INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 4, No. 47
Nov. 26, 2018

IN THIS ISSUE

Drug safety? There (should be) an app for that, FDA says .....Page 3

International stakeholders report progress at IMDRF meeting .....Page 3

Quality failures plague Ultrasonic Services..Page 5

Failure to document OOS results lands Symmetry Medical 483 .....Page 6

Heartware cited for failure to correct repeated quality problems .....Page 6

Senate reports on auto-injector price hike ....Page 7

Approvals: New parameter cleared for Terumo's blood monitor … Beckton Dickinson's CPO detection test cleared … Abbott's neuropathic pain blocker wins marketing clearance … FDA grants premarket approval for QView Medical's automated breast ultrasound system … Canon Medical's MRI system cleared … Philips' ventilator system gains CE Mark .....Page 7

Draft Brexit Agreement Spells More Uncertainty for Devicemakers

A new draft Brexit agreement announced last week would provide an almost two-year transition period whereby U.K. and European device companies will continue as they have under EU rules.

Although the proposed deal is short on details, the fact that a draft agreement is in place is providing some hope that relief that the details for a future trading relationship will eventually be hammered out.

Under the draft plan, a transition period will be in place until December 2020; however there would be no UK participation in EU institutions or EU bodies, and the UK would have no role as a leading authority — meaning it would "not have a role as rapporteur or reference Member State," the European Medicines Agency said.

The UK will remain subject to obligations of international agreements concluded by the EU and its notified bodies will remain intact during the transition period.

(See **Agreement***, Page 2)*

FDA Issues Updated Medical Device Safety Action Plan

The FDA plans to continue building out its National Evaluation System for health Technology (NEST) and it is increasing its focus on device therapies unique to women, Commissioner Scott Gottlieb and CDRH Director Jeff Shuren said in a joint announcement.

Gottlieb and Shuren said NEST will provide another source of information for medical device manufacturers to assess the safety and effectiveness of their devices and continue to develop innovative improvements.

Calling funding the principal barrier to establishing NEST, the FDA requested $46 million in the FY 2019 budget for CDRH to support the system and conduct postmarket studies intended to address device-specific safety concerns. It also allocated $3 million in

(See **Plan***, Page 2)*

Agreement, *from Page 1*

But the EMA warned that industry "should not rely on the transition period as there is currently no certainty that it will apply." The agency said the transition is subject to the withdrawal agreement, and outstanding points being negotiated are not expected to be agreed and ratified until 2019.

"The EC urges all industry stakeholders to prepare now for the consequences of the UK becoming a 'third country' on March 30, 2019," the EMA said.

Brexit "could have serious implications for patients' access to medicines and medical technologies," according to the Brexit Health Alliance (BHA), whose members include the Academy of Medical Royal Colleges, the Association of British Healthcare Industries, the NHS Confederation, and other stakeholders.

A lack of EU-UK cooperation on medical devices "could put public health at risk," the alliance said.

BHA warned that the UK leaving the EU without a formal withdrawal agreement could have a detrimental impact on supply chains — an estimated 50 percent of the assessment work for authorizing products to reach the EU market is done in the UK. "There is already limited capacity in this area across Europe and any possible loss of capacity could clearly impact the availability of medical devices," the alliance said.

The alliance also called for aligning the U.K. as much as possible with the EU's regulation of medicines and medical devices in the interest of patient safety and public health.

Plan, *from Page 1*

agency funds towards developing the system and "building out active surveillance capabilities." NEST's coordinating center has begun eight test case demonstration projects using real-world data, in a cooperative agreement with the Medical Device Innovation Consortium.

The FDA also announced its next move for the Women's Health Technologies Coordinated Registry Network (WHT-CRN), a partnership with women's health groups that focuses on device therapies unique to women. The next step for the CRN, the agency said, is the development of an implementation guide for participating registries that will help them to extract clinical data from electronic health records.

"Similar to NEST, the WHT-CRN holds great promise as we advance new tools and approaches for using data to improve outcomes for women and ensure they have access to safe, effective and innovative devices," Gottlieb and Shuren said.

AdvaMed welcomed the agency's updated FDA action plan. "FDA's latest updates to its Medical Device Safety Action Plan are another positive step in this collective effort, and we're ready to work with the agency and other stakeholders on ways to support the continued safety and effectiveness of medical devices," said AdvaMed President and CEO Scott Whitaker.

"While we're still reviewing the details of FDA's updated Safety Plan, industry has long supported many of the programs highlighted, including development of [NEST] to more efficiently generate better evidence on device performance and deployment of a unique device identification (UDI) system to ensure companies can effectively identify their products through their distribution and use while ensuring patient access to the most innovative, life-saving technologies." — James Miessler

Drug Safety? There (Should Be) An App for That, FDA Says

The FDA is seeking public comment on how it should regulate prescription drug software apps and says some might have to be regulated as a device — such as a software program that uses advanced algorithms to scan skin lesions for evidence of cancer.

"Our aim is to establish a bright line between those apps that are coupled to drugs in a way that require their review as part of the pre-market drug application and those apps that can be safely advanced to patients without pre-market review," Commissioner Scott Gottlieb said in remarks at a meeting on real-world evidence on the agency's White Oak campus in Silver Spring, Maryland. "[T]hese lower-risk apps can be subject to post-market surveillance and monitoring," he added, inviting public comment on a proposed framework for regulating such apps.

The agency says it's leaning toward a light-touch approach to digital drug apps but wants to hear from the public before making any decisions. In most cases, mobile apps that are tied to specific drugs will probably be considered (and regulated as) labeling if they're regulated at all. So a mobile app that measures movement probably won't have to pass FDA muster for labeling. But if that same app is branded with, say, an osteoarthritis drug to help the drug's sponsor's patients monitor their movements, it probably will come under labeling scrutiny.

"Under that approach, we expect that the output of most apps used with prescription drugs wouldn't need to come to the FDA for premarket review," Gottlieb said.

The FDA is considering a draft guidance to flesh out some of these ideas.

Read the notice on the proposed framework here: www.fdanews.com/11-19-18-Notice.pdf.
— Bill Myers

International Stakeholders Report Progress at IMDRF Meeting

The recent International Medical Device Regulators Forum (IMDRF) meeting in Beijing featured presentations by international regulatory authorities on their significant regulatory changes.

Chinese regulators highlighted recent reforms aimed at encouraging innovation while at the same time making review processes more efficient. One such provision will fast-track reviews for innovative devices that are new to the country. The new review procedure replaced the earlier green channel that was launched in 2014.

Deep reforms were made to China's clinical trials procedures that are expected to make conducting trials in China more attractive. China is now accepting overseas clinical trial data, and it has simplified its device renewal process.

China's Drug Administration amended its regulations to exempt some Class II devices from listing. It also prohibited the sale of used devices.

To strengthen supervision, it established a professional inspectorate and added penalties for responsible persons that act as legal representatives for foreign device companies operating in the country. CDA also defined the obligations of agents for those imported devices.

To beef up compliance, CDA established a more centralized adverse event reporting mechanism that includes a process for continuous and periodic risk analysis. Under the new process, China's Ministry of Health will re-evaluate whether certain devices represent new risks and what action should be taken.

Japan Considers Regulatory Overhaul

It's been more than five years since Japan amended its Pharmaceutical Affairs Act, which also governs devices, and a new committee is considering areas that need to be revised. Topics under discussion are the approval framework and quality management system audits.

(See **IMDRF***, Page 4)*

IMDRF, *from Page 3*

Japan has revised its good post-marketing study practices to incorporate a reliability standard for conducting observational studies using databases such as its MID-NET medical information database network.

The Pharmaceuticals and Medical Devices Agency's Science Board recently published a paper on artificial intelligence and considerations for reviewing devices that incorporate AI technology. A PMDA consultation will evaluate points for diagnostic imaging products incorporating AI technologies.

Japan sees six significant areas for AI adoption: genomic medicine, diagnostic imaging, clinical decision support, drug development, dementia care and surgery support.

Japan's Ministry of Health, Labor and Welfare also recently issued guidance on cybersecurity for medical devices.

Brazil Launches National Implant Registry

Brazil's ANVISA launched a national implant registry that will compile voluntary registrations on surgical procedures for hip and knee prostheses and coronary stents. The registry will initially be voluntary, but it will likely become compulsory and may be expanded to include other implantable devices.

Brazil is also requiring unique device identifiers to be placed on patient cards of cardiovascular stents, and hip and knee prostheses.

In addition, blood glucose monitoring devices were required to be compliant with ISO 15197/2013 by November 2018, or they would be removed from the market.

Brazil's regulators also reported on MDSAP progress to date, reporting that 127 MDSAP audits have been conducted and ANVISA has recognized 13 auditing organizations.

ANVISA also has a consultation process underway on replacing its current registration process for low-risk devices with a notification pathway that would no longer require premarket reviews (*IDDM*, May 21).

Australia Unveils Expedited Reviews

Australia's TGA has introduced an expedited review process for certain novel devices under new regulations aimed at getting innovative devices to market faster.

The TGA said it will accept approvals from comparable overseas regulators, which initially include the European Union, the U.S., Canada and Japan. Medical Device Single Audit Program (MDSAP) certification is also required as quality management system evidence, the agency said.

Australia is aligning its regulations to be on par with Europe, and the TGA followed the EU's lead on up-classification of surgical mesh and requiring patient information cards for implantable devices (*IDDM*, Aug. 13).

The agency is also strengthening postmarket monitoring and is integrating IMDRF adverse event terminology and codes into its databases.

Quality System Failures Plague Texas-Based Ultrasonic Services

Numerous quality system failures were observed at Ultrasonic Services' Houston, Texas facility during an Aug. 24 to Aug. 27 FDA inspection, after which the devicemaker landed a seven-item 483.

The firm failed to analyze or document device failures following customer complaints about its USI 25 M and USI 25 MPLC Ultrasonic dental scalers. Corrective and preventive action procedures fell short in that numerous activities that should have triggered CAPA procedures did not.

Design changes for two scalers had not been adequately established for the device that was cleared in 2006. The firm also failed to maintain a design history file for the Class II device.

Procedures to ensure that incoming products conform to specific requirements were found to be lacking. Ultrasonic Services didn't evaluate and select its suppliers based on their ability to meet requirements, and it didn't have documentation on supplier evaluation and selection, nor did it maintain records of acceptable suppliers.

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

Medical Device Reporting Requirements

Effective complaint management is a complex undertaking, involving staffing, training, data storage, trend analysis, reporting, information sharing, and meeting federal and international quality standards.

Complaint management involves all levels of a devicemaker's business: manufacturing, research, customer service, sales, field service, quality assurance, regulatory affairs, all the way up to the executive suites where the big decisions are made. And everyone who has a stake in the process must have access to the data, with the amount and type of access determined by job responsibilities.

Multisite and global corporations must deal with the challenges of sharing information across geographic – and cultural – boundaries. A tightly structured, comprehensive complaint management system is a devicemaker's safety net, making sure that nothing falls through the cracks and the company misses no opportunity for improving its products or preventing disastrous errors.

The FDA's regulations in 21 CFR Part 803 – Medical Device Reporting require that companies evaluate all device complaints to determine if they involve an adverse event that must be reported to the agency.

Malfunctions must be reported when the chance of death or serious injury resulting from recurrent malfunctions is not remote. Malfunctions also need to be reported when the consequences of the malfunction affect the device in a catastrophic manner that might lead to a death or serious injury.

Manufacturers often have the most trouble determining when the likelihood of a future malfunction resulting in death or serious injury is not remote. One of the factors the FDA looks at is whether or not that particular type of malfunction has caused a death or serious injury in the past two years. If it has, the agency concludes that the risk is not remote and the event must be reported.

In addition, manufacturers must report malfunctions when:

- They cause the device to fail to perform its essential function, compromising the device's therapeutic, monitoring or diagnostic effectiveness, and could cause or contribute to a death or serious injury, or other significant adverse device experience;
- They would prevent a long-term device implant from performing its function;
- The device is considered life-supporting or life-sustaining, and thus essential to maintaining human life; or
- The manufacturer takes or would be required to take action under Section 518 or 519(f) of the Food, Drug and Cosmetic Act, which deals with recalls and tracking products.

The timeline for reporting an event to the FDA depends on the immediacy and severity of the problem. Manufacturers must submit an MDR either within 30 days of becoming aware of an event or, in the case of possible "unreasonable risk of substantial harm to the public health," within five days of learning about the event.

Excerpted from the FDAnews management report: *Complaint Management for Devicemakers — From Receiving and Investigating to Analyzing Trends*.

Failure to Document OOS Results Lands Symmetry Medical 483

Failure to document OOS results and to find the root cause of defects landed surgical instrument and orthopedic implant manufacturer Symmetry Medical in hot water with the FDA following a Sept. 5 to Sept. 10 inspection of its Claypool, Indiana facility.

An investigation of an "out-of-tolerance" gage that "potentially" was affected by out-of-calibration equipment was not documented, and corrective actions were not initiated for non-conforming material, the FDA Form 483 said. An investigation into potentially affected product was missing in all of the quality alert notifications for the gage, the FDA said.

Between August 2017 to May 2018, the firm documented seven nonconformance reports related to a Class I high performance femoral sizer, but CAPA investigations were not initiated for this "high-risk recurring defect," the FDA said.

A CAPA investigation into another defect for a different product did not address the root cause of the defect, according to the 483. In addition, product holds to prevent shipments of certain products did not include a hold for all parts requested to be held.

The FDA also said the firm's sampling plans were not based on valid statistical rationale. The 483 notes that an inspection for critical dimensions of a tibial spiked uprod used for knee implants was reduced without documented rationale for the change.

Read the Symmetry Medical Form 483 here: www.fdanews.com/11-20-18-symmetrymedicalinc483.pdf.

Heartware Fails to Correct Earlier Warning Letter, 483 Observations

A May 17 to July 12 FDA inspection found that Miami Lakes, Florida-based devicemaker Heartware fell short on repeated quality system observations that were cited in a 2014 warning letter and a 2016 FDA Form 483.

The 16-page 483 highlighted numerous system quality issues for the firm's ventricular assist device (HVAD). The device was recalled in June due to an unintended disconnection of the power source.

The firm had not established design control procedures in that design input requirements don't always translate into a final design output following validation activities. For example, several CAPAs and quality plan activities were opened in reference to design requirements but the firm reported device failures related to inadequate implementation of design controls.

Numerous CAPAs related to connector bent or damaged connector socket pins on power connector ports, and investigations into the causes of the bent pins and connectors showed continuing failures of the firm to address the root causes.

"Your firm failed to implement [CAPAs] in that a broad-based systemic approach, going across product lines, processes, and quality management systems when investigation and developing corrective/preventive action plans was not always used," the agency said.

The firm also fell short on complaint handling procedures and medical device reporting procedures were not implemented. In addition, Heartware failed to adequately train personnel, and it's HVAD risk assessment documents were not updated.

Read the 483 here: www.fdanews.com/11-20-18-heartwareinc483.pdf.

483, *from Page 5*

Finally, procedures for quality audits had not been established, and the firm's president told the inspector that no documented management reviews had ever been conducted.

Many of the same QS failures were also cited in a 2006 FDA warning letter for the firm's ultrasonic dental scalers and equipment.

Read the Ultrasonic Services Form 483 here: www.fdanews.com/11-20-18-ultrasonicservicesinc483.pdf.

Senate: Naloxone Auto-Injector Price Hike Cost Taxpayers Millions

Kaléo's massive price hikes for its naloxone auto-injector Evzio have cost taxpayers more than $142 million over the past four years, says a new Senate report.

The Senate Homeland Security and Governmental Affairs Committee's investigations subcommittee said the company exploited the nation's opioid crisis by raising the price of its opioid overdose reversal treatment by more than 600 percent.

Congressional researchers found that Kaléo ignored recommendations from industry experts to set the tab for the auto-injector at $250 or $300 per unit and offer discounts and rebates — and instead initially settled on $575 per unit, which it upped to $3,750, and, less than a year later, increased to $4,100 as part of a new distribution model.

"The distribution model employed a sales force charged with encouraging prescribers to route prescriptions through specialty pharmacies, which handle any prior authorization paperwork for insurance coverage," the report says.

After the price jump, pharmacy benefit managers (PBMs) CVS and Express Scripts blocked Evzio from its formularies, barring client insurance plans from covering the product. Both also ended commercial coverage contracts with the Richmond drugmaker — meaning the company no longer paid administrative fees or rebates to the PBMs.

Read the full report here: www.fdanews.com/11-19-18-CombattingOpioidCrisis.pdf.
— James Miessler

APPROVALS

FDA Clears New Parameter For Terumo's Blood Monitor

The FDA granted clearance to Terumo Cardio's CDI blood parameter monitoring system to monitor oxygen delivery in real-time.

The device is now approved to measure 12 critical blood parameters.

Measuring oxygen delivery is used during cardiopulmonary bypasses to help reduce acute kidney injury, a common complication of cardiac surgery.

Beckton Dickinson Gets Clearance For CPO Detection Test

BD's Phoenix carbapenemase-producing organism (CPO) phenotypic detection test received marketing clearance from the FDA.

The device is the latest addition to BD's diagnostics product line, which includes the BD Phoenix M50, an automated microbiology system used to test susceptibility.

The phenotypic detection test is used to identify CPO-caused infections. It can deliver results in less than 36 hours and may be faster than conventional phenotypic methods.

Abbott's Neuropathic Pain Blocker Cleared for Marketing

The FDA and EU have both cleared Abbott's DRG Invisible Trial system for marketing, a device designed to help people suffering from neuropathic pain.

The device targets the dorsal root ganglion (DRG), a nerve structure near the spinal cord that transmits chronic pain to the nervous system.

By transmitting electrical pulses through a thin wire placed in the spinal column near the DRG, the system blocks pain signals from reaching the nervous system.

FDA Grants PMA for QView Medical's Automated Breast Ultrasound System

The FDA has given premarket approval for QView Medical's GE Invenia 3D automated breast ultrasound system (ABUS), designed for dense breast screening.

Breast density can increase the risk of breast cancer in women and make screening more difficult.

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

Approvals, *from Page 7*

The device is meant for breast screening in asymptomatic dense breasted women whose mammograms returned negative.

Canon Medical's MRI System Cleared

The FDA granted 510(k) clearance for Canon Medical's Vantage Orion 1.5 Tesla magnetic resonance imaging (MRI) system.

The device includes new technology meant to improve productivity, patient comfort and clinical confidence.

The system uses rapid scan technology, a dockable table for improved patient handling, high resolution imaging and advanced diagnostic technology.

FDA Clears SIG Medical's Anterior System

The FDA granted 510(k) clearance to SIG Medical's AdvantageRib anterior system, a minimally invasive system designed to treat rib fractures.

The AdvantageRib comes with titanium plates and screws used to treat rib fractures with an anterior approach. The system's adaptable straight plates allow for custom fits in challenging clinical situations and the titanium screws are designed for ribs of all sizes.

The clearance marks the second rib fracture system the Hershey, Pennsylvania devicemaker is commercializing.

Philips' Ventilator System Gains CE Mark

Philips received CE Mark approval for its V60 Plus ventilator system, used for early interventions into respiratory failure.

The system features both noninvasive ventilation and high flow therapy, which allows it to be used with changing patient conditions without having to switch devices.

The device allows for quick therapy and interface transitions and lessens the time physicians need to use for equipment set up.

Implanet Receives CE Mark For Jazz Cap System

Implanet received the CE Mark for its Jazz Cap System, a device for securing screws in poor-quality bone.

The single-use, sterile implants were developed for the main purpose of supporting the treatment of degenerative conditions in adult patients.

The system includes a set of implants consisting of a screw, a band and the company's patented locking mechanism.

ThermoGenesis Gains Marketing Clearance for Blood Banking Platform

Cesca Therapeutics subsidiary ThermoGenesis received 510(k) clearance from the FDA for its AXP II AutoXpress platform for clinical blood banking and harvesting of stem and progenitor cells.

The AXP II is the next-generation of the original AXP system, which received market clearance in 2007.

The upgraded platform features an improved docking station and XpressTRAK software for regulatory compliance. ThermoGenesis is developing an automated CAR-TXpress platform to streamline the manufacturing process for the emerging CAR-T immunotherapy market.

FDANEWS
wcg market intelligence & insights

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

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

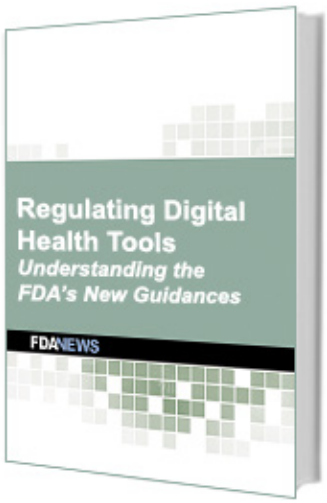
Ad Sales: Jim Desborough
+1 (703) 538-7647
jdesborough@fdanews.com

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

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • www.fdanews.com

Reporters: Zack Budryk, James Miessler, Bill Myers

President: Cynthia Carter



Regulating Digital Health Tools: *Understanding the FDA's New Guidances*

Clinical decision support software … software as a medical device … artificial intelligence and machine learning – rapid developments in digital technology are blurring the line between FDA-regulated medical devices and unregulated "lifestyle apps."

To keep pace, the FDA has issued a slew of guidances to explain what and how it will regulate software-driven devices. The final guidance *Software as a Medical Device* and two draft guidances, *Clinical and Patient Decision Support Software* and *Multiple Function Device Products*, aim to clear up the confusion, but devicemakers still need a map for navigating the regulatory maze.

Regulating Digital Health Tools — based on a presentation by noted regulatory expert Bradley Merrill Thompson — combs through the guidances and sets out the rules devicemakers must follow. You'll learn:

- How the FDA's new policy allows sponsors to comply with postmarket surveillance requirements
- How the FDA is working with industry to promote innovation in the development of digital health functions, as well as how these novel products can be integrated into advanced therapeutic options for patients
- The status of the FDA's precertification pilot program and how it may determine future regulation
- Industry reaction to the FDA's efforts

Regulating Digital Health Tools: *Understanding the FDA's New Guidances* gives readers a complete understanding of how the FDA is regulating software applications and digital health devices — and where a device falls on the spectrum from unregulated "lifestyle" apps to high-risk regulated medical devices.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/56517
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 ***Regulating Digital Health Tools: Understanding the FDA's New Guidances*** 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

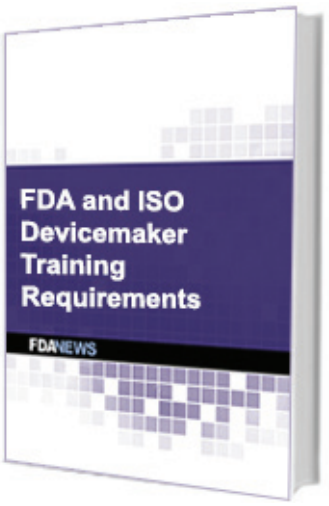
Credit card no. _____

Expiration date _____

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

Virginia customers add 6% sales tax.

18FLYR-N



FDA and ISO Devicemaker Training Requirements

Device manufacture is a complicated business, but few areas are more rulebound than QMS. Many a devicemaker has come up short trying to stay abreast of the FDA's QSR, ISO 13485:2016, and other ISOs while trying to comply with competence, training and awareness rules.

It takes more than teaching simple skills to achieve the state of job readiness and performance required of devicemakers' workforces. Regulators agree that a comprehensive training program should consider employee education, experience, background and skills. What they don't agree on is what those concepts mean and how to incorporate them into training.

FDA and ISO Devicemaker Training Requirements breaks down training requirements in both the FDA's QSR and international standards ISO 13485, 9001 and 10018 — among others — shows where they overlap and where they differ and provides a plan for developing a training program that fills in all the gaps. You will learn:

- The four elements of competency
- Definitions of key terms and requirements
- The concept of a "designated individual" and the qualifications for the role
- The importance of a well-written job description
- The difference between a "job" and a "role"
- Factors in employee awareness and how to foster them
- How to evaluate your training program for compliance and effectiveness

Order your copy of **FDA and ISO Devicemaker Training Requirements** and create a training program that checks all the boxes, both in the U.S. and internationally.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/56014
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 ***FDA and ISO Devicemaker Training Requirements*** 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.

18FLYR-N