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IN THIS ISSUE

Regulatory Reshuffle in China Brings Sweeping Reforms to Device Oversight

Multinational medical device companies operating in China will want to keep a close eye on the shifting leadership changes in the country's new State Market Regulatory Administration.

The newly formed SMRA will absorb and oversee responsibilities previously held by the China Food and Drug Administration, establishing a new State Drug Administration that will maintain its own branches at the provincial level, leaving post-approval enforcement to municipal and country branches.

The SMRA will also oversee the responsibilities of the State Administration for Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the Certification and Accreditation Administration; and the Standardization Administration of China.

The new restructuring plan is considered the "most comprehensive government restructuring that China has undertaken since the

(See **China***, Page 2)*

Trump Administration's China Tariffs Hit Medical Devices, Components

U.S. medical device manufacturers could be impacted by the Trump administration's proposed 25 percent tariffs on thousands of Chinese goods, which include medical devices and device components.

The tariffs would hit a large number of devices such as catheters, imaging devices, anesthetic instruments and defibrillators, as well as hearing aids, pacemakers and artificial body parts, according to the administration's tariff list. Components used in medical devices would also be taxed, such as parts of medical and laboratory sterilizers and medical mirrors and reflectors.

China represents "the most significant growth market for the medical device industry today and for the foreseeable future," according to AdvaMed, and many of the association's members have established research and manufacturing facilities there.

(See **Trump***, Page 2)*

Trump, *from Page 1*

In response to the administration's tariff list, China announced its own proposed tariffs on $50 billion of U.S. goods, spanning 106 products in a range of categories that did not appear to include medical devices. The implementation date depends on when the United States imposes its tariffs, the Chinese Ministry of Finance said.

The tariffs are likely to impact U.S. medical device companies more than Chinese firms, especially for imaging products, according to China regulatory specialist Grace Fu Palma, founder and CEO of China Med Device.

"The tariffs could have more negative effects on the medical imaging industry, as many firms that once manufactured scanners in the U.S. have moved operations to China to take advantage of lower labor costs," she says.

"However, most of the imaging products made in China are mid to low end products. U.S. hospitals tend to purchase higher end products. Imaging centers and outpatient centers who are more price sensitive may hurt more," Palma says.

The tariffs could also affect the domestic Chinese imaging equipment export industry. Homegrown Chinese companies have begun to look for customers in the U.S. and Europe, among other locations. A 25% tariff could negate much of the price advantage of these companies but mostly in the mid to low end tier, she says.

Read the administration's tariff list here: www.fdanews.com/04-04-18-Section301.pdf.
— James Miessler

China, *from Page 1*

country implemented its 'Open Door' policy in the 1970s," said law firm Ropes & Gray in Shanghai.

"With the change, the Chinese leadership has tapped the SMRA as the single most powerful market regulator to address the public's ever-mounting concerns, including drug and food safety, protection of intellectual property and product quality issues," the law firm said. The SMRA will also oversee anti-trust and price supervision functions.

This means that the SMRA will oversee medical device safety supervision, quality inspections, fair competition and commercial bribery, business registrations, certifications and accreditations, management of intellectual property rights and comprehensive supervision and management of the market.

A key policy objective is to "enhance enforcement efficiency and consistency." For example, SMRA 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.

Even with the formation of the SDA, devicemakers could still have the challenge of having to answer to multiple regulatory bodies, the law firm said.

"It is unclear at this point whether the local MRAs and the national or provincial SDAs will interpret rules and regulations consistently — this will be a critical question going forward," it said.

Given the SMRA's broad regulatory, inspection and enforcement responsibilities, companies will likely have more communication with the agency, but the integration could result in more uniform procedures in dealing with "one window" rather than many.

One potential concern, however, is that the SMRA could be both "a player and a judge in the same playground," Ropes & Gray said.

Former CFDA Director Jingquan Bi, who is also the Communist Party secretary and deputy director, will lead the SMRA. The SDA will be led by former CFDA Deputy Director Hong Jiao and Communist Party Secretary Li Li, the former deputy governor of Jiangxi Province.

The new SDA body under the SMRA "could continue to implement the previous CFDA reform initiatives driven by Deputy Director Bi. However, the personnel reshuffle on the next level of bureaucracy might delay actual implementation of these initiatives," the law firm said.

Stakeholders Seek Clarification Of Investigational IVD Draft Guidance

Stakeholders lauded the FDA's efforts in developing draft guidance on the use of investigational in vitro diagnostic devices in clinical trials but said the agency needs to provide more specific examples for the guidance to be useful.

AdvaMed commended the agency on developing the draft and described it as a positive step in supporting innovators bringing new diagnostics to the U.S. to advance personalized medicine.

The FDA issued the draft guidance in December 2017, noting the growing interest in personalized medicine that relies on the use of IVDs to detect and measure biomarkers and other individual characteristics of diseases or other conditions to better manage patient treatment (*IDDM*, Jan. 1).

CDRH said it was concerned that study sponsors and Institutional Review Boards are unaware that many IVDs are investigational and their safety and effectiveness are still being assessed.

Extended List

In its comments, AdvaMed said it would like to see an "extended, comprehensive list of the known types of uses of IVDs in therapeutic product trials and clear instruction as to whether certain uses are considered investigational."

Examples of each type of IVD use and whether it falls within the scope of the guidance would be helpful, the industry group said.

AdvaMed said it supports allowing submission of all investigational device exemption components to an investigational new drug application rather than requiring both an IDE and an IND. It said this approach would promote efficiency and speed the review process. It also supported pre-submission meetings with the FDA to help coordinate reviews among the FDA centers and to agree on study designs that support validation of the IVD.

The Biotechnology Innovation Organization also asked the FDA to provide a comprehensive list of "known, potential and/or most common uses of IVDs in therapeutic product trials and provide explanation as to why it is considered investigational vs. non-investigational."

BIO pressed the agency to clarify that if the intended use of a cleared IVD is unchanged, then the IVD would not be considered investigational. It also sought clarification on what steps a sponsor should take when a change in risk status of an investigational IVD is noted. The association said risk determinations are not consistent, and more clarification was needed.

On the question of whether the agency should require both an IDE and an IND or one or the other, BIO said the process should remain flexible depending on circumstances, because sometimes it would be more beneficial to submit the IDE as part of an IND.

Three Categories

In its comments, Ilumina also welcomed the guidance and it commended the agency on the three categories of device studies outlined for significant risk studies, non-significant risk studies and exempt studies.

However, the company said the descriptions for making significant risk determinations are "terse and fail to recognize how difficult these risk determinations can be." It suggested that the FDA provide concrete examples from its regulatory review experience.

PerkinElmer said in its comments that although it appreciated FDA's effort to clarify when an IVD is investigational, "we believe the document is ambiguous as to whether laboratory-developed tests are by default considered to be investigational based on the definition of 'an IVD that is legally marketed'."

The devicemaker asked the agency to clarify where it stood on the applicability of laboratory-developed tests in the final guidance document, particularly since many clinical trials rely on the testing of samples submitted to labs in the absence of an available IVD.

PerkinElmer also pointed out that the guidance assumes that the IVD maker would have knowledge of the clinical study, but the device maker stressed that this is not always so clear.

CDRH's Case for Quality Program Continues to Evolve

CDRH's Case for Quality program manager highlighted changes on the horizon at the FDAnews 15th Annual Medical Device Quality Congress.

"We want to expand the appraisal focus from manufacturing to design. Design allows us to actually implement the same kind of rapid changes into the 510(k) space," said CDRH's Cisco Vicente.

The program will focus on simplification over the next couple of years to "incorporate the most concepts" moving forward, he said.

The agency also plans to streamline non-product computer validation systems to encourage risk-based approaches to validation, he said, noting that implementing automated data analysis and manufacturing technologies can create delays due to the perceived regulatory burden and outdated auditing procedures.

The FDA will apply streamlined approaches and practices and issue guidance centered around related assurance activities, in addition to running modified computer system validation protocols with industry participants.

The Case for Quality program also aims to shift away from inspecting and controlling and move towards rapid learning, error-proofing and continuous improvement.

"Inspect and control doesn't always lead to the best results," Vicente said. "Sometimes you need to be able to rapidly change to get better results."

The Case for Quality program is a collaborative effort that directs the sector's focus from regulatory compliance to continual high quality production in order to enhance patient safety and medical device quality.

CDRH launched a pilot program in January, the Capability Maturity Model Integration (CMMI), which focuses on assessing and appraising medical device facilities as opposed to inspecting and auditing.

The third-party maturity appraisal "evaluates the execution of the quality system in varying degrees of maturity" to evaluate a medical device company's capability to produce safe, high quality devices, Vicente said.

"Appraisals are really more interview focused," he said. "They're not really there to go back and look at your documents all over again. Now they want to see, are those documents really working? Are they working across your project? They'll sample several projects, they'll talk to the people at all levels."

Compared to an FDA inspection, the CMMI appraisal facilitates open conversation, involves many participants outside the quality assurance and serves as an opportunity for the agency to study facility practices instead of enforcing regulations. Whereas an FDA inspection does not encourage discussing future plans or improve opportunities, the CMMI appraisal does.

"We like to see future improvements, and not every 483 needs to be a CAPA, but we've never been clear about, so that's just some of the things that started to get exposed," Vicente said. "Maybe we can be a little more collaborative and transparent about what our expectations are in these areas."

Vicente said that in the future, the agency will seek to reduce burdens on facilities that arise from the current appraisal process.

"The process itself shouldn't be a burden for your own staff," Vicente said. "We've seen that even with some of the benchmarking activities, where things get taken out of what would be a natural flow… that's something we need to figure out a better dynamic around."
— James Miessler

PEOPLE ON THE MOVE

Smith & Nephew named **Namal Nawana** as its chief executive officer effective May 7. Nawana was most recently CEO of Alere, where he oversaw its $5.3 billion acquisition by Abbott in 2017. He joined Alere as chief operating officer in December 2012. Prior to Alere, he spent more than 15 years at Johnson & Johnson, primarily in its medical devices and diagnostics operations in the USA, Asia and Europe. In 2011 he became worldwide president of J&J subsidiary DePuy Synthes Spine.

483 Roundup: FDA Flags Four Firms For Validations, Design Controls

The FDA cited to four devicemakers for a range nonconformances including problems with design controls.

HLPR: The FDA issued a Form 483 to HLPR saying the device contract manufacturer did not properly validate its processes or calibrate equipment.

The agency issued the form following a November/December 2017 inspection of the company's Hamel, Minnesota facility. A process used for the company's External Pulse Generator Disposable Pouch was not properly validated, according to the FDA, and a required test was not being performed.

The company also did not properly calibrate equipment used in the production of the disposable pouch, despite a provision in the company procedures stating that all equipment used for accepting product must be maintained and calibrated routinely and prior to use.

The facility lacked adequate device history records for the disposable pouch. The company also failed to maintain training records for at least two operators who assembled pouches in late 2014 and early 2015.

Modal Manufacturing: Modal Manufacturing drew a Form 483 from the FDA for problems with its procedures for ensuring all products it received conformed to specification and for inadequate design risk analysis.

The FDA issued the form following a December 2017 inspection of its Palm Beach Gardens, Florida facility. Investigators found that four of the facility's suppliers did not have any on-site audits as required by the company's standard operating procedures, and it did it complete a required desk audit at its instrument supplier facilities.

Investigators also found that the company conducted several processes that were not properly validated. In addition, the company's risk analyses for its Hip Total Hip System and Knee Systems did not properly include class 2 instruments in its process failure mode and effects analysis.

Spectra: The FDA cited Spectra Therapy for deficiencies in design control, medical device reporting and CAPA procedures.

The agency issued a Form 483 following a November/December inspection of the device manufacturer's Troy, Michigan facility. According to investigators, the company designed and

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

Will the FDA Respond to a 483 Response?

Question: Once we've submitted our response, should we expect a response from the FDA and how long does it usually take?

Answer: There's really no measuring stick for how long it may take to get a response.

Sometimes you won't get much of a response from the agency. Sometimes it will be months and months and months down the road. And that can mean a number of different things. It could mean the FDA isn't fully satisfied yet and officials are making decisions about what to do next. It could also mean that your response is just caught up in the agency's backlog.

You typically will get a response from the FDA at some point if the agency is satisfied, just letting you know that it received and reviewed your responses and considers them adequate.

Sometimes you can get some insight into what might be going on. If you contact your district office and request a copy of the Establishment Inspection Report, but the FDA is unwilling to release it to you, that indicates that the agency considers it an ongoing enforcement matter. The FDA won't release an EIR until it considers all issues to be closed out.

Excerpted from the *FDAnews* management report: *Effective 483 Responses: Focus on CAPA Violations*.

483s, *from Page 5*

developed its Spectra A-100 Impulse Laser Device without design control procedures.

The agency also faulted the facility on its written MDR procedures. The facility lacked written procedures to ensure timely identification and evaluation of events that potentially require MDRs, or a standardized review process for determining which events are reportable, or for timely transmission of MDRs.

The facility also had not established a purchasing control procedure setting out requirements suppliers, contractors and consultants must meet, and had no established procedure for acceptance of incoming product.

TriMed: The FDA cited TriMed for numerous deficiencies such as faulty design control, inadequate design change procedures and incomplete risk analysis.

The agency's November 2017 inspection of the firm's Santa Clarita, California facility revealed issues with a design control procedure after the inspector reviewed the design history files for the firm's Distal Humerus Fixation system (DHFS) and the Nitinol Sterile Staple system (NSSS).

For example, design inputs for the DHFS did not address performance requirements, such as expected product reliability under its stated uses. The sole design verification report only addressed the mechanical strength of the plates, with no records showing that other device aspects were verified.

The firm also had deficient procedures for design changes. A complaint received for a Dorsal Wrist Hook Plate alleged that "a screw went through the dorsal hook plate" and the plate seemed to be manufactured incorrectly. After investigating the complaint, it was determined that the failure was related to an unverified and unapproved design change made to the product that was not validated.

In addition, design changes made to the firm's Humeral Supracondylar Medial Nail plate were not verified or validated, although the engineering change release lists the parts as "Use".

In addition, the firm conducted inadequate risk analysis. It initiated corrective and preventative actions to address customer complaints about hex drivers with epoxy melting and coming off after undergoing sterilization at the user's facilities.

Because the malfunctions risked dropping particles into surgical sites, they were deemed reportable to the FDA as medical device reports. However, the firm's analysis for the fixation systems failed to document and assess the risks.

The firm also lacked written CAPA or complaint procedures.

Read the HLPR Form 483 here: www.fdanews.com/04-05-18-hlprinc483.pdf.

Read the Modal Manufacturing Form 483 here: www.fdanews.com/04-05-18-modal483.pdf.

Read the Spectra Therapy Form 483 here: www.fdanews.com/04-05-18-spectratherapyllc483.pdf.

Read the TriMed Form 483 here: www.fdanews.com/04-06-18-trimedinc483.pdf.

— Zack Budryk and James Miessler

BRIEFS

Indian Parliament Critical of Policy That Favors FDA-Approved Devices

India's Parliamentary Standing Committee was critical of a health department policy that required U.S. FDA approval or CE marking for devices sold in India where Indian standards are not available.

The critics were responding to a health department circular that said organizations that procured devices could insist on FDA approval or European CE marking when domestic quality standards were questionable.

Domestic associations also were critical of the ministry, saying that other standards such as ISO or ICMED could be used to verify quality standards.

Japan Updates Standards For Device Connectors

Japan's Pharmaceuticals and Medical Devices Agency is revising standards for connectors of medical devices to prevent misconnections across different product areas.

The regulator said new standard products in each product area should be marketed in sequence and that new and old standard products will not connect with each other.

The standards will apply to neuroaxial applications, breathing systems, enteral applications, urethral and urinary applications and limb cuff inflation applications.

Brazil Requires Anatel Certification for Wireless Devices

Brazil's National Agency of Sanitary Surveillance is requiring wireless medical devices to be certified by Anatel, the country's telecommunications agency, and devicemakers wanting to register wireless devices in Brazil, must include an Anatel certificate when they submit their applications.

The regulator said the move would help ensure safety and efficacy of health products and the technologies with which they interface.

APPROVALS

Siemens Receives CE Mark for PCR Assay

Siemens' Fast Track Diagnostics earned a CE Mark for a real-time PCR assay that can detect 14 human papillomavirus subtypes that put patients at high risk of abnormal growths.

The assay detects HPV 16, HPV 18 and 12 other high-risk HPV strains.

More than 90 percent of HPV infections are resolved within two years, but a small fraction of the 14 high-risk subtypes can cause neoplastic lesions.

LivaNova Aortic Valves Approved For Expanded Use Labeling

LivaNova earned a CE Mark and approval for expanded use of its Bicarbon aortic valves with lower dose blood thinners in low-risk patients.

The expansion means that a lower international normalized ratio — the standard for measuring blood coagulability — can be targeted following implantation of the valve in low-risk patients going through mechanical aortic valve replacement.

After implanting the aortic heart valves in patients with low risk of thromboembolic events, physicians can work with a lower-range level of anticoagulant therapy, potentially reducing the risk of bleeding without increasing the risk of blood clots.

Dexcom's Glucose Monitoring System Receives FDA Approval

The FDA gave Dexcom's continuous glucose monitoring system Dexcom G6 marketing approval and classified the product as a Class II device.

The Dexcom G6 can integrate with other medical devices and electronic interfaces like insulin pumps, blood glucose meters and automated insulin dosing systems.

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

Approvals, *from Page 7*

The device is a small patch that users apply to their abdomen. A sensor within the device continuously measures glucose in the user's body fluid and transmits readings every five minutes to its smartphone app.

FDA Clears inPrint 3D Software

Materialise's Mimics inPrint software, designed to print 3D anatomical models for diagnostic use, received 510(k) clearance from the FDA.

The device converts DICOM medical image data to anatomical 3D models.

It is designed for pre-operative planning and printing physical models used for patient management, treatment and communication among surgeons.

7SBio's Blood Collection Device Receives CE Mark

Seventh Sense Biosystems' TAP, a one-step blood collection device, received a CE Mark in Europe.

The single-use device is painless and around the size of a stethoscope bell. It can hold up to 100 microliters of blood and secures the needles inside the device.

The device also is designed for attachment to future accessories, such as for connectivity and sample separation.

Emosis' HIT Diagnostic Test Approved for Marketing by EC

The European Commission granted Emosis' heparin-induced thrombocytopenia (HIT) diagnostic test a CE Mark.

The flow cytometry-based HIT Confirm test provides results in a half hour by reading selected platelet biomarkers.

The test can contribute to the diagnosis of potentially lethal HIT in patients treated by the anticoagulant.

Senseonics' Eversense Recommended for Approval by FDA

Senseonics received a unanimous recommendation for approval from an FDA advisory panel for its implantable continuous glucose monitor for use in adults with diabetes.

The device is a fluorescence-based system that is implanted in the upper arm in a 5-to-10 minute office-based procedure. The implanted sensor lasts ninety days after which it is removed with another short procedure and replaced.

An external transmitter is taped on the skin above the implant to allow the glucose monitor to work with its accompanying smartphone or tablet mobile app, which displays and stores the glucose readings.

DxNow Cleared for ZyMot Sperm Separation Devices

The FDA granted 510(k) clearance for DxNow's ZyMot ICSI and ZyMot Multi, devices intended for preparing motile sperm from semen to be used in infertile couples.

The devices facilitate the separation and preparation of highly-motile sperm with normal morphology to be used in assisted reproductive technology procedures.

The ZyMot devices can be used to prepare sperm for intracytoplasmic sperm injection, intrauterine insemination and in vitro fertilization procedures.

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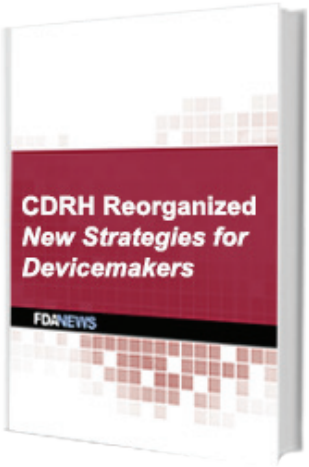

CDRH Reorganized: *New Strategies for Devicemakers*

Device regulation is about to change in ways large and small, as the CDRH moves toward a total reorganization.

CDRH's reorganization plan — to be carried out over the next two years — aims to replace current siloes of responsibility with a team approach that follows a device from development to application to premarket planning and ultimately to postmarket surveillance, with the same people working together at each stage.

CDRH Reorganized lays out all of the moving pieces and lets you know what to expect, how to take advantage of new opportunities and how to influence the direction of the new system. And you'll hear it from one of the people most qualified to interpret the changes, former CDRH Associate Director of Policy Paul Gadiock.

Gadiock recommends devicemakers get in on the ground floor of this reorganization. "Disruption can be unsettling," he says, "but if you're attentive, it also presents opportunity for new ideas because there's less inertia standing in your way."

You will learn:

- The planned structure of CDRH's regulatory and clinical evidence offices
- The most effective strategies for communicating with the FDA post-reorganization
- How the center's new focus on total product life cycle will drive premarket and postmarket data collection
- How the new CDRH Digital Health unit will help streamline the review process for digital health devices
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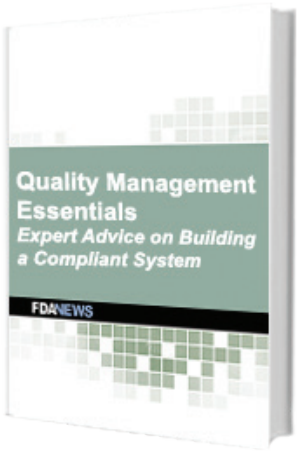

Quality Management Essentials: *Expert Advice on Building a Compliant System*

A strong quality management system is the foundation of a drug or devicemakers success. A shaky quality system is sure to lead to a company's downfall.

In this new report from FDAnews, top authorities in quality management give insight and advice on the features that make a system strong and effective. This collection of essays from five of the drug and device industry's most knowledgeable practitioners illustrates exactly how to create or update a quality management system that hits all the right notes.

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- The role senior management should play in the quality system
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Step into the classroom. These five experts average more than three decades of experience in developing effective quality systems:

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- Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.
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