International Devices & Diagnostics Monitor

Vol. 3, No. 16
April 17, 2017

IN THIS ISSUE

Congress Unveils MDUFA Reauthorization Package

Congress Friday unveiled its first draft of MDUFA user fee reauthorizations, with total dollar amounts in line with those previously negotiated by regulated industry.

The draft bill would extend the existing MDUFA programs through 2022, but would include new fees related to de novo medical device reviews. Capitol Hill chose not to adopt President Trump's proposal, released earlier this year, for collecting more fees overall.

The base fee total to be collected over fiscal 2018 for devices would be $183.3 million, up from $130.2 million for the current fiscal year. That target amount would increase annually over the next five years, ending at $213.7 million for fiscal 2022.

The MDUFA reauthorization would also establish a pilot program allowing the FDA to certify and audit laboratories performing conformance testing, and would require the FDA to evaluate at least five device types.

(See **MDUFA**, *Page 2)*

FDA Publishes List of Class I Devices Exempt From 510K Reporting

The FDA has exempted more than 70 class I devices from premarket notification requirements—seven of which are subject to some limitations.

The list of exempt devices includes a range of instruments, from clinical chemistry and clinical toxicology devices to some neurological and radiological devices.

Exemptions from premarket notification requirements are, in some cases, limited to specific devices within a listed device type. For example, FDA lists the "exemption of the ataxiagraph device as 510(k) exempt, but limits the exemption to such devices that do not provide an interpretation or a clinical implication of the measurement.

(See **Exempt**, *Page 2)*

USITC to Investigate Infusion Therapy Product Trade Violations

The U.S. International Trade Commission (USITC) says it will investigate patent infringement/trade violations for certain intravascular administration sets and components, based on a March 13 complaint.

The complaint, against Yangzhou WeiDeLi Trade, of Yangzhou, China, was filed by Curlin Medical, and Moog, both of East Aurora, NY, and Zevex, of Salt Lake City, UT.

The devices are infusion therapy products, such as infusion pumps and disposable tubing used to deliver nutrients or medication into a patient's body.

The complaint alleges violations of section 337 of the Tariff Act of 1930 on the importation into the U.S., of products that allegedly infringe complainants' patents. Complainants requested that USITC issue a limited exclusion order and a cease and desist order. — William Schulz

Exempt, *from Page 1*

Under the 21st Century Cures Act, the FDA was required to publish the determination within 120 days of the date of enactment of the law, and at least once every 5 years thereafter, as the agency deems appropriate.

"Industry will no longer have to invest time and resources in 510(k) submissions for certain Class I devices, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review," the agency says.

The list was published in an April 13 *Federal Register* notice.

Read the full list here: www.fdanews.com/04-13-17-PremarketNotification.pdf.
— William Schulz

AdvaMed Predicts Repeal Of Medical Device Tax

Despite the failure of the American Health Care Act, which included a provision to repeal the 2.3% device tax introduced under the Affordable Care Act, AdvaMed President and CEO Scott Whitaker said he's confident Congress will find another way to get rid of the tax.

"We feel pretty good that if we move to another vehicle, whether its tax reform, [State Children's Health Insurance Program] SCHIP reauthorization, tax extenders, that the Chairman and the leadership of the House—and the Senate, frankly—will support moving it to another vehicle," Whitaker said April 11.

"I think in the second quarter or third quarter of this year, it'll move to the appropriate vehicle. I'm pretty confident it'll get done this year," Whitaker added.

A standalone bill would have broad bipartisan support, Whitaker said. As evidence, he cited legislation to repeal the tax, H.R. 184, the Protect Medical Innovation Act, that was introduced in January by Rep. Erik Paulsen (R-Minn.) and with the support of more than 220 lawmakers from both parties.

A Senate report from 2015 notes that the tax negatively impacts the domestic medical device industry, disproportionately affects small businesses, and is applied unfairly, as exported devices are exempt.

Congress passed a two-year suspension of the medical device excise tax last year as part of the Consolidated Appropriations Act of 2016.
— William Schulz

MDUFA, *from Page 1*

In addition, the bill would renew the agency's pediatric humanitarian device exceptions and consortia research grants, as well as the HHS secretary's ability to set device types appropriate for third-party review.

A summary of the draft bill is available here: www.fdanews.com/04-14-17-FDAUFASummary.pdf.

The full text of the draft bill is available here: www.fdanews.com/04-14-17-FDAUFADraft.pdf.

FDA Warns Abbott Over Defibrillator Manufacturing Issues

The FDA has issued a warning letter to Abbott citing serious CAPA and other violations at its St. Jude Medical defibrillator manufacturing facility in Sylmar, Calif.

During a Feb. 7-17 inspection, the agency found the firm underestimated the problem of premature battery drainage on some devices, and continued to ship the devices.

The agency says Abbott shipped 10 implantable cardiac defibrillators from one of its distribution centers despite a recall of its Fortify, Unify, and Assura products because of the battery drainage problem.

The company repeatedly concluded that the cause of the battery draining "could not be determined" although a supplier's analysis indicated the problem was caused by shorting of the lithium clusters.

Abbott based its risk evaluation on "confirmed" cases and did not consider the potential for "unconfirmed" cases to have been shorts, so it underestimated the occurrence of the hazardous situation, the agency said.

The firm failed to follow it CAPA procedures and conducted a risk assessment and a corrective action outside the CAPA system, the agency said.

The FDA also cited Abbott for failure to ensure that the defibrilltors only grant remote access to authorized users — placing the devices at risk of cyber hacking.

Read the Abbott warning letter here: www.fdanews.com/04-13-17-Abbott.pdf. — William Schulz

IMDRF Issues Final Guidance On Adverse Event Reporting Terms

The International Medical Device Regulators Forum has released final guidance on harmonized terminology for reporting adverse events related to medical devices and IVDs.

The use of a single terminology and coding system should improve signal detection by AE management systems, allowing a faster response by industry and regulatory agencies, IMDRF says.

IMDRF's Adverse Event Working Group has defined four distinct sets of terminologies and their associated alphanumeric codes: medical device problem, cause investigation, patient problem, and component. The working group advises coding to the most detailed level possible in agreement with the requirements of relevant jurisdictions.

The sets of terminologies are intended for use by reporters of AEs, in accordance with regulations in each jurisdiction. The terminologies are also for use by regulatory authorities—which may be national or supranational bodies charged with monitoring and analyzing AEs.

Precise criteria for AE reporting are defined by each regulatory jurisdiction and are not subject to the guidance, the working group says.

Using defined terms as well as associated codes to describe problems with medical devices, the working group says, can improve the accuracy of capturing and reporting device-related AEs; reduce ambiguity so as to increase effectiveness of the evaluation process, and it is more readily usable—in contrast to narrative text—for sophisticated approaches to signal detection, including advanced querying functions and data visualization.

Due to the fast-changing nature of the medical device industry and the implementation of new technologies, materials, designs, and so on, the working group says it anticipates the need for periodic review and maintenance of the AE terminology and associated codes.

However, changes to the AE terminology should be restricted to those absolutely necessary—such as new terms for new devices, designs, and materials, the working group says.

Read the IMDRF's guidance document here: www.fdanews.com/04-10-17-IMDRFterminologies.pdf. — William Schulz

Philips' Whole Slide Imaging System Wins FDA Approval

That FDA has granted de novo clearance for a Philips' imaging system that allows pathologists to read and interpret tissue slides digitally, rather than directly from a microscope.

The Intellisite Pathology Solution uses proprietary hardware and software to scan and digitize conventional surgical pathology glass slides prepared from biopsied tissue at resolutions equivalent to 400 times magnification.

The system enables pathologists to read tissue slides digitally in order to make diagnoses, rather than looking directly at a tissue sample mounted on a glass slide under a conventional light microscope.

Because the system digitizes slides that would otherwise be stored in physical files, it provides a streamlined slide storage and retrieval system that may ultimately help make critical health information available to pathologists, other health care professionals and patients faster," said Alberto Gutierrez, director of CDRH's Office of In Vitro Diagnostics. — William Schulz

PEOPLE ON THE MOVE

Relay Therapeutics has appointed **Sanjiv K. Patel, M.D.** as president and chief executive officer. He was most recently chief strategy officer at Allergan. Prior to that role, he was a management consultant at Boston Consulting Group in London.

Varian Medical Systems has named **Gary E. Bischoping, Jr.** as CFO. Mr. Bischoping has served Dell for the last 17 years, most recently as CFO of its client solutions group.

Defibtech has selected **Robert Reinhardt** as CEO. He previously served at Guidant, Johnson & Johnson and, most recently, Olympus Medical Systems Group, where he spent 17 years in technical, marketing and management leadership roles.

Minerva Surgical Claims Patent Infringement Against Hologic

Minerva Surgical, Redwood City, Calif., has filed suit in federal court in San Francisco claiming patent infringement by Hologic, of Marlborough, Mass., for its endometrial ablation device.

Minerva hopes to block U.S. sales of Hologic's endometrial ablation system, which also uses radiofrequency energy to remove endothelial tissue. Hologic began selling its NovaSure Advanced system in the U.S. in February. The company launched the device in Europe, Canada, and Australia in 2016.

Minerva's rival device, called Aurora, won FDA pre-market approval in 2015 but the company has not yet launched the service.

Minerva reported a funding round worth $16.7 million in December 2016, and said it wanted to raise $10 million more to support the Aurora system. — William Schulz

10 FDA Answers on 'Driving a Culture of Quality for Devicemakers'

By Daniel R. Matlis, President, Axendia

Last month, I had the privilege to moderate a discussion with Capt. Sean Boyd, deputy director for regulatory affairs in CDRH's Office of Compliance, and Francisco (Cisco) Vicenty, acting program manager of Case for Quality in CDRH's Office of Compliance.

During the webinar hosted by *FDAnews*, we discussed topics including:

- The Case for Quality – Why does it matter?
- Are we playing regulatory whack-a-mole?
- How is the role of FDA evolving to encourage a culture of quality for device makers?
- Have "Compliance First" regulatory approaches slowed innovation?
- Who benefits from a focus on quality?
- Are there appropriate substitutes for routine FDA inspections or pre-approval inspections?
- What are the quality outcomes metrics FDA will collect and monitor?
- How will FDA operate as we shift from documents to data/metrics as a result of using quality tools?

In addition, Capt. Boyd and Mr. Vicenty addressed the following audience questions:

Q1: How is the CfQ program different than Quality by Design?

A2: Quality by Design (QbD) is the systematic approach used in the pharmaceutical space for development that focuses on risk management and predefined objectives for product and process control. QbD is more analogous to Design Controls in Quality System Regulation. Case for Quality is an effort to work together with a community of stakeholders to incentivize performance and product quality. This collaboration will allow for faster and better data to drive purchasing decisions and FDA activity.

Q2: How will you measure the success of this program?

A2: This initiative is focused on moving past the compliance base-line and incentivizing manufacturers who produce high quality medical devices through transparency and working to bring these high-performing products to the hands of users faster. One of the efforts of this program has identified seven key outcome measures that will be used to monitor the performance of the products. This program shifts the focus from compliance to continuous improvement. These measures and metrics will become the gauge for success as the program evolves.

Q3: Eliminating device makers from routine inspections, is there a proposal for how long that would last? Such as permanent while CfQs are provided?

A3: This is part of the proposal being developed. FDA is pursuing options for how this would work. First, we want to clarify that the goal isn't about removing the routine inspection. FDA recognizes that any inspection can be a disruption and we want to adjust for that. We want to be able to leverage data and results to assure that the systems are working through less disruptive means. It moves to better and faster information in place of the routine inspection. CfQ is the title of the larger initiative. There will be a capability appraisal and then submission of the data will be used to monitor. The need for any additional audits or appraisals will be variable based on the capability of the facility and the data shared. As the program matures, an evidentiary appraisal to [Capability Maturity Model Integration] maturity levels will be possible, these then occur every 3 years.

Q4: You suggested "access to data which we haven't had before….could be uncomfortable…" What type of data do you think would help you better understand the firm's state?

A4: This is still in development, but there are several KPIs that a manufacturer uses now

(See **Webinar***, Page 6)*

Webinar, *from Page 5*

internally to assess the health of the system. No one is the gold standard, it really is about which is best for your organization. There may be key trends or results that the Agency would care about. These are the ones we would like to have visibility into. Yes, these could be uncomfortable, which is why we are working through a third party to collect and anonymize the data at first. Part of the effort is very dependent on transparency. We understand this needs training and context. Additionally, it means that we need to engage on the trend and how a manufacturer responds, not on how the single instance in time looks. This will be a learning period for all those involved and we are looking to establish principles for how that will be governed.

Q5: Do you think that FDA will actively encourage medtech companies to implement fully electronic DHRs to give full visibility to traceability of production history and quality?

Capt. Sean Boyd

As medical device manufacturing becomes more complex, with more use of electronic components and automation, the practice of validation and verification become directly opposed to manufacturers' goals of fast changes to processes or operations. What are your thoughts on if this difficult task is inhibiting manufacturers from becoming fully 'smart' in the context of the Internet of Things and Industry 4.0 concepts?

A5: FDA will not actively prescribe that a manufacturer needs to implement specific systems. That is driven by the needs and capability of the manufacturer, but we can actively acknowledge the benefits these systems bring, the improved product quality, the improved analysis, and the improved responsiveness. That brings a manufacturer into much higher organizational levels and quality performance. We are prepared to actively encourage that performance. This could have an effect of encouraging implementation and adoption of better systems. FDA can then actively work to clear the path implementation.

Q6: You mentioned possibly needing more information from companies. Are there pieces of information you already clearly believe you need? Does it come from current EQMS, or are there new capabilities needed?

Are regulators from Europe or elsewhere in the world involved in CfQ-type conversations also?

A6: This data is available in various systems that now exist. We don't have a defined set of data that we need, what we as an agency are working to establish is a defined set of assurances that we need and are working with manufacturers to establish the metrics and data that provide that assurance. As the data evolves and we learn, new capabilities may become apparent, but that will be driven by the whole ecosystem, not FDA.

Currently, this is an FDA regulatory effort and other regulators are not involved yet. A key tenet of Case for Quality is about not creating new regulation, but using data and real world evidence, to be smarter and more efficient in how the regulations that exist are fulfilled.

Q7: Is there a consideration of the interaction of CfQ with global initiatives, such as MDSAP?

A7: Yes, we are engaged with the MDSAP teams to leverage their output as a way to establish a baseline compliance. The elements on assessing capability and performance beyond the baseline are outside the scope of current regulatory models.

Q8: Is the CfQ for a specific product to be submitted for approval or the company as a whole?

A8: CfQ is looking to assess an organization's capability as a whole. The assessment and maturity model can be applied down to the device, project, or organizational unit. We are looking to incentivize a focus on quality performance, a

(See **Webinar**, *Page 8)*

483 Roundup: FDA Targets Four Device Facilities

The FDA has cited four device firms for a range of compliance issues including inadequate complaint procedures.

Following a November 2016 visit to Koros USA's Moorpark, Calif., facility, FDA inspectors observed that the company had established inadequate complaint procedures. Specifically, the facility's procedures did not include requirements to ensure that all complaints were evaluated to determine if an investigation was needed and whether the complaint was reportable. The procedures also failed to address; (2) any complaint involving the possible failure of a device, labeling, or packaging to meet its specifications was investigated; and (3) investigation records were maintained.

According to a Form 483, Koros also failed to update its written medical device reporting procedures to reflect current requirements for timeliness and for a standardized review process.

In addition, inspectors found that several of the company's corrective and preventive action records were marked as effective, but there was no documentation to show how this was determined.

The company's final inspection procedure did not include requirements to ensure that finished devices were not released for distribution until required activities were completed, until the associated data and documentation was reviewed, the release was authorized by a designated individual, and acceptance records were maintained.

Ascent Consumer Products: FDA inspectors visited Ascent Consumer Products' Melville, N.Y., facility in November 2016 and observed that the company failed to make required reports and to provide other information relating to classification, safety, and effectiveness.

Specifically, Ascent did not evaluate the need to file information with FDA regarding the micro-filter squeeze product, which includes a filter intended to allow the use of potable water for nasal irrigation.

Ascent also failed to present adequate scientific evidence that the micro-filter squeeze product was safe and effective. In addition, it did not conduct studies to provide supporting data that the filter units had effective anti-microbial properties over the assigned expiration period when properly used, cleaned, and stored.

Vacumed: A facility belonging to Vacumed, a division of Vacumetrics, received a Form 483 following a visit from FDA inspectors in June 2016.

According to the Form 483, the facility's procedures for design change were inadequate. Procedures failed to ensure that all design changes were validated, forms were not completed for design changes made to certain products, and documents were not handed in accordance with established procedures.

In addition, procedures for receiving, reviewing, and evaluating complaints by a formally designated unit were not adequately established. A complaint handling procedure failed to require an investigation of complaints involving possible failures in devices, labeling, or packaging. For example, certain devices were labeled and shipped incorrectly, but no investigation was conducted to ensure that appropriate corrective actions were implemented.

A.R. Hinkel: The FDA issued a Form 483 to A.R. Hinkel for failing to adequately validate design changes at its Chatsworth, Calif., facility.

The company's procedures required documentation and approval of design changes through an Engineering Change Order Form, but it did not require that all design changes be validated.

For example, the electrical jacks on a device were redesigned to correct a problem involving electrical current delivery. However, no records were provided to show that this change was validated, reviewed, and approved. In addition, an Engineering Change Order Form was not initiated for this design change.

The companies did not return requests for comment.

Read the Form 483s here: www.fdanews.com/04-14-17-FourForm483s.pdf.

Webinar, *from Page 6*

manufacturer can decide how they want to tackle their internal efforts, but the real value is when the whole company is part of the process. That is where we ultimately want to be as a community. It is not an immediate switch that is turned on and we want to be flexible to that.

Q9: Is this something that industry software providers can partner with CfQ program? For example, MES and PLM providers specific to medical devices?

Francisco Vicenty

A9: Yes, one of the key points to this effort is that everyone has a role to play in delivering improved patient outcomes. We have been engaged with industry software providers and they have been an asset in our learning. There is a need for everyone's expertise in this effort and we welcome any involvement.

Q10: Is this initiative being implemented through the 21st Century Cures Act?

A10: No, this initiative was started in 2011 as a result of Jeffrey Shuren, CDRH director, challenging the entire medical device ecosystem to find a better way. If we are all focused on the goal of improving patient outcomes and delivering high-quality product, then we can find a win-win-win model that can deliver that result. We believe the 21st Century Cures Act provides more opportunities to do that.

See the recorded webinar here: http://axendia.com/wp/fda-discusses-driving-a-culture-of-change-for-devicemakers-webinar/.

BRIEFS

FDA Clears Roche CINtec Histology Test

Roche has received FDA marketing clearance for the CINtec Histology test. The p16 biomarker test, when used in conjunction with hematoxylin & eosin (H&E) staining, helps pathologists determine which women should receive treatment for cervical pre-cancer.

The test is a part of Roche's cervical cancer portfolio, which also includes the Cobas HPV test and the CINtec plus cytology3 test.

FDA Approves Marketing of Alere Reader

Massachusetts–based Alere has won FDA marketing clearance for its Alere Reader, a diagnostic analyzer that can be used in point-of-care and laboratory settings.

The device will be initially available for use with the BinaxNOW Influenza A & B Card 2, with other lateral flow applications and assays to follow. The reformulated test card has achieved Class II designation under the new FDA reclassification requirements.

REVA Receives CE Mark for Its Bioresorbable Coronary Scaffold

REVA Medical has received a CE mark for its Fantom, which is a drug-eluting bioresorbable coronary scaffold. The device is fully visible under x-ray.

The device is an alternative to using metal stents to treat coronary artery disease. Scaffolds restore blood flow, support the artery through the healing process, then disappear from the body over time. The resorption allows the return of natural movement and function of the artery, which is not possible with permanent metal stents.

FDANEWS

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

Editor: William Schulz +1 (703) 538-7634 wschulz@fdanews.com

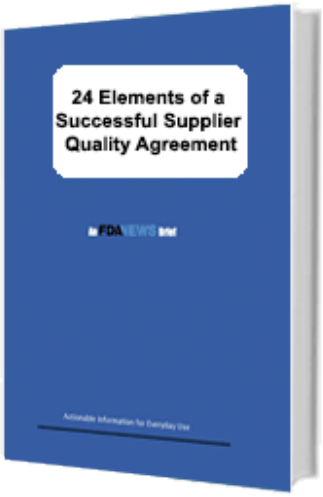
Ad Sales: Jim Desborough +1 (703) 538-7647 jdesborough@fdanews.com

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: Cynthia Jessup, Conor Hale, Zack Budryk **Managing Editor:** Declan Conroy **President:** Cynthia Carter

FDANEWS



24 Elements of a Successful Supplier Quality Agreement

Supplier quality is a fundamental topic of perennial importance.

Your agreements with suppliers must be written and executed to cover every possible contingency and ensure that the materials that go into your products are exactly what you require and are available when you need them.

Today's minor mistake by your supplier could easily turn into tomorrow's major recall. And if you don't catch all the oversights in your quality agreement, odds are the FDA will.

In this FDANews Brief, 20-year industry veteran Steven Sharf, explains the elements that need to go into your quality agreement:

1. Calibration and Maintenance
2. Batch Documentation
3. Change Control
4. Deviations / OOSs
5. Field Alerts / Recalls
6. Material Inspection / Testing / Release
7. Labeling Controls
8. Rejected Materials
9. Complaint Handling
10. APR / PQR Inputs
11. Audits / Inspections
12. Specifications
13. Subcontracting
14. Dispute Resolution
15. Warehousing and Distribution
16. Technical Transfer
17. Validation / Qualification
18. Record Retention
19. Sample Retention
20. Reprocessing / Reworking
21. Supplier Qualification
22. Stability Programs
23. Contact List
24. Responsibility Matrix

Use this 24-point plan to make sure you've covered all your bases and keep your suppliers well in hand. Order your copy today.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/52994
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***24 Elements of a Successful Supplier Quality Agreement*** at the price of $177 for each PDF.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

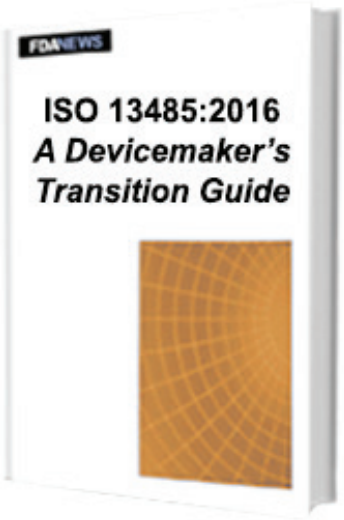
Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

Virginia customers add 6% sales tax.

17FLYR-N



ISO 13485:2016
A Devicemaker's Transition Guide

The ISO 13485 have rules changed — and you need to know how.

Our team of experts have spent hours parsing out every clause in the new version of the rules and compared them to ISO 13485:2003.

ISO 13485:2016 — *A Devicemaker's Transition Guide* saves you valuable time. It has a clause-by-clause, line-by-line, 46-page comparison of the old and new versions of 13485 that shows you exactly what and where the new requirements are.

In this management report you will also learn:

- The major differences between ISO 13485:2003 and ISO 13485:2016
- The role of ISO 13485:2016 in the MDSAP and Canada's plan to adopt it
- The status of EN ISO 13485:2016 and issues related to the product directives
- Some potential concerns related to ISO 13485:2016 and FDA's QSR
- How recent revisions to ISO 9001 compare to the new 13485

The report interprets the four key areas in the 2016 version — risk management, design control, supplier management and corrective and preventive action — and explains what kind of changes the new standard will require.

Based on the insight of one of the world's foremost ISO experts, this report is essential for any devicemaker that hopes to survive the coming transitions. Order your copy of **ISO 13485:2016 — *A Devicemaker's Transition Guide*** today.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/53254
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews
   300 N. Washington St., Suite 200
   Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of **ISO 13485:2016 — *A Devicemaker's Transition Guide*** at the price of $397 for each PDF.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

Virginia customers add 6% sales tax.

17FLYR-N