with many hospitals only able to replace about 10 percent of devices in a given year," the AHA wrote. The association called for a single, FDA-coordinated source of data for device security, timely patches and coordinated disclosures.

The Advanced Medical Technology Association supported such a coordinated system in its comments, writing that security is a collective responsibility between regulators, providers and manufacturers.

The AHA called on the lawmakers to ask the FDA to broaden its guidance beyond simply pre- and post-market guidance to make security for legacy devices mandatory. Currently, the AHA said, there is little financial incentive for device manufacturers to upgrade security. "Unfortunately, the healthcare sector, including the device sector, continues to be confused as to whether FDA guidance on post-market cybersecurity is binding," the association said.

The American Medical Association, meanwhile, said it "strongly urges" that federal regulators adopt policies to better distribute the risk of liability between doctors, manufacturers and technology vendors. "When considering implementing policy changes to improve cybersecurity surrounding legacy technologies, the Committee should consider properly allocating the risk across all involved parties," the AMA wrote. "It should align incentives so those best positioned to have knowledge of risks and best positioned to minimize harm through design, development, validation, or implementation are incentivized to do so."

Read the full comments here: www.fdanews.com/07-06-18-Comments.pdf. — Zack Budryk

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conduct local trials, which added a considerable amount of time to approval timelines.

"China studies are only required for products that are high risk or support or maintain life, and the clinical trial authorizations are deemed issued after 60 days from the date of IDE filing in the absence of a rejection or deficiency notice, " Wang said, noting that clinical evaluation is only mandatory for Class III devices.

The draft regulation redefines marketing authorization holder obligations. Previously MAH holders needed to secure a separate device distribution approval, or GSP certificate, but that will no longer be required and MAHs will be able to distribute their devices. Foreign MAHs will need to appoint a domestic agent to take on the same post-market responsibilities as domestic MAHs and be jointly liable with the foreign MAHs for product quality and service issues.

Regulatory authority is also being transferred from provincial authorities and will be consolidated with the new national drug administration. Previously, lower-risk devices were reviewed by local authorities, but the national administration will now have wider authority to review and approve lower-risk products as well.

The amendment also calls for easing controls for certain Class II devices to simplify distribution for lower-risk devices. To that end, the administration is expected to publish a catalogue of Class II devices that will be exempt from the record filing requirement, Wang said.

The draft amendment calls for joint inspections with the national authority, the provincial authorities and local authorities for GCP, GMP and GSP inspections, but the national authority would be responsible for overseas inspections.

A key policy objective is to "enhance enforcement efficiency and consistency." For example, CNDA officials will have access to databases and enforcement records that earlier may have been "siloed" in different regulatory bodies. This means it will likely be easier for enforcement teams to share information and coordinate enforcement efforts better (*IDDM*, April 9).

"While the 2017 draft already enhanced the penalties for non-compliance the draft amendment introduces more rigorous sanctions," Wang said. For example, it introduces the term "disguised medical devices" that it defines as: "(a) an unapproved device; (b) a non-device that is claimed to be a device; (c) a device that is approved based on a misrepresentation or falsified information; (d) a device that is in reliance of a forged regulatory approval," Wang wrote.

Fines for these "disguised medical devices" can be as high as 15 to 30 times the sales value of a device.

The amendment adds a provision that prohibits importation and distribution of used devices, and it also requires that all medical devices bear a unique device identifier.

The comment period closes on July 24.

13th Annual
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So much has changed since last year's Inspections Summit that it sometimes feels difficult to keep up. The FDA is focused on any number of new topics: more generics, lower prices, opioids, internal restructuring, and much more. But one thing that hasn't changed is that they are still doing inspections….and the regulated community is still making mistakes.

The FDA will always — **always** — do inspections, and Commissioner Scott Gottlieb and the FDA have certainly not provided any hint that they are going to stop doing them any time soon. You can't afford to be caught off guard. Warning letters, 483 citations, and hits to your reputation can cost you time, energy and money!

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483 Roundup: Four Firms Flagged For Quality and Other Failures

Republic Spine: Republic Spine found itself in hot water with the FDA for inadequate risk analysis and CAPA procedures as well as failure to develop written medical device procedures and design controls, following a March 2018 inspection of its Boca Raton, Florida facility.

The devicemaker received a five-item Form 483 for deficiencies related to its Dark Star triple-lead pedicle spinal screw system.

A complaint handling procedure did not include requirements for transmitting medical device reports to the FDA and it lacked documentation and recordkeeping requirements. The firm also failed to fully implement design control procedures, the agency said, pointing to inadequate design planning, design verification, design validation, design reviews and design changes.

For example, the design plan did not include a development schedule with all tasks, review stages and milestones clearly defined, nor did it identify all contributors to the development process and their responsibilities. The design history file also lacked evidence that the design verification was performed on the physical characteristic input requirements listed on the design input/output matrix, the FDA said.

Moreover, there was no approved protocol in the design history file to perform design validation to include an explanation for a simulated environment. The investigator found two different design development validation forms with different dates and no explanation for the discrepancy.

The FDA said the firm's risk analysis was inadequate in that it failed to justify how it arrived at certain ranges for the spinal system, and some of the risk mitigation methods did not describe changes implemented to mitigate risk. The firm was also not using feedback such as complaints to review its failure mode effects analysis (FMEA) to "determine if new hazards have been identified and may require mitigation."

For example, one complaint identified a new at-fault hazard of device fractures due to improper continuous loading/unloading, but the hazard was not added to the FMEA document.

Greenwald Surgical: Greenwald Surgical landed a Form 483 for failing to document rework and reevaluation activities for its surgical products.

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Gathering Data for CAPAs

Some data necessary to develop and implement a good CAPA system may be generated in-house, but in many cases key data will come from sources such as suppliers or contract manufacturers. So companies must ensure that suppliers have CAPA processes that align with the client company.

This does not mean that the manufacturer should force its exact procedures on the supplier or contractor, cautioned John Freije, principal medical device consultant at Freije Quality Engineering. What works for one company may be less effective and practical for another. What is important is that the supplier and manufacturer work closely together toward the same goals.

Both companies need to use common terminology and have similar ways of setting priorities for dealing with CAPA issues. Agreed upon timelines are essential. For instance, "ASAP" as a deadline is not specific enough. Responses from the supplier, whether for providing necessary data or documents or for taking certain actions, should be specific.

"If it deals with a complaint or an MDR, then you definitely need to have expeditious CAPA reporting and corrective actions done," Freije said.

In terms of defining a problem, it is the responsibility of the product manufacturer to define the problem — and the solution — clearly enough to ensure that the supplier can take appropriate action.

Excerpted from the *FDAnews* management report: *Creating QSR-Compliant CAPA Systems: A Practical Guide for Devicemakers*.

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A March 2018 inspection of its Lake Station, Indiana facility revealed that the maker of urological and electrosurgical instruments and accessories didn't document nonconforming subassemblies used in manufacturing finished products as nonconforming, and instead reworked them without documentation or evaluation, according to the Form 483.

Assembly operators told FDA inspectors that flexible endoscopic electrodes that failed an in-process inspection were repaired and retested, but the nonconforming product was not documented as nonconforming and the process of repairing the product was not documented as rework, the agency said.

The FDA also found fault with the firm's device acceptance procedures because they did not ensure that acceptance activities required by the device master record were completed.

Electro Cap International: Failure to validate its products and undefined rework of nonconforming product, as well as other quality system failures, landed Electro Cap International a Form 483 following a March 2018 inspection of its Eaton, Ohio facility.

The firm failed to validate its induction sealer used for sealing its Electro-Gel jars that was installed in February 2015. The president of the firm told inspectors that there were no records documenting the validation of the sealer.

The FDA inspectors noted that five of eight product nonconformity reports included rework processes for the firm's electro caps, but the rework processes were not defined or approved.

The device history record didn't demonstrate that the devices were manufactured according to the device master record, because it didn't include all process steps defined in the device master record, the agency said.

The FDA noted that in-process acceptance is defined for each assembly stage in the device master record but there was no documentation for in-process acceptance.

The agency also cited the firm for inadequate design change procedures because it didn't document changes made to its manufacturing process of the electro-gel. The agency also flagged the firm for inadequate corrective and preventive actions, because it wasn't analyzing repairs and service of its product "as a quality data source to identify existing and potential causes of nonconforming product or other quality problems."

American Thermal Instruments: The FDA called out American Thermal Instruments, a devicemaker based in Moraine, Ohio, for failing to evaluate suppliers and receive notifications of product changes, in addition to having device master record problems.

The agency's February inspection revealed that the firm did not complete evaluations of potential suppliers and contractors. The company lacked agreements between suppliers and contractors that ensured notifications of any changes in products or services.

The firm also had device master records that were not properly maintained. The work instructions contained in two device master records were incorrect and the company did not maintain its electronic device master records as instructed by its procedure.

In addition, CAPA procedures failed to identify all quality data sources that would be analyzed to determine that a CAPA is necessary. The procedures did not include a statistical method for analyzing data. The firm also did not have a procedure for handling supplier corrective action requests.

Read the Republic Spine Form 483 here: www.fdanews.com/07-02-18-republicspinellc483.pdf.

Read the Greenwald Surgical Form 483 here: www.fdanews.com/07-02-18-greenwaldsurgicalcompanyinc483.pdf.

Read the Electro Cap International here: www.fdanews.com/07-02-18-electrocapinternationalinc483.pdf.

Read the American Thermal 483 here: www.fdanews.com/07-05-18-americanthermal483.pdf.

'Blind' PMA Panels More Likely To Give Thumbs Up, Analysis Finds

Changes to premarket approval application advisory panels appear to have made it easier for panelists to say yes to medical devices, a new analysis finds.

The FDA changed rules governing the panels in 2010, creating a "blind," simultaneous voting system—where all panelists vote at the same time and don't discuss their vote. Previously, panelists had voted publicly and sequentially.

The agency also changed the question panelists had to ask about a proposed medical device. Before 2010, panelists were asked to vote only on whether a device should be approved. Now, panelists vote separately on whether the device is safe, effective and whether the benefits outweigh the risks.

The rules apparently have made it easier for panelists to say "yes," according to a new analysis by attorney Jeffrey N. Gibbs, chairman of the Food and Drug Law Institute and his, son, David A. Gibbs, a research analyst with the World Resources Institute.

Before the 2010 changes, panelists voted "yes" 71 percent of the time. Since the 2010 changes, panelists have voted "yes" 80 percent of the time, the researchers found.

"The widely shared expectation was that blind voting would lead to greater independence, or less agreement, among panel members," the pair wrote.

The panels represent "a small minority of all applications received by FDA" but because their votes are public record, they offer a chance to test for correlations. The Gibbs say they will focus on the timing and likelihood of approval in a future analysis.

Read the analysis in the Regulator Affairs Professionals Society's Regulatory Focus here: https://bit.ly/2IXwq8G. — Bill Myers

APPROVALS

FDA Approves Zephyr Endobronchial Valve

The FDA granted approval for PulmonX's Zephyr endobronchial valve for treating breathing difficulties in patients with severe emphysema.

The device is placed in the lung airways of patients using a flexible bronchoscope during a hospital procedure. The valves close during patient inhalation, keeping air from entering the damaged area of the lung and open during exhalation, releasing trapped air and relieving pressure.

TransMed's Soft Tissue Biopsy Platform Receives 510(K) Clearance

The FDA cleared TransMed's SpeedBird platform used for soft tissue biopsies.

The device is made up of a single element constructed from three hypodermic tubes with twin opposed cutter blades. It can be fully automated or manually operated and provides a pathway to transport multiple tissue samples by using a closed-circuit flush and vacuum mechanism that sends the samples into a removable chamber.

It is intended to address issues with current biopsy devices, such as sharp and potentially traumatic needle tips and needle gauge and tissue type restrictions.

Medtronic Gains Expanded Indication for Bone Cement

The FDA granted expanded 510(k) clearance for Medtronic's Kyphon HV-R bone cement, designed to fixate pathological fractures of the sacral vertebral body.

The bone cement already has an indication for fixing pathological fractures of the sacral vertebral body or ala using sacroplasty or sacral vertebroplasty.

The bone cement's expanded indication now allows it to treat fractures caused by

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

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osteoporosis, cancer or benign lesions by using a cementoplasty procedure.

LumiThera's Dry AMD Treatment Device Gains CE Mark

LumiThera's LT-300 device, used for treating dry advanced macular degeneration, has earned a CE Mark.

The device uses the company's LT-300 light delivery system to treat patients who suffer from a loss of central vision.

The treatment incorporates low level light therapy, applying red and near-infrared light to improve and repair tissue that has experienced degeneration or injury.

Plum Medical's Portable Medical Imaging Device Cleared by FDA

The FDA granted approval to Plum Medical Solutions' second version of Med-Tab, a portable medical imaging workstation.

The tablet is used for medical image analysis and reading and is calibrated for the DICOM standard.

The device is designed for use in radiology practices, hospital radiology departments and other disciplines that rely on medical imaging for diagnosis and therapy.

Zetta's MRI Software Algorithm Cleared by FDA

The FDA granted 510(k) clearance for Zetta's MRI software algorithm used for image quality enhancement and image optimization of short scanning techniques.

Zoom works with all MRI models from major manufacturers and allows imaging staff to automatically process all MRI imaging techniques, such as short scans that are time sensitive.

The software uses the DICOM communications standard to receive and process data and automatically sends the enhanced images to picture archiving and communication systems.

The software can manage incoming data from multiple scanners in the case of aggressive workflow demands.

Shape Memory Medical Gains 510(k) Clearance

Shape Memory Medical's Impede embolization plug gained 510(k) clearance from the FDA for use in obstructing the rate of blood flow in the peripheral vasculature.

The device, used for treating conditions that require blockage of the peripheral vasculature, is available in three sizes to treat vessels up to 10mm in diameter.

The plug features porous materials that can change from a catheter-deliverable shape to a larger, memorized shape.

Apollo Endosurgery Cleared For Endoscopic Suturing System

The FDA granted special 510(k) clearance for Apollo Endosurgery's OverStitch Sx endoscopic suturing system used for advanced endoscopic surgery.

The special 510(k) clearance addresses an accessory added to the system to improve attachment to compatible endoscopes.

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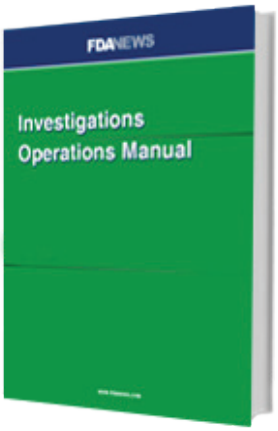

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EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements*

The new EU Medical Device Regulation is massive… complex… and confusing… and you must be ready to comply by May 26, 2020.

When the European Union revised its system of rules for medical device manufacturers in 2017, it replaced a longstanding set of directives on specific topics with one large document that covers all aspects of making devices in EU countries.

Not only did they consolidate all the rules, they gave them greater weight. Previously, medical device directives provided guidance but did not have the force of law. The new MDR, however, contains mandates that are legally enforceable by EU member countries.

The FDAnews report **EU MDR Compliance** can help. Our editors have combed through the regulations, picking out the most minute compliance points and building them into a checklist of 200+ requirements you can use to confirm that you are satisfying all the EU mandates for device manufacturing. The report provides:

- Definitions of key terms in the EU MDR
- Knowing where to find specific requirements in the 150+ page regulation
- Checklists that walk you through every aspect of manufacturing, safety and performance requirements
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