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IN THIS ISSUE

Digital Health Takes the Stage In FDA's 2018 Policy Roadmap

Advancing digital health technologies will take precedence over other FDA efforts in the medical device space this year, the agency's new 2018 strategic policy roadmap suggests.

Digital health technologies provide a significant opportunity for regulatory modernization as they are "characterized by highly iterative cycles of innovation" and "new software advances are introduced into products sometimes on a near-constant basis," the 18-page policy roadmap states.

As part of the FDA's Digital Health Innovation Plan, there are two main goals identified in the roadmap as a focus this year – finalizing guidance on which digital health products fall outside the scope of FDA authority to take enforcement actions; and developing a tailored regulatory approach that can adapt to rapid innovation through the Pre-Certification Program.

(See **Policy**, *Page 2)*

China Releases Review Guidelines For Mobile Medical Devices

China's Food and Drug Administration released technical review guidelines for mobile medical devices to guide devicemakers in preparing applications for the devices and to help control the risks associated with mobile computing technology.

The technical guidelines are based on China's National Security Law, CFDA device regulations and information security standards relevant to cloud computing, big data, and mobile terminals. They also draw upon FDA guidelines as well as EU and International Medical Device Regulators Forum (IMDRF) documents.

The guidelines apply to equipment or software that combines a medical use with a non-invasive mobile computing terminal. Implantable and invasive medical devices are not included in the category.

When making a judgment about the device classification, CFDA recommends considering the intended use of the mobile computing device

(See **China**, *Page 4)*

Taiwan FDA Advances First Medical Device Act

Taiwan recently took a major step in advancing legislation that would revamp how its medical device system is regulated.

The Republic of China's Executive Yuan approved the Medical Devices Act draft, issued last summer by the Taiwan Food and Drug Administration, and recommended it to the Legislative Yuan in mid-December. The act recognizes that Taiwanese regulations on medical devices should be separated from the Pharmaceutical Affairs Act of 1993.

If enacted, the legislation would introduce several new requirements for medical device manufacturers, including the submission of annual reports on the devices, and the creation of tracking mechanisms to provide up-to-date information on existing devices. They would also be required to comply with TFDA's good distribution practices (*IDDM*, July 14, 2017).

The aim of the legislation is to achieve "a sound system for life cycle management of medical devices and promote development of the medical device industry," TFDA said in its July 2017 announcement of the draft regulation.
— Ana Mulero

Policy, *from Page 1*

Technology innovation will require the agency to modernize its approach to ensure its policies can address existing challenges, such as the increasing time and costs of medical product development.

"Our work is taking place during an inflection point in both science and policy," FDA Commissioner Scott Gottlieb said in announcing the new roadmap. "We have more opportunity to deliver on the promises of science that at any time before."

Gottlieb stressed that recent legislation, including the 21st Century Cures Act of 2016 and the FDA Reauthorization Act of 2017, have allowed the agency to "harness the full potential" of the emerging opportunities in the industries it regulates. New gene-based and remote monitoring technologies are examples of the products that are presenting novel challenges, he said.

The agency issued draft guidances in December on the digital health products that should not be regulated as medical devices, as the Cures Act had previously clarified (*IDDM*, Dec. 8, 2017).

A total of nine participants, including Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Alphabet's Verily, were selected by the agency in September to pilot the Pre-Cert program and provide feedback to help the agency and industry reach a consensus on the "standard of excellence" for digital health software, CDRH associate director for digital health Bakul Patel told *FDAnews* at the time (*IDDM*, Sept. 29, 2017).

Another FDA initiative that will also be a priority at CDRH this year is the Medical Innovation Action Plan. The goals identified in the roadmap for advancing this plan include: Creating a new Total Product Life Cycle Office; and issuing guidance on a new 510(k) pathway alternative that can provide greater flexibility to devicemakers by allowing the use of performance criteria.

Last September, Gottlieb said CDRH's move to launch the TPLCO is among the policy advances at the center that "are going viral" across the entire agency as it is designed for more holistic product evaluations (*IDDM*, Sept. 29, 2017).

The plan to design a new 510(k) pathway as well as to issue draft guidance on "acceptable levels of uncertainty" to strike a balance between pre- and post-market data for timely patient access to quality medical devices was announced last December, with Gottlieb predicting the draft versions on both policy documents to be released by early this year (*IDDM*, Dec. 15, 2017).

The goals identified in the policy roadmap are intended to "yield results over the next two years," Gottlieb said. — Ana Mulero

FDA Approved Record Number Of Novel Devices in 2017

The FDA approved a record number of novel devices in 2017, with a total of 95 approvals — more than four times the 2009 number — up from 91 the year before.

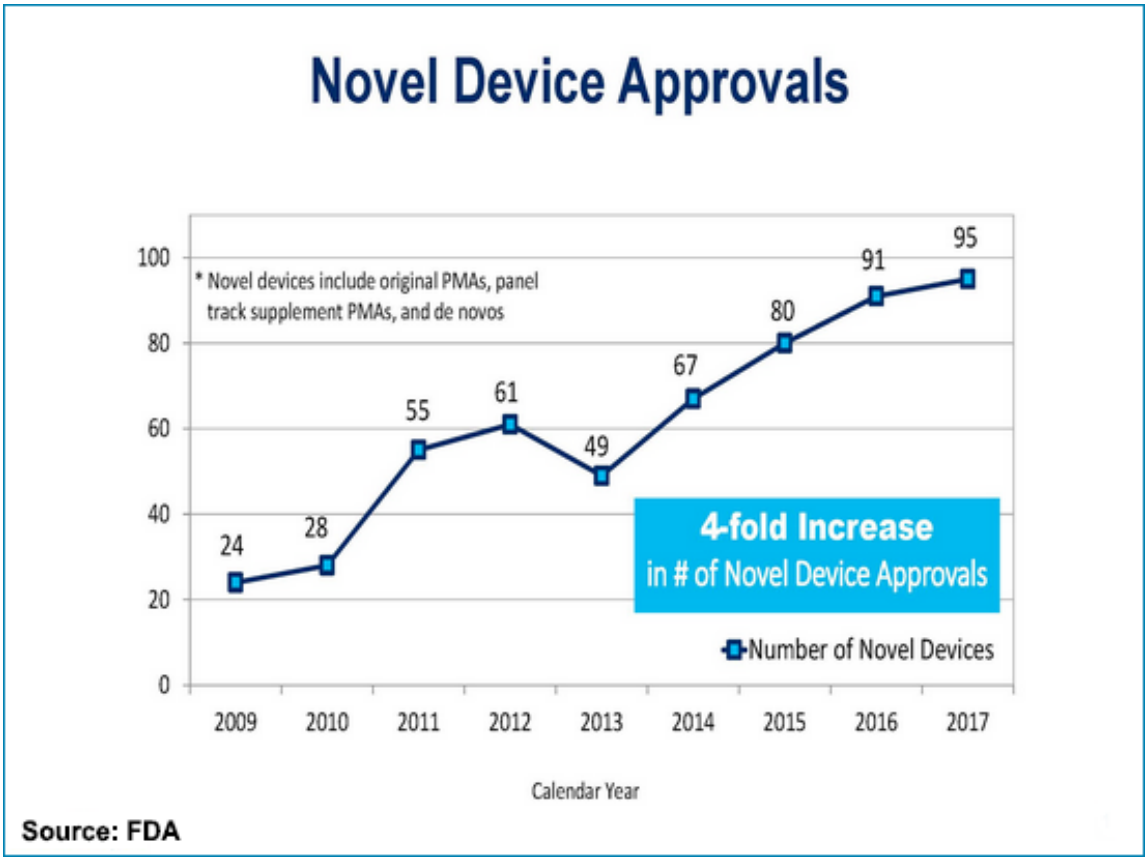
FDA Commissioner Scott Gottlieb attributed the results to the use of the agency's least burdensome approach, which directs agency staff and industry to use the minimum amount of information for regulatory activities. "This policy approach is a hallmark of our efforts to help innovators generate high quality evidence that can support marketing approval as efficiently as possible," Gottlieb said, in a blog post.

Last December, the agency issued draft guidance to update its 2002 policies on the least burdensome principles in light of more recent legislation, including the 21st Century Cures Act of 2016, underscoring the need to rely more on post-market activities for mitigating risks when making premarket regulatory decisions to ensure timely patient access (*IDDM*, Dec. 29, 2017).

The agency has also been encouraging the use of different product development processes, such as the 510(k)-CLIA waiver dual submission pathway, that are intended to aid device manufacturers in getting their products to the market at a faster pace. Draft guidance on this pathway for new in vitro diagnostic devices was also issued late last year (*IDDM*, Dec. 1, 2017).

The FDA/CMS Parallel Review Program also provides a "fast-track" pathway for manufacturers to have new device applications undergo expedited regulatory reviews while the Centers for Medicare and Medicaid Services simultaneously proposes insurance coverage for Medicare patients. Gottlieb pointed to the FoundationOne CDx, manufactured by Roche's Foundation Medicine, as an example of a novel diagnostic device approved last year.

FoundationOne CDx is the first next-generation sequencing-based in vitro diagnostic test with breakthrough designation and only the second product to be approved under the FDA/CMS review program. It can detect mutations in 324 genes and two genomic signatures by sequencing DNA in solid tumor samples. — Ana Mulero



Health Canada to Pilot Medical Device Electronic Submission Process

Heath Canada intends to begin piloting the use of its Regulatory Enrollment Process through the Common Electronic Submission Gateway for medical device applications by this summer.

The REP — currently being tested by sponsors of pharmaceuticals and biologics to electronically send applications — was designed to "reengineer existing administrative processes to take advantage of the tools and capabilities of an electronic processing and review environment," Health Canada said.

The goal is for the collection of web-based templates, which capture metadata in an XML format, to provide for consistency across different types of regulatory activities.

For sponsors, potential benefits include reducing the time spent on submissions and the associated costs. This is because the CESG allows Health Canada to "partially populate internal systems ahead of time and automate certain procedures when a submission is received" in an electronic common technical document (e-CTD) format, the agency said.

Health Canada began accepting regulatory submissions in the standardized e-CTD format in 2004. It stopped accepting paper copies of the submissions as of last April, after which non-eCTD electronic-only formats became the only ones accepted for Class III and IV medical devices. The pilot seeks to expand the scope of non-eCTD formats that the CESG can accept. — Ana Mulero

China, *from Page 1*

or software, the target population and the core functions. Types of mobile medical devices include:

- Mobile medical equipment that uses computer terminals or other components for its intended use;
- Mobile independent software; and
- Mobile medical accessories that control the operation of medical devices.

The guidelines acknowledge that there is no clear dividing line between mobile medical devices and mobile health electronic devices, so the applicant must determine this based on the device's intended use.

Generally, if a device is intended for health management of healthy populations, it is not considered a medical device, CFDA said. Rather, it is expected that a medical device would be used in managing disease or diagnosing and treating patients for rehabilitation.

Devicemakers will need to conduct additional risk studies to assess the risks of mobile computing technology. The assessments should consider risks relating to mobile computing terminals and the risk management of independent software. Risk management of the mobile medical accessory controlled by the software should be integrated with the medical device.

The CFDA guidelines include technical considerations such as network security capabilities, display restrictions, environmental light impact, battery capacity limits, and cloud computing services.

Devicemakers should follow network security, cloud computing and big data-related national laws, regulations and standards to ensure that mobile medical devices protect patient privacy, CFDA said.

Given the wide range of mobile medical devices, devicemakers will need to submit documentation based on the type of mobile medical device and the characteristics of the mobile terminal, along with clinical evidence of the product's safety and effectiveness.

Devicemaker Hit for Auditing, CAPAs, Complaint Handling Issues

Palo Alto Health Sciences drew a Form 483 from the FDA for inadequate CAPA and complaint procedures, and for incomplete internal auditing and supplier profiles.

The agency observed in its October 2017 inspection that the facility's complaint handling procedure required all product complaints to be assessed for adverse event reporting. However, none of the company's complaints from 2016 or 2017 reviewed by the FDA had been evaluated.

Corrective and preventative actions were not properly documented, the agency found. The firm opened a CAPA to address a Freespira breathing session's failure to upload, applying a software update to fix the issue. However, evidence of the update's effectiveness had not been documented in the CAPA.

The company also retained a supplier that did not have a supplier company profile on file, a requirement of the firm's supplier evaluation procedure. The supplier had also neglected to provide the firm a copy of its accreditation — required for suppliers approved based on accreditation. In addition, the firm's internal audit procedure did not commit to formal internal audits of key quality system areas as required.

Read the Palo Alto Health Sciences Form 483 here: www.fdanews.com/01-09-18-paloaltohealthsciencesinc483.pdf.

Earpiece Manufacturer Cited For Quality, Calibration Issues

Westone Laboratories' manufacturing facility in Oregon drew a Form 483 from the FDA for significant quality system nonconformities and equipment calibration issues.

A November 2017 inspection revealed the firm's quality system had deficiencies in all 11 costumer complaint records reviewed by the agency investigator.

In addition, the firm's recordkeeping made it unclear if the issues described in the complaints represented adverse events that should have been reported to the FDA, and the efficiency of its

(See **Westone**, *Page 6)*

Common Audit-Related Citations

A properly designed and executed audit program holds the key to preventing most, if not all, of the leading 483 observations related to quality control unit issues.

Four common mistakes keep showing up on 483s and warning letters. One of the most common citations is for companies using internal auditors who have direct responsibility over the area they are reviewing. For instance, if complaint handling falls under the purview of the quality systems manager, that individual should not audit the complaint handling process. Independence of the auditors is a requirement under 21 CFR Part 820, the Quality System Regulation.

Another common citation is for companies that don't do internal audits at all, or don't do them with sufficient frequency, which for the FDA means at least once a year.

Failure to establish procedures for internal audits, along with the related citations of failing to establish adequate procedures or failing to follow written audit procedures, are a third common citation in 483s and warning letters. Devicemakers need to have a document that states what they will do regarding internal audits and then follow those procedures.

The fourth top citation is failure to adequately document audit findings. It doesn't matter how well a company may have conducted an audit or followed its audit procedures if there is no documentation of that fact. Documentation procedures should be included in the overall audit procedures and followed scrupulously.

Excerpted from the FDAnews management book: *Effective Internal Audits & Quality Control Units for Devicemakers*.

Westone, *from Page 5*

complaint processing could not be determined from the data on record, the agency said.

Westone Laboratories' medical device reporting compliance procedure stated that all complaints involving hearing protection products would be evaluated by the compliance manager to determine if an investigation was necessary. Yet the FDA investigator did not find evidence of this being implemented in any of the reviewed records.

The agency found that the firm did not have a management representative with the authority to ensure the satisfaction of quality system requirements. A quality unit responsible for implementing quality systems regulations was found to be lacking as well.

Cleaning and equipment maintenance schedules were also not fully or adequately established at the time of the FDA's visit. The investigator revealed that preventative maintenance of facility ovens used in the manufacturing of hearing protection devices was discontinued in March 2017, and the last calibration conducted for oven thermometers was conducted in November 2014.

Read the Westone Laboratories 483 here: www.fdanews.com/01-11-18-westonelaboratories inc483.pdf.

EC Adds Products to Classification Manual for Medical Devices

The European Commission added 12 products to its manual on "borderline and classification cases" for medical devices.

The manual provides clarifications on which products are defined as medical devices within the scope of the EU's Medical Device Directive. For products considered medical devices, the manual describes case-by-case classifications.

The commission updates the manual regularly based on consensus among member states and other stakeholders. How a product is defined and its classification are left up to individual member states, and may vary.

It remains unclear how the interpretations may change when the EU's new medical device and in vitro diagnostic regulations are applied in 2020 and 2022, respectively.

Half of the newly added products are not considered medical devices. These include: products intended to reduce the effect of alcohol; radiation shields; D-mannose for the prevention of urinary tract infections; solution of 8-MOP in extracorporeal photochemotherapy; microplate washers; and a mobile application for managing pictures of moles.

The other six, which are considered to be medical devices, are: Alum styptic pencils (Class IIa); tissue expanders used on the breast (Class III); dura guard for use with a craniotome (Class III); heart bypass machine (Class III); liquid nitrogen for cryopreservation of cells and tissues of human origin for medical purpose (Class IIa); and a mobile application for the assessment of moles (Class I). — Ana Mulero

FDA Warns BD Facility In Ongoing Lead Test Probe

The FDA issued a warning letter to Becton Dickinson for distributing adulterated and misbranded devices, among other significant GMP violations, as part of its ongoing investigation of inaccurate blood lead test results associated with Magellan's LeadCare test systems.

The agency's inspection of the device manufacturer's Franklin Lakes, NJ facility revealed that the firm did not have an approved application for premarket approval for its BD Vacutainer K2EDTA Tubes product, and did not notify the agency of its intent to commercially distribute the product after making significant changes to its rubber stoppers.

"We are continuing to aggressively investigate this issue, including whether the use of BD tubes led to inaccurate lead test results," said Donald St. Pierre, CDRH's acting director of in vitro diagnostics and radiological health and deputy director of new product evaluation.

Tests the firm ran to predict the impact of the modifications on the product were deemed inaccurate and did not include clinical testing. The inspector noted that the modifications could have a large impact on the product's safety and effectiveness, as well as on other products, and warranted submissions of new premarket notifications.

The inspection also found numerous failures to meet GMP requirements. In one instance, the firm did not have adequate procedures in place to manage complaints, neglecting to document a complaint about negative bias in blood test results collected in Vacutainer tubes.

In response to the FDA's warning, Richard Byrd, worldwide president of BD Preanalytical Systems said in a statement, "We are carefully reviewing the agency's feedback outlined in yesterday's letter with the highest sense of urgency, and we will provide a full response to FDA on or before their Feb. 1 deadline."

Read the Becton Dickinson warning letter here: www.fdanews.com/01-12-18-BectonDickinsonCo.pdf. — James Miessler

APPROVALS

Xcision Medical Breast Cancer Device Scores FDA Clearance

Maryland-based Xcision Medical Systems achieved FDA 510(k) clearance for its noninvasive stereotactic radiation therapy system indicated for breast cancer treatment.

The GammaPod system features thousands of focused radiation beams and a vacuum-assisted cup for immobilizing the breast during a treatment procedure to preserve healthy tissue around the tumor.

Masimo Sensors for Oxygen Reserve Index Monitoring Score CE Mark

Masimo, a Swiss manufacturer of noninvasive monitoring technologies, received a CE Mark for its RD rainbow Lite SET sensors.

The sensors are intended to enable clinicians to noninvasively monitor the company's Oxygen Reserve Index as well as its RPVi — a multi-wavelength version of the Pleth Variability Index.

The lightweight sensors have a flat, soft cable with smooth edges, so that they lie comfortably on a patient's hand or foot.

FDA Expands Evoke Neuroscience System Use Indications

Evoke Neuroscience achieved 510(k) marketing clearance to expand the indications for use on its eVox System.

The new indications are electroencephalography and event-related potentials to aid in clinical diagnoses.

The device enables physicians to assess patients' memory loss using the biomarkers it acquires.

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

Approvals, *from Page 7*

Bausch + Lomb Achieves FDA Clearance for Crystalsert Injector

The FDA issued 510(k) marketing clearance for the Bausch + Lomb Cystalsert 2.6 injector.

The first-of-its-kind FDA-cleared injector can be used across the company's suite of intraocular lenses.

The CI-26 allows for easy wound entry and helps prevent tissue snagging via an incision as small as 2.6 mm, the company said.

Mevion Secures FDA Clearance For Proton Therapy System

Mevion Medical Systems achieved FDA clearance for its MEVION S250i Proton Therapy System.

The system is designed to deliver radiation treatments using the company's HYPERSCAN pencil beam scanning technology.

The technology uses energy layer switching and automated systems to deliver pencil point radiation treatments.

FDA Approves MRI-Conditional Labeling on Two Abbott Defibrillators

The FDA approved Abbott's MRI-conditional labeling for two of its defibrillator devices.

The new labeling on the Quadra Assura MP cardiac resynchronization therapy defibrillator, and its Fortify Assura implantable cardioverter defibrillator will aid in clinical assessments.

The ICDs are intended for restoring normal heart rhythms, whereas CRT-D implant devices are designed to assist the lower chambers of hearts and improve blood flow throughout the bodies of patients with progressive congestive heart failure.

Hologic Gets CE Mark for Tissue Removal Treatment Device

American devicemaker Hologic received a CE Mark for its MyoSure MANUAL device.

The device features an integrated vacuum and a see-through tissue trap to enable clinicians to visually confirm the tissue being removed.

It is intended to "simplify tissue removal procedures regardless of setting," the company said.

Canada Approves DermTech Pigmented Lesions Assay

California-based manufacturer of molecular dermatology DermTech secured approval to market its Pigmented Lesions Assay and its biopsy kit for detecting melanoma in Canada.

DermTech Canada will market and sell the assay in the country, and biopsy samples will be processed at the company's central laboratory in La Jolla.

The assay is designed to analyze skin biopsy samples through a noninvasive adhesive patch.

FDA Clears Cerebrotech Neurological Spectroscopy Device

The FDA cleared Cerebrotech Medical Systems' Cerebrotech Visor, a bioimpedance spectroscopy device designed to aid clinicians in assessing cerebral fluid volumes.

The clearance includes a broad indication for use in assessing fluid volume differences between the cerebral hemispheres in patients undergoing neurologic assessment.

Nevro Wins FDA Nod for Spinal Cord Stimulation System

Nevro has received FDA approval for its Senza II spinal cord stimulation system.

The system delivers the company's proprietary HF10 therapy, which provides the spinal cord with electrical pulses to treat pain by interfering with nerve impulses. The company has been battling in federal court against Boston Scientific over patent infringement allegations involving its SCS therapy.

Zimmer Biomet Scores FDA Clearance For Shoulder Treatment System

Devicemaker Zimmer Biomet received FDA clearance for its Sidus stem-free shoulder system.

The shoulder arthroplasty device is intended for anatomical restoration and bone preservation.

The company initiated a Class I recall in early 2017 of certain reverse shoulder system models due to a high fracture rate.

FDA Sets UDI Compliance Deadlines For Class I, Unclassified Devices

The FDA issued "immediately in effect" guidance for manufacturers of class I and unclassified medical devices on compliance dates for meeting unique device identification requirements.

For the standard date formatting, labeling and Global Unique Device Identification Database (GUDID) data submission requirements, the newly established compliance date is Sept. 24, 2018. For UDI direct mark requirements, the compliance date is Sept. 24, 2020.

Enforcement Dates

These differ from the agency's enforcement dates, however. The agency does not intend to enforce UDI labeling, GUDID data submission or standard date format requirements for class I and unclassified devices manufactured or labeled on or after Sept. 24, 2018 until Sept. 24, 2020.

For those devices that were manufactured or labeled before the compliance date, the enforcement date for these requirements is set for Sept. 24, 2021, as the FDA is required to provide a three-year transition period for finished devices.

The Sept. 24, 2022 FDA enforcement date for both pre- and post-compliance date class I and unclassified devices to meet direct mark requirements gives device firms two and one more years, respectively, as the agency believes it would better serve public health to allow them to first focus on fully implementing UDIs.

The guidance does not apply to class I or unclassified implantable, life-supporting or life-sustaining devices. Compliance dates for these devices as well as class II, and class III devices have already passed for most UDI requirements.

Final guidance on direct mark requirements for devices of all classifications was issued last November, and notes the approaching compliance date for class II devices of Sept. 24, 2018, as well as the Sept. 24, 2019 deadline for meeting UDI labeling requirements if manufactured or labeled after the initial compliance date, which was Sept. 24, 2016 (*IDDM*, Nov. 17, 2017).

High Risk, High Priority

The new guidance goes into immediate effect. The agency said it will consider, however, any stakeholder comments and make any needed revisions.

The FDA said it received a "large number of inquiries from labelers of class II, class III, and I/LS/LS devices" about the implemented UDI requirements and it "anticipates receiving a similarly high volume of questions from labelers of class I and unclassified devices."

But the agency will prioritize issues with higher risk devices.

"To fully reap the public health benefits and a return on investment of the unique device identification system, the agency intends to focus its resources on addressing existing implementation challenges and optimizing the quality and utility of UDI data for high-risk devices before focusing on UDI implementation issues for lower-risk devices," the FDA said.

Read the full guidance document here: www.fdanews.com/01-12-18-UDI.pdf. — Ana Mulero

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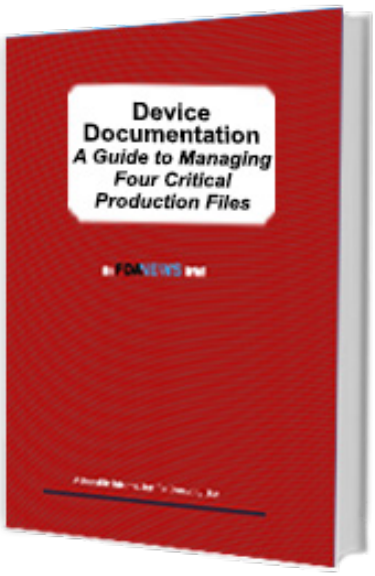

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