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IN THIS ISSUE

FDA's Device Safety Monitoring System Is Inadequate, Senate Report Finds

A Senate report that followed an investigation by Sen. Patty Murray's (D-Wash.) office has found that the FDA's regulatory system for monitoring the safety of devices failed to quickly identify and resolve the spread of antibiotic-resistant infections linked to duodenoscopes.

In September 2013, the FDA started investigating how closed-channel duodenoscopes could spread infection despite proper cleaning, but the agency did not alert the public of the risks for 17 months, says the report, issued by Murray, ranking member of the Senate HELP Committee.

Also, three duodenoscope manufacturers failed to meet regulatory requirements — Olympus submitted incomplete and misleading medical device reports, and Pentax and Fujifilm filed late and incomplete reports, the report says. In addition, several hospitals failed to send required adverse event forms (*IDDM*, Aug. 21, 2015).

"While responsibility for the slow response is shared among Olympus and the other device manufacturers, hospitals, and FDA,

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FDA Nominee Califf Sails Through Senate Committee Vote

In a unanimous voice vote, the Senate's Health, Education, Labor and Pensions Committee on Jan. 12 voted in favor of Robert Califf to be the next commissioner of the FDA.

But the nominee will face one more barrier as the vote moves to the full Senate. Committee member Sen. Lisa Murkowski (R-Alaska) reiterated her intent to block Califf's approval until she has reassurances from the agency on mandatory labeling requirements for genetically modified salmon.

Califf received strong support from Committee Chairman Lamar Alexander (R-Tenn.), who praised the nominee as having "impressive qualifications." Ranking Member Patty Murray (D-Wash.) said he would be a "valuable partner" at the helm of the FDA. She added that

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his record as a former cardiologist and Duke clinical researcher is "a clear indication that he will be a strong, independent FDA commissioner."

During a hearing before the Senate HELP Committee last fall, Califf defended his record, emphasizing he would not lower standards for approvals (*IDDM*, Nov. 20, 2015).

Califf is calling for reform of clinical trials but does not believe new FDA regulations are needed. Instead, he is calling for a combination of small, focused trials for precision medicine and large retrospective trials using electronic health records to lower the costs of clinical trials. Those comments were in response to inquiries from Alexander and Murray during Califf's confirmation hearing in November 2015.

A full Senate vote on Califf's confirmation has not yet been scheduled. — Michael Cipriano

Standard for Measuring Exposure To Ionizing Radiation Gets an Update

The ISO's standard for measuring exposure to ionizing radiation has been updated, taking into account the new limit on equivalent dosing to the lens of the eye, as recommended by the International Commission on Radiological Protection.

The new version of ISO 15382 takes considers learnings from the latest studies and helps improve routine dosimetry measurements, says Alain Rannou, chair of the technical committee that developed the standard.

Released last month, the standard has been extended to the medical field, with an eye toward improving routine monitoring of workers who are most likely to experience exposure to their extremities and the lens of the eye.

Ionizing radiation is used in a wide range of settings and industries, such as medical diagnostic and radiotherapy. The revised standard, known as *Radiological protection – Procedures for monitoring the dose to the lens of the eye, the skin and the extremities*, replaces the 2002 version. — Jonathon Shacat

Monitoring, *from Page 1*

the investigation overall demonstrates that FDA's device surveillance system is overly-reliant on device manufacturers and user facilities to make quick and complete reporting of safety issues over their own competing priorities," the report says.

The report calls for:

- The FDA to update its guidance to clarify when manufacturers are required to seek clearance when medical devices are modified, and Congress to clarify the FDA's authority to consider a 510(k) application incomplete in the absence of sufficient data to demonstrate a medical device can be safely cleaned and reused;
- Congress to require unique device identifiers to be included in insurance claims and fully fund a National Medical Device Evaluation System to ensure that the FDA is able to effectively monitor device safety rather than relying on adverse event reporting;
- The FDA to quickly evaluate the design of closed-channel duodenoscopes and implement a phased recall to fix or modify the devices if necessary; and
- The FDA to more quickly disseminate information to healthcare providers when it becomes aware that patient safety might be compromised by a device.

The Senate report follows the FDA's release of draft guidance highlighting the need to disclose what it calls "emerging signals" that may affect the benefits and risks of marketed products at the same time it evaluates and analyzes data, rather than after completing its review (*IDDM*, Jan. 11).

Murray applauded the FDA's proposal, although she said more needs to be done. The Senate report calls the proposal a positive step that will allow the agency, the public and hospitals to take action sooner when new device issues arise.

Read *Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients* here: www.fdanews.com/01-16-Senate-Report.pdf. — Jonathon Shacat

FDA Proposal Would Reclassify ECT Devices

The FDA is seeking stakeholder feedback on a proposal to reclassify electroconvulsive therapy devices from Class 3 to Class 2 for treating severe major depressive episodes associated with major depressive or bipolar disorder.

The reclassification would apply to patients 18 and older who are treatment-resistant or who require a rapid response due the severity of their condition, according to a proposed administrative order.

In separate draft guidance, the FDA says it also is proposing to require that sponsors identify technical parameters — including waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy and the type of impedance monitoring system necessary to characterize and compare the device performance.

In addition, the proposal would require that nonclinical testing confirm the electrical characteristics of the output waveform. Companies also would be required to perform appropriate software verification, validation and hazard analysis.

The FDA also is proposing the filing of a premarket approval application for ECT devices for certain specified intended uses. Sponsors would be required to submit a PMA application within 90 days after a final order is issued.

In general, the reclassification as proposed is not popular, according to submissions in 2009 public docket. Roughly 80 percent of 3,000 respondents opposed reclassification, with the majority citing adverse events from ECT treatment, including memory adverse events, other cognitive complaints, brain damage and death.

The FDA says the proposed special controls can effectively mitigate health risks, based on findings from an agency review that included examining the results of more than 60 randomized, controlled clinical trials. These studies evaluated ECT against either placebo or antidepressant therapy.

Comments are due by March 28. Read the draft guidance here: www.fdanews.com/01-16-FDA-ECT.pdf. The proposed order is here: www.fdanews.com/01-16-ECT-Order.pdf.
— Jonathon Shacat

Device Evaluation System Tops FDA's Strategic Priorities

The FDA plans to establish a system that would allow for the use of "real-world evidence" to help the agency more quickly identify safety signals and address concerns, according to its list of strategic priorities for 2016-2017.

The infrastructure, dubbed the National Medical Device Evaluation System, would use electronic clinical data, such as electronic health records, registries and medical billing claims in which device identifiers have been incorporated.

The agency aims to gain access to 25 million electronic patient records with device identification by Dec. 31, and 100 million records by the end of next year. The FDA also aims to increase the use of real-world evidence to support regulatory decisions by 40 percent by the end of this year and by 100 percent by Dec. 31, 2017.

The goals come as a new Senate report calls on Congress to require unique device identifiers to be included in insurance claims and fully fund a National Medical Device Evaluation System to ensure that the FDA is able to effectively monitor the safety of devices on the market rather than relying on adverse event reporting (*see story, page 1*).

The FDA's list of strategic priorities also aims to boost patient interaction to advance the development and evaluation of innovative devices and monitor the performance of marketed devices. By Dec. 31, 2017, 90 percent of CDRH employees will interact with patients as part of their job duties, according to the goals.

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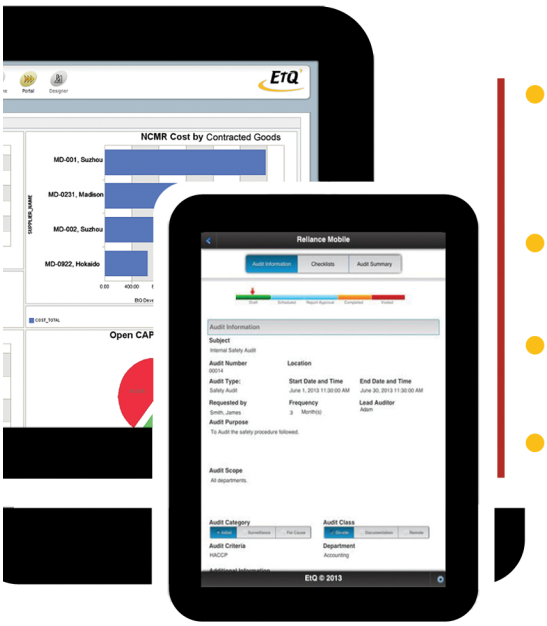

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Thornhill Recalls Ventilator Due to Battery Problem

Thornhill Research is recalling its MOVES System emergency ventilator after receiving reports about battery problems.

The recall — designated Class 1 by the FDA, involves 83 units distributed in Virginia and in Singapore, the agency says. Customers reported that the batteries were not responsive after storage, were not recognized by the main device and were perpetually enabled.

The company became aware of the battery issue via a customer complaint, says Thornhill CEO Kipton Lade.

Thornhill sent a recall letter in December, identifying the affected products and actions to be taken. It instructed customers to update their device software.

A new version of software was provided in a Feb. 19, 2015 service bulletin. The software update incorporated the cycling of charge to the battery into the power manager for automatic recovery without user intervention, such as inserting and removing the battery from a MOVES several times, Lade tells *IDDM*.

Read the recall notice here: www.fdanews.com/01-16-Thornhill-Recall.pdf. — Jonathon Shacat

Stryker Recalls Device Due to Potential Catheter Breakage

Stryker is recalling its Fuhrman pleural and pneumopericardial drainage set because of the potential for the device's catheter to break during insertion.

The recall, designated as Class 1 by the FDA, involves 34 devices, which were manufactured from Nov. 6, 2009 to Oct. 21, 2011, and distributed between Dec. 12, 2009 and Oct. 28, 2011.

The company received reports that the catheter included in the drainage set broke off in the pleural cavity of two patients, according to an FDA recall notice. The agency says both cases resulted in the need for medical intervention, and that this issue could cause serious patient injury or death.

The device is used to remove air from the pericardium or to drain air or fluid from the pleural cavity that protects the lungs.

Stryker sent notification letters on Nov. 17, 2015, telling customers to discontinue use of the product and explaining steps to return affected devices. The voluntary recall was issued by Stryker for the sets, which were originally manufactured by Cook Medical.

The devices subject to recall are part of Stryker's expired/unused program, which is strictly a sterilization service for open, unused devices. Devices sterilized through the service were not used clinically prior to being sent to Stryker for repackaging and sterilization, the company says.

Single-use devices remanufactured and reprocessed by Stryker are not affected by the recall, Chris Sugg, the senior director of regulatory affairs and quality assurance at Stryker Sustainability Solutions, tells *IDDM*.

Read the recall notice here: www.fdanews.com/01-16-Stryker-Recall.pdf. — Jonathon Shacat

FDA Classifies Intravaginal Culture System in Class 2

The FDA issued a final order on Jan. 5 classifying the intravaginal culture system into Class 2 with special controls.

The order spells out specific risks and mitigation measures for the products, which are identified as a prescription device intended for preparing, holding and transferring human gametes or embryos during intravaginal *in vitro* fertilization or intravaginal culture procedures.

The decision went into effect on Nov. 2, 2015, following a request from INVO Bioscience for classification of the INVOcell intravaginal culture system (*IDDM*, Nov. 4, 2015).

Read the final order here: www.fdanews.com/01-16-ICS-Order.pdf. — Jonathon Shacat

Medical Device Industry Sees $2.7B in Funding in 2015

Private companies looking to attract the interest of venture capital firms had some success last year, taking in more than $2.7 billion.

That's according to "The MoneyTree Report by PwC and the National Venture Capital Association based on data from Thomson Reuters," unveiled Friday, which provided venture capital funding numbers for the fourth quarter and the year.

During the fourth quarter, the life sciences sector — which includes biopharma and medical device companies — saw $2 billion go into 172 deals, representing a decline of 31 percent in dollars and 16 percent in deals versus the third quarter, according to the MoneyTree Report.

Compared with 2014, total investments were up 12 percent; however, the number of deals was down 3 percent.

Looking at device companies specifically, Greg Vlahos, life sciences partner at PwC, tells *IDDM* that those companies that focus on cardiovascular products continue to enjoy funder interest. He adds that 2015 funding for the industry was in line with previous years, although it is on the high-end of the typical $2 billion to $3 billion range the industry tends to rake in.

Medical device funding fell from about $836.1 million in Q3 to $589.3 million in Q4. The total number of deals remained steady, falling one to 77 in Q4. Interestingly, the top 8 deals of Q4 were larger in terms of cash brought in than the leading deal of Q3, which brought in $26.5 million.

EndoGastric Solutions led the pack in Q4, reeling in just under $50 million. The round was led by CRG, which was joined by existing investors Advanced Technology Ventures, Foundation Medical Partners, Canaan Partners, Chicago Growth Partners and Radius Ventures. Redmond, Wash.-based EndoGastric is focused on incisionless procedures for gastroesophageal reflux disease.

Coming in second for the quarter was Nxthera, which took in $40 million in a round led by Boston Scientific. Joining the funding round were Aberdare Ventures, GDN Holdings, Ally Bridge Capital Partners and Arboretum Ventures. At the same time, Nxthera, which focuses on men's health, announced the expansion of the company's debt facility with East West Bank. Nxthera intends to use the proceeds to expand sales of the FDA-cleared Rezum system to treat benign prostate hyperplasia.

Coming in third for the quarter was Irvine, Calif.-based Axonics Modulation Technologies, which raised $38.5 million in Series B funding. New investors Advent Venture Partners and Cormorant Asset Management joined Neomed Management, Edmond de Rothschild Investment Partners, Legend Capital, The Alfred E. Mann Foundation and other private partners in the round. The company says it will use the proceeds in a study involving overactive bladder patients that will start early this year in the U.S. and EU.

Rounding out the top 5 are Fractyl Laboratories with $37.2 million and BAROnova with $36.5 million. — Elizabeth Hollis

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Companies Make New Investments in Israel

Israel's medical device industry is the focus of millions of dollars of new investment — including recent ventures led by Johnson & Johnson Innovation.

Last week, V-Wave said it had raised $28 million to support further development of its unidirectional interatrial shunt to treat heart failure. Participants in the funding round included new investors JJDC, TriVentures, Pura Vida Investments and BioStar Ventures, as well as existing investors BRM Group, Pontifax and Edwards Lifesciences.

Also last week, CartiHeal said it had raised $15 million to support commercialization of its CE-marked cell-free, cartilage regeneration technology — an investment led by JJDC together with existing investors: Elron, Accelmed, Access Medical Ventures and Peregrine Ventures.

Other Ventures

At least one other Israeli company announced completion of new financing so far this year. PiCardia, which developed a catheter system to treat aortic valve stenosis, raised $10 million, including investments from Italian funds Innogest and Fondo Atlante Ventures, Chinese fund VI-Ventures and existing investors in the company, including Clal Biotechnology Industries and Anatomy Medical Technologies Fund.

Meanwhile, Teva Pharmaceutical Industries and Royal Philips are continuing to make progress on Sanara Ventures, which began in March 2015. Sanara operates as a technological incubator under a license granted by the Administration of the Technological Incubator Program at the Israeli Office of the Chief Scientist in the Ministry of Economy.

The companies have committed to invest up to roughly $25 million over eight years. Last July, Sanara announced the first two investments — in Kaleidoscope Medical and MGD, says Steve Klink, spokesman for Philips. Kaleidoscope is developing an X-ray radiation shielding system for use during catheterization procedures, while MGD is developing a portable device for measuring lung functions.

Recently, a third company was enrolled in the incubator program. Sanara plans to announce the name of the third company at a later stage, Klink tells *IDDM*. — Jonathon Shacat

Vice President's Office Meets With Experts on Plan to Cure Cancer

The future of cancer research is the focus of new attention, following Vice President Joe Biden's "moon shot" vision to find a cure for the disease.

Members of the American Association for Cancer Research met with Biden's office earlier this month and pushed for the federal government to help set up an infrastructure for interaction between the centers in the U.S. that obtain genomic, genetic and clinical information from cancer patients.

The effort would allow for all of the information that is generated nationwide to be pooled together in large database so individuals can share it, says Victor Velculescu, an AACR board member and co-director of Cancer Biology at John's Hopkins Kimmel Cancer Center.

AACR members also met with the FDA earlier this month to discuss next-generation sequencing, laboratory-developed tests and companion diagnostics. The meeting comes in the wake of concern over how easy or difficult it will be to use the products in the context of FDA rules, Velculescu tells *IDDM*.

Biden — who lost his son to brain cancer last year — has vowed to increase the amount of resources devoted to fighting cancer, calling for collaboration and information sharing. "The goal of this initiative is simple — to double the rate of progress. To make a decade worth of advances in five years," he said. — Jonathon Shacat

Strategic, *from Page 3*

Another goal aims to increase the use of patient input in the agency's decision making. By Sept. 30, 2017, 100 percent of PMA, de novo and humanitarian devices exemption decisions will include a public summary of relevant patient perspective data considered. By that same date, the agency will increase the number of patient perspective studies used in support of premarket and postmarket regulatory decisions, and increase the number of expedited access pathway data development plans or regulatory submissions that consider patient perspectives.

In addition, the agency plans to strengthen its culture of quality, setting a goal to increase by 25 percent the number of CDRH staff with quality and process improvement credentials by Sept. 30, 2017.

The agency also highlighted its accomplishments in the past two years towards its 2014-2015 Strategic Priorities, including:

- Establishing a clinical trials program, developing clinical trials education for staff and industry, developing new policies and processes and establishing investigational device exemption performance metrics;
- Conducting a retrospective review of all 210 high-risk device product codes, which required more than 275 postmarket analyses, resulting in a reduction in premarket data requirements and/or a recommendation to downclassify a technology for about 30 percent of the product codes;
- Establishing a regulatory pathway for breakthrough devices that, when appropriate, allows for shifting appropriate premarket data needs to the postmarket setting; and
- Completing 14 premarket process improvement projects, resulting in the implementation of all 11 recommendations stemming from the MDUFA III assessment of the premarket review process.

Read the *CDRH 2016-2017 Strategic Priorities* here: www.fdanews.com/01-16-FDA-Priorities.pdf and the *CDRH 2014-2015 Strategic Priorities Accomplishments* here: www.fdanews.com/01-16-FDA-Accomplishments.pdf. — Jonathon Shacat

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ANVISA Easing Industry Burden With New Requirements for Devices, IVDs

Brazil's ANVISA has issued new regulations defining registration requirements for medical devices and *in vitro* diagnostics that likely will require industry to revise technical documents by Oct. 26.

In RDC 40, ANVISA removed a list of Class 1 and 2 devices that still required the longer *registro* process. Most Class 1 and 2 devices went through the abbreviated *cadastro* process — now all will.

In RDC 36, Anvisa now has included Class 2 IVDs in the *cadastro* process. Class 1 IVDs already were under *cadastro.*

Also, IVD equipment, which in the past was under the general medical devices regulation, is now included in the IVD regulation.

IDDM asked Marcelo Antunes, regulatory affairs strategy consultant at SQR Consulting in São Paulo, to explain how the new regulations will affect industry.

IDDM: *What kind of burden will this impose on industry?*

Antunes: Industry will probably need to revise technical documents — for both IVDs and all other devices — because there are new requirements related to the technical dossier.

On the other hand, *cadastro* will be exempted from the five-year renewal (meaning that they won't need to be renewed anymore — the maintenance of the *cadastro* will be tied to compliance to the requirements of Good Manufacturing Practice, applicable technical standards and specific regulations, when they exist).

Devices under *registro* still need a five-year renewal, but there's a proposal to extend that to 10 years.

IDDM: *Do you anticipate any challenges for devicemakers in coming months?*

Antunes: There are new requirements — for example, a new, explicit requirement for human factors/usability — that will require some work on the part of manufacturers.

The revised requirements from the technical dossier are in line with International Medical Device Regulators Forum expectations. However some, such as human factors/usability will be "new" to Brazilian regulations.

IDDM: *What do you see as the biggest impediment for manufacturers to remain in compliance as they prepare for the changes related to regulations?*

Antunes: The technical requirements — for example, those for human factors and software, as well as revised ones for clinical information — will be problematic.

In the case of imported devices, a typical problem is that the original manufacturer does not want to share technical information with the Brazilian registration holder — now it must.

IDDM: *What is the single most important piece of advice you can give industry as it prepares for the changes resulting from the regulations?*

Antunes: ANVISA has been very clear in saying that, although they are lessening the regulatory burden (in the case of *cadastro*, they removed the renewal requirement, for example) it wants manufacturers and importers to have all of the technical documentation in place, and also have active process in place, including risk management and post-market surveillance. In the case of devices with mandatory certification, the validity of the *cadastro* is now tied to the certificate.

In general, the regulations now are much more technical in nature, and manufacturers and importers have to plan carefully and implement a strategy to deal with these and other new and expected requirements.

More information is here: www.fdanews.com/01-16-Anvisa-RDC.pdf.

BRIEFS

Smith & Nephew Buys Blue Belt Holdings

Smith & Nephew has completed its acquisition of Blue Belt Holdings, which focuses on orthopedic robotics-assisted surgery, for $275 million. Blue Belt manufactures the NAVIO surgical system, which provides robotics-assistance in unicondylar or partial knee replacement surgery using CT-free navigation software, as well as a hand-held robotic bone-shaping device. Smith & Nephew also announced intentions to expand the NAVIO platform into total knee, bi-cruciate retaining knee and revision knee implants.

Health Canada Blesses FebriDx Test

Health Canada has issued a device license to RPS Diagnostics for its FebriDx test. The diagnostic helps to identify a pathogen-induced immune response to viral or bacterial acute febrile respiratory infection with a fingerstick blood sample. Results are available in 15 minutes, enabling the establishment of an effective patient treatment plan, RPS says. The test detects heightened levels of Myxovirus resistance A, an intracellular protein that increases when an acute viral infection is present. It also simultaneously tests for C-reactive protein, acute-phase protein that elevates in the presence of a bacterial infection.

FDA Clears Modified Duodenoscope

The FDA has blessed Olympus with clearance for its TJF-Q180V duodenoscope with modifications to the device's design and labeling. Its new design of the elevator channel sealing mechanism looks to create a tighter seal and reduce the potential for leakage of fluids and tissue into the closed elevator channel. The modifications — which aim to help reduce the risk of bacterial infections — come amid several reports of duodenoscopes being linked to the transmission of antibiotic-resistant infections. Olympus says it will implement a corrective action in the U.S. for currently used TJF-Q180V duodenoscopes. The action involves replacing the forceps elevator mechanism with a new forceps elevator design.

AdvaMed Names Barney to Lead RT

Shandi Barney has joined AdvaMed as vice president and sector lead of radiation therapy. The newly created sector will address the regulatory and payment challenges facing this area of medtech innovation, and promote the benefits and value of RT, including radiotherapy, brachytherapy and proton therapy. Barney has in-depth knowledge in the area of radiation therapy, which is providing safe and effective solutions for patients afflicted with devastating conditions, especially cancers.

Boston Scientific Launches Ureteroscope

Boston Scientific has launched its LithoVue single-use digital flexible ureteroscope in the U.S. and Europe. The device is designed for minimally invasive endoscopic procedures to diagnose and treat stones and other conditions of the kidney, ureter and bladder. According to the devicemaker, the ureteroscope brings high-quality digital visualization and seamless navigation for consistent clinical performance. The device also is available in New Zealand.

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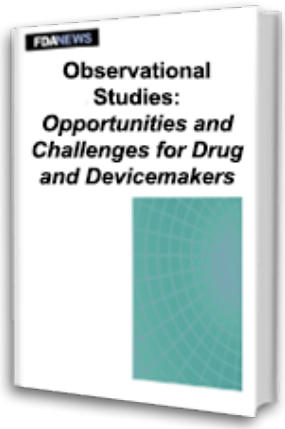

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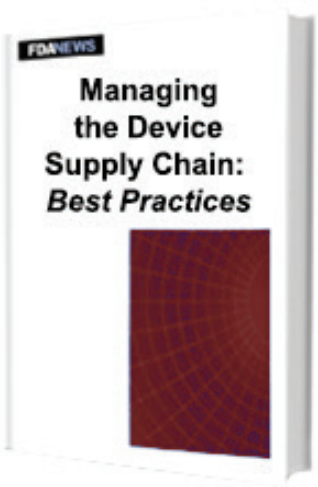
Managing the Device Supply Chain: *Best Practices*



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