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IN THIS ISSUE

European Commission Clarifies UDI Manufacturer Obligations Under New Regs

Distributors and importers that assume the obligations of device manufacturers also assume responsibility for unique device identification labeling, the European Commission said.

This means that distributors and importers must apply for registration as manufacturers and receive a single registration number, according to Article 16 under the EU's Medical Device Regulation (MDR).

The entities would apply for the appropriate conformity assessment procedure and provide UDI-product registration, the Commission said in five newly released guidances that provide clarification on UDI provisions.

However, if the manufacturer is identified on the label rather than the distributor or importer, the manufacturer is responsible for meeting the UDI obligations under the quality system regulation, the Article 16 guidance clarified.

(See **UDI***, Page 2)*

TGA Proposes New IVD Device Regulations

Australia's Therapeutic Goods Administration outlines a proposed new regulatory framework for in vitro diagnostic devices in a new consultation paper.

The proposal would make 10 key alterations to current agency regulations of IVD devices. The proposed amendments range from requiring unique product identifiers for all IVD companion diagnostics in applications for inclusion on the Australian Register of Therapeutic Goods to a proposal to require a compulsory audit of all IVD companion diagnostics before inclusion on the ARTG.

The proposals are primarily based on other international agencies such as the FDA and European Medicines Agency's IVD companion diagnostics regulations, and are the TGA's response to increased use of precision medicine and continual efforts to harmonize international regulations.

(See **IVD***, Page 2)*

UDI, *from Page 1*

Released by the Medical Device Coordination Group (MDCG), which is comprised of representatives from all EU member states, the guidances clarify roles and responsibilities for manufacturers of medical devices, in vitro diagnostics and software as a medical device.

UDIs are required for procedure packs and systems that are not custom made devices. The Commission defines procedure packs as a combination of products packaged together and placed on the market intended for use for a specific medical purpose. A system is a combination of products packaged, either together or separately, that are intended to be "inter-connected or combined to achieve a specific medical purpose."

The Basic UDI-DI — the key device-related information identifier in the Eudamed database — identifies systems and procedure packs as having the same group of components and the same intended purpose, regardless of the original components manufacturers. For example, first aid kits and skin traction kits would be procedure packs, while x-ray systems would be an example of a system.

According to Article 29 of Annex VI, the system or procedure pack producer is required to provide the UDI database with information, including quantity per package, indication, manner in which the pack is controlled (including the expiration date, lot number and serial number), name and address of the system or pack producer, device nomenclature code, risk class and trade name along with other requirements under Article 29.

The MDCG released a trio of guidances in May that clarified devicemakers' responsibilities for implementing UDI systems under the new MDR. Along with guidance on the basic attributes for a device identifier (DI), the group released documents on the database and the architecture for the new UDI system (*IDDM*, May 7).

A separate guidance on medical device software clarifies that only software that is commercially available on its own or that constitutes a device in itself is subject to UDI requirements under the EU MDR and IVDR regulations.

The guidance specifies that a new UDI-DI is required "whenever there is a modification that changes the original performance, the safety of the software or the interpretation of data," according to Annex VI, Part C. The modifications include new or modified algorithms, database structures, operating platforms, architecture, user interfaces and new channels for interoperability, which are considered "significant changes."

The guidance on Basic UDI-DI notes that a UDI is required "whenever there is a change that could lead to misidentification of a device and/or ambiguity in its traceability."

Finally, a guidance on language clarifies that information in the UDI database must be publicly available and "easily understandable by any European citizen." The user interface of the UDI database "shall be available in all official languages of the Union," the Commission said.

Information on special storage or handling conditions as well as warnings or precautions should be provided in English as well as in the languages of the countries where the device is marketed.

Read the UDI guidances here: www.fdanews.com/10-26-18-ECGuidances.pdf.

IVD, *from Page 1*

The consultation paper addresses the definition of a device, which currently has no clear definition under Australian regulations, and proposes to follow the FDA's model by clarifying the definition through guidance rather than regulation, allowing the agency to amend or update the definition as needed in case of unintended interpretations.

The FDA uses the term "complementary diagnostics" to refer to those IVDs that are considered to aid in the benefit-risk decision-making about the use of a medicine in a clinically meaningful way. TGA is not currently proposing to adopt this terminology.

Read the paper here: www.fdanews.com/10-25-18-TGA.pdf. — Zack Budryk

FDA Issues New Classification For Bone Conduction Hearing System

The FDA issued a final order reclassifying the active implantable bone conduction hearing system as a Class II device with certain special controls.

Clinical performance testing for the device must characterize any adverse events that occur during clinical use and implantation, and the testing must also demonstrate that the device serves its intended purpose under the anticipated conditions of use, the agency said.

Non-clinical testing, meanwhile, must demonstrate that the device performs as intended, including performance data that validates force output, mechanical integrity testing, and reliability testing that aligns with expected device life.

The device manufacturers must also conduct impact testing in a clinically relevant anatomical model. The FDA also instructs manufacturers to show that any components of the device making direct contact with the patient are biocompatible, and performance data must prove the components' sterility as well as the shelf life of the device.

This data must also show the device's wireless and electromagnetic compatibility as well as its electrical safety, and manufacturers must perform hazard analysis as well as software verification and validation.

Labeling for the device must include a summary of clinical testing that includes a rundown of any complications or adverse events, instructions for use and implantation, a shelf life for sterile components, a user manual and a patient identification card.

Read the final order here: www.fdanews.com/10-25-18-Device.pdf. — Zack Budryk

FDA Revises List of Recognized Consensus Standards

CDRH has revised its list of recognized consensus standards for medical devices and in vitro diagnostics.

The move comes on the heels of guidance issued last month explaining how the FDA implements its standard recognition program that allows it to recognize consensus standards developed by international and national organizations in satisfying portions of premarket review submissions.

The FDA's Oct. 22 notice describes the addition, withdrawal and revision of close to 90 FDA-recognized standards. The draft guidance will assist devicemakers who elect to declare conformity with consensus standards to meet certain requirements.

There are two appropriate uses of consensus standards in the premarket process, the agency said. The first is a declaration of conformity, which certifies that a device is in compliance with a consensus standard recognized by the FDA, after which the agency will determine in its review whether the submission complies with applicable premarket requirements.

The second is general use, where a submitter chooses to comply with a consensus standard but does not submit a declaration of conformity. The reasons for this may include the manufacturer making changes to the consensus standard methodology or the manufacturer choosing to use a consensus standard without a recognition number (*IDDM*, Sept. 17).

Changes to the revised standards are outlined in two tables. The first table lists the withdrawal of standards and their replacement with others; correction of errors made by the FDA in listing previously recognized standards; and changes to supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In the orthopedic section, a number of standard specifications for several procedures have been withdrawn and replaced with newer versions. Similarly, some standards were withdrawn in the

(See **Consensus**, *Page 4)*

IMDRF Issues Final Guidance On Optimizing Standards

The IMDRF's Standards Working Group issued final guidance on optimizing standards for regulatory use, noting that optimized standards offer a way to streamline regulatory processes as medical devices grow in complexity and international markets expand.

The guidance offers recommendations for regulators, standards developing organizations (SDOs) and other stakeholders for improving standards globally. The working group concluded that standards could be improved by engaging with regulators and getting them to participate in groups like IMDRF.

Although regulatory processes among IMDRF regions differ, 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."

Shortcomings

The working group identified shortcomings in the way standards are currently written, including problems with representation, decision-making and processes, and a lack of understanding in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) about what regulators need.

"Discussions with ISO and IEC leadership lead us to conclude that, while challenging, these problems can be resolved" through collaboration, the working group said.

IMDRF outlines three key expectations for developing regulatory-ready standards:

- A commitment to IMDRF's essential principles of safety and performance of medical devices and IVDs;
- An emphasis on performance over design stipulations in writing standards; and
- A consensus approach.

Standards should be crafted in such a way that conformity can reduce the burden of regulatory review, the guidance states. To achieve this, standards content needs to contain "objective and specific requirements that clearly indicate how conformance can be achieved and conveyed."

At every stage of developing standards, "careful thought should be given to how a standard can be used by regulatory authorities," and the effect on regulatory practices and industry should be evaluated early on, the guidance suggests.

In justifying the need for a standard, content should clearly identify the purpose in its scope and specify how it will achieve the purpose. Standards developers should carefully study the market, regulatory and safety needs when crafting a business plan. Once drafting is underway, input should be sought from working groups and industry stakeholders.

Consensus, *from Page 3*

IVD section and replaced with newer versions, and a few tests were withdrawn completely.

The changes also affect recognized standards in the materials area, including sensor systems as well as surgical implants within several different medical specialties. Sterility, radiology, cardiovascular and obstetrics-gynecology sections have also had several standards either withdrawn and replaced with newer version or reaffirmed.

A second table lists new entries and consensus standards not previously recognized by the FDA. New entries to the list of recognized standards cover cardiovascular; ear, nose and throat; quality systems and risk management; IVDs; materials; orthopedic; radiology; sterility; and tissue engineering.

The agency said it will announce modifications and revision to the list of recognized consensus standards at least once a year, and more often if needed.

Read the revised consensus standards here: www.fdanews.com/10-26-18-Consensus.pdf.

Build Quality Milestones Into Device Trial Sites, Auditor Urges

Sponsors of device trials should build quality milestones into site contracts as an insurance against FDA inspections, a veteran auditor told the MAGI clinical research conference in San Diego last week.

Fran Ross, a senior consultant of CGI, says that it can be all too easy to lose control over a trial, especially when using contract research organizations (CROs), so sponsors should "start with the contract" and build in a payment schedule that revolves around quality deadlines — such as the first visit of a first patient.

Ross was joined on stage by Lee Truax-Bellows, president and CEO at Norwich Clinical Research Associates in Norwich, N.Y. Both shared horror stories from their experiences auditing trials gone horribly wrong.

Things can go wrong quickly in any event but it's especially galling that device sponsors are even more exposed if the FDA finds problems in the trials, Truax-Bellows said. Federal regulations governing device trials don't mention CROs, so even if a contractor screws up, they can escape punishment.

One device sponsor received a Form 483 with 32 pages worth of errors, most of them chalked up to the CRO's malpractice, she said. It took more than a year and a half to audit all 60 sites in the trial and it cost the sponsor more than $1.5 million in audit fees. Nearly a decade later, the device still awaits approval. The CRO changed its name and is still in business, Truax-Bellows said.

(See **MAGI***, Page 6)*

QSR-Compliant Equipment Control

When the FDA sends investigators to inspect a device manufacturing plant, it's a sure bet that they will scrutinize equipment controls, which are emphasized in the Quality System Regulation (QSR). The agency expects devicemakers to have and follow QSR-compliant procedures for installing, operating and maintaining every piece of equipment used in the course of device manufacture, including any ancillary equipment that affects production, such as environmental systems and contamination controls.

Production and process control failure is one of the most frequent citations in warning letters issued to devicemakers. According to data from the FDA, in the 2008-2016 period, about 30 percent of warning letters citing QSR problems included production and process control issues; about 18 percent of those citations specifically mentioned 21 CFR §820.70(g), which covers equipment control.

Paying close attention to equipment controls, therefore, can be an important step toward avoiding a 483 or warning letter. The challenge for devicemakers is finding all of the equipment requirements, which show up in a variety of places within QSR. The basic requirements appear in §820.70(g), but other sections include requirements for specific equipment applications.

QSR requires that "Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented."

The maintenance schedule should be developed to ensure that the equipment will consistently produce medical devices that meet all design specifications and regulatory requirements. As with any QSR activity, it is important that devicemakers maintain records of all maintenance performed, including the date and individuals performing it. FDA investigators will check these records against the published maintenance schedule and SOPs.

Each piece of equipment needs to have an established maintenance schedule that covers any cleaning, adjustment or calibration needs specific to that particular machinery. Information learned during the course of performing maintenance—for instance, if calibration is required more frequently in certain conditions of use—should be used to keep the schedule current. The schedule must include all tasks required, such as lubrication, cleaning and adjustments. Maintenance records must cover each activity and should include enough information to allow analysis of the results.

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

Experts Discuss How Device Trials Should Handle Adverse Events

Sites running clinical trials for devices should document all adverse events and investigators' responses even if they don't ultimately report the events to regulators or Institutional Review Boards, a contract research organization executive told the MAGI clinical research conference in San Diego last week.

Drug trials must report all adverse events but device trials have a little more leeway. Still, in the old researchers' saying, "If it's not documented it's not done," said Rachel Silver-Kessler, director of clinical support services at IMARC Research, a Cleveland-based CRO.

She suggests that research coordinators track any adverse events that come up during a device trial and build a database around simple "yes/no" propositions, such as "was the event serious?" or "was it associated with the device?"

Silver-Kessler shared the stage with Kenneth Kleinhenz, the vice president for regulatory affairs for CSSi Lifesciences, a Baltimore-based CRO. Once a device is approved for market, there are still federal reporting requirements for adverse events. Two of those — death or malfunction — are fairly straightforward. But requirements to report any adverse event that causes "serious injury" can often trip up device sponsors, Kleinhenz said.

A good rule of thumb is to report any event that requires any kind of medical intervention — something as seemingly banal as a dose of antibiotics, Kleinhenz said. Some device companies try to litigate their way around the vagaries of reporting requirements — the definition of "permanent" damage, for instance — but "you're going to lose that argument every time" when the FDA comes calling, he said. — Bill Myers

MAGI, *from Page 5*

Before hiring a site or CRO, sponsors should create a checklist starting with a good monitoring plan, Truax-Bellows suggested. Sponsors should hash out which party is responsible for the monitoring. Sponsors should push to have an internal employee in charge of monitoring any regulatory issues and get clarity about what kind of impact they as a sponsor will have if there are concerns.

They should also insist on clear lines of approval. Even in the best circumstances, it might be worth it to bring in a third party auditor because sometimes even internal employees can "lose the forest for the trees," Truax-Bellows said.

Ross urged sponsors and sites to invest in new technologies to monitor quality. "There's an explosion in telemedicine," she said. "There should be an equivalent explosion in tele-monitoring."

Both women agreed that sponsors and sites should welcome whistleblowers. "If you're a smart sponsor, you should say, 'Bring it. Let's dig in, find out if something really is wrong and fix it,'" Ross said.

If a sponsor don't support its whistleblowers, sites shouldn't work with that sponsor again, she said. — Bill Myers

FDA Classifies Humidified Oxygen Devices, Assigns Special Controls

To give a reasonable assurance of safety and efficacy of high flow humidified oxygen delivery devices, the FDA has organized them into Class II and identified their special controls in a final order.

The final order identifies risks to health associated with the devices and their mitigation measures — such as adverse tissue reactions, device interference, electrical shock injuries and software failure that delays therapy — and notes that a device must comply with the order's special controls to remain in Class II.

In order to demonstrate the device is reasonably safe and effective, numerous device functions and components need to be tested by the sponsor. For instance, the sponsor must show its patient-contacting parts are biocompatible and it should also test its alarm system, humidity output and blender performance during non-clinical performance testing, and assess electrical, thermal, mechanical safety, among other safety considerations.

The FDA noted that sponsors of humidified oxygen delivery devices do not need to conduct environmental assessments or issue an environmental impact statement, as it found the devices do not have a significant impact on the human environment.

The agency explained its decision to place the oxygen delivery devices in Class II as opposed to a Class III assignment — which occurs automatically without FDA action — saying that the placement into a lower device class would reduce regulatory burdens and enhance innovation.

Read the full final order here: www.fdanews.com/10-25-18-OxygenDeliveryDevice.pdf.
— James Miessler

APPROVALS

FDA Clears Viseon's Voyant System

Viseon's Voyant system received 510(k) clearance for use in minimally invasive spinal surgery access, visualization and illumination.

The device includes HD imaging sensor and illumination technology, and consists of a single-use sterile disposable retractor and a reusable controller for moving the site image.

The system allows surgeons to change the depth of focus and view the surgical site on HD flat-panel display monitors in the operating room.

Co-Diagnostics Gains CE Mark For Zika Screening Test

Co-Diagnostics received the CE Mark for its Logix Smart Zika screening test.

The polymerase chain reaction test can detect Zika's presence in plasma collected from patients suspected to be infected.

Studies have linked Zika with cases of microcephaly, a neurological disease that affects the brain development of fetuses.

Dexcom Wins CMS Coverage For Continuous Glucose Monitor

Dexcom announced that the Centers for Medicare & Medicaid Services agreed to cover its G6 continuous glucose monitoring system for Medicare beneficiaries.

The system features a redesigned applicator that inserts a small sensor below the user's skin to continuously measures glucose levels for up to 10 days and transmit the data to a display device.

The G6 won FDA approval in March and a CE Mark in April. The company expects to start shipping the system to Medicare customers in early 2019.

Matrix Surgical's OmniPore Implants Cleared for Marketing

Matrix Surgical USA received 510(k) clearance from the FDA to market its OmniPore DUROMAX surgical implants for non-weight-bearing applications of maxillofacial and orbital reconstruction, cosmetic surgery and repair of maxillofacial and orbital trauma.

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

Approvals, *from Page 7*

The orbital implant builds upon the company's previously cleared high-density polyethylene craniofacial implant platform by adding titanium inside the porous polyethylene framework. The titanium retains shape after manipulating by hand and is radiopaque on post-operative computer tomography (CT) scans, unlike regular porous polyethylene implants.

Additional variants are currently in development and are expected to be launched in early 2019 in markets where the company has regulatory clearances.

FDA Clears OrthoPediatrics' Scoliosis System

The FDA granted 510(k) clearance to OrthoPediatrics' Response 4.5/5.0mm system for treating complex scoliosis in younger patients of smaller stature.

The clearance expands the pediatric orthopedic devicemaker's Response platform, enabling it to treat smaller patients. It allows the surgeon to choose between a 4.5mm CoCr rod or a 5.0mm titanium or cobalt chromium/chrome rod.

OrthoPediatrics expects to launch the system in the fourth quarter of 2018.

OssDsign's Regenerative Cranial Implant Cleared by FDA

The FDA cleared OssDsign's Cranioplug, a cranial implant used during neurosurgical procedures to cover and plug holes made in the skull during surgery.

The Cranioplug, which is composed of an osteoconductive calcium phosphate ceramic and reinforced with titanium mesh, is meant to help reattach cranial bone taken out during surgery.

Its ceramic component resorbs and is eventually replaced by bone as the healing process takes its course. It can be used in patients aged 12 and older.

FDA Expands Indication of Levita's Magnetic Surgical System

Levita Magnetics received FDA clearance for an expanded indication of its magnetic surgical system for use in bariatric procedures.

The shaftless device — an external magnet placed on the skin that controls a detachable grasper — was originally indicated for gallbladder removal procedures, and can now reduce the amount of incisions and trocars needed in bariatric procedures.

The implant enables surgeons to move instruments without being restricted by a fixed-position pivot point and improves their visualization of the surgical site.

Gogoa Mobility Robots Earns CE Mark for Exoskeleton

Gogoa Mobility Robots earned a CE Mark for HANK, its lower limb exoskeleton system for use in rehabilitation of adults such as stroke patients following neurological injury. The system can also be used for gait compensation in patients who have paralysis of the lower limbs following spinal cord injuries.

HANK is the first exoskeleton for clinical use with a CE Mark and the first medical exoskeleton of its class with motorized ankles, allowing for more natural range of motion, the company said.

"Europe is the new hotbed for start-ups in the robotic rehabilitation field and we are proud to be the first EU company to get the certification," said Gogoa's CEO Carlos Fernandez.

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Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editorial: Declan Conroy
+1 (703) 538-7644
dconroy@fdanews.com

Ad Sales: Jim Desborough
+1 (703) 538-7647
jdesborough@fdanews.com

Multi-User Sales: Jeff Grizzel
+1 (703) 538-7669
jgrizzel@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • www.fdanews.com

Reporters: Zack Budryk, James Miessler, Bill Myers

President: Cynthia Carter

FDANEWS

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
- A training tool for employees new to the regulations

EU MDR Compliance: *A Checklist for Meeting Manufacturing, Safety and Performance Requirements* is the tool that collects all the requirements, explains them and itemized them in an easy-to-use form to ensure compliance.

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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 …

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