International Devices & Diagnostics Monitor

Vol. 1, No. 48
Dec. 7, 2015

IN THIS ISSUE

Ireland Launches Device eAlert System, Quality Assessment Tool

To help prevent recurrences of medical device-related adverse events, Ireland has launched a national eAlert system intended for healthcare facilities.

The web-enabled system will help in the selection of a designated person at healthcare delivery organizations to take responsibility for receiving device alert notifications and distributing the information.

"A key component of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of an incident or to alleviate the consequences of such incidents," the country's Health Products Regulatory Authority says.

The national eAlert system receives a notice directly from the HPRA of all medical device safety notifications. A priority level is assigned to each alert in accordance with the HPRA traffic light system of red, amber

(See **Ireland**, *Page 2)*

TGA Issues Guidance on Requirements for Fee Reductions

With an eye toward ensuring consistency and transparency, Australia's Therapeutic Goods Administration has unveiled guidelines explaining how medical device and in vitro diagnostic companies can save up to 70 percent on assessment fees.

Specifically, the guidelines offer additional information about the requirements and procedures used by the TGA to determine if fees can be lowered for application audit and conformity assessments. To that end, applicants must clearly demonstrate that the supply of the device is crucial to ensuring public health. If similar devices are already available on the Australian market, it is unlikely the fees would be reduced, the TGA says.

According to the regulator, the guidance is needed to help TGA staff determine if an abridged assessment and reduction of fees is appropriate. In addition, it will help make the fee assessment process more transparent and consistent for applicants.

(See **TGA**, *Page 2)*

C.R. Bard Scoops Up Liberator Medical for $181 Million

Murray Hill, N.J.-based C.R. Bard is acquiring Liberator Medical, a direct-to-consumer distributor of durable medical equipment, for $181 million in cash, as the multinational company aims to enhance its position in the U.S. home care market.

The deal is a strategic fit for Bard, which develops, manufactures and markets vascular, urology, oncology and surgical specialty products. Liberator has an estimated 20 percent market share in the urology segment, says Lawrence Biegelsen, a senior analyst with Wells Fargo Securities.

Richard Newitter of Leerink Research adds that the deal is in line with recent Bard buyouts, such as Medafor for $200 million and Rochester Medical for $262 million. "While we think the Urology franchise will take a breather from M&A as it digests [Liberator], we would expect [Bard] to still be acquisitive and in the market for similar size transactions across its other franchises going forward."

The Bard-Liberator transaction is expected to close in the first quarter of 2016.

National expenditures within the DME market will increase from $45.8 billion in 2015 to $71.3 billion in 2023, according to the Centers for Medicare &Medicaid Services.

Liberator's key competitor, 180 Medical, was acquired for $231 million by Convatec in 2012, says Biegelsen. — Jonathon Shacat

Ireland, *from Page 1*

and green. Each notification has a response timescale within which the designated person reports to the Health Service Executive's central Information Communication Technology system on whether the relevant action was completed or not applicable.

Implementation of the eAlert system coincides with the launch of the HSE Medical Device Management Quality Assessment and Improvement Tool.

The tool provides opportunities for service areas to gain an informed picture of the quality of services and practices in relation to medical device equipment. The assessment process allows services to identify gaps in current service provision, develop improvement plans to address these gaps and demonstrate accomplishments achieved in the management of medical device equipment, says Ronnie McDermott, medical equipment management lead at Cavan Monaghan Hospital.

"The QA+I tool will support the collation of information generated from the assessment process whilst enabling the development and monitoring of any associated derived quality improvement plans to progress compliance with the HIQA standards," he says. — Jonathon Shacat

TGA, *from Page 1*

The requirements are only likely to be met for devices of low value and limited sales potential. Applicants would need to provide details of potential sales figures and profit margins for the agency to consider the commercial viability of supplying the device, according to the guidance.

The TGA issued revised guidance in April on reducing fees for audits and conformity assessments for devices, but the new guidance was updated to include IVDs (*IDDM*, May 1).

The new guidance doesn't detail exact reduced fee amounts, but rather describes scenarios for shortening the assessment and provides a description of how to determine the reduced fee.

The regulations include provisions for reducing fees for application audit assessments and conformity assessments, if information is available that allows the assessment to be shortened, the TGA says.

"It may be possible for the TGA to lower the assessment fee according to the degree of regulatory assessment already undertaken, either by the TGA, or by a recognized conformity assessment body (e.g. European Notified Body), if sufficient evidence is available that allows the TGA to abridge the assessment," says the guidance.

Read the guidance here: www.fdanews.com/11-15-TGA-Fees.pdf. — Jonathon Shacat

Notified Body Leader Looks to Future of Device Regs

Gert Bos, a leading spokesman on behalf of European notified bodies, is leaving BSI Group to join global regulatory consultancy firm Qserve Group as executive director and partner. This change comes as device and diagnostics companies prepare for big changes in EU regulations. *IDDM* asked Bos about the timeline for the upcoming changes, as well as what companies can do to prepare.

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

Bos: The impact of the new regulation will be quite different for manufacturers under the medical device regulation (MDR) and the in vitro diagnostics regulation (IVDR). Under MDR, the most likely outcome will be the demand for much more clinical data derived from the product of the manufacturer itself, so an end to market entry based on equivalence for high-risk devices and lower risk implants.

Evidence of such will be transparent in public summaries of clinical evidence, as well as annual reports on postmarket surveillance reviews and trend analysis, and may well be questions in formal scrutiny procedures. With this added transparency on data and increased central oversight, there will be no escape, and much more clinical data will need to be gathered.

For IVDR, this highlights the ambiguity currently still present around the requirements that are being worded towards clinical performance and postmarket clinical performance follow up. As these new requirements are not well defined yet, interpreting them in preparation of getting into compliance is a difficult task.

The second biggest impediment would be ensuring to have enough resources internally, supported by external experts and subcontractors, as well as securing resources in their notified bodies available for reviews and audits.

IDDM: *How is the trilogue progressing?*

Bos: Since Oct. 13, four political trilogues and six technical meetings have been held, with one or two political trilogues and a technical meeting to go before Christmas. The trilogues are reported to make some progress, whereas speed in the technical meetings is said to be low.

The upcoming Dutch presidency is preparing for the remaining trilogue and technical meeting to be held in the first four or five months of 2016. Negotiations have been split into four parts, the last of which deals with key topics such as (special) notified bodies and market surveillance, essentials from the Dali Action Plan following the PIP scandal in 2012. Any agreement reached until then is only preliminary, as only when in the last trilogues an agreement is reached will the final consensus be definitive. Until then, positions may change in further negotiations on upcoming topics. The target now set is an 'early second reading agreement' in the middle of June 2016.

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

Bos: I would say the most important thing is to 'stay calm and make the transition.' At this stage, that means start making a strategic assessment on impactful changes for your company and product portfolio, making a gap assessment between current compliance levels and future expectations. Based on that work, make a priority plan if a larger number of products are involved. Compliance building then should focus on getting evidence in place for priority files first, as well as starting the generation of data for second tier products if the gap assessment reveals long-term data collection will be needed. For larger portfolios, discussion might focus on which products to transfer, and which ones to fade out. To make this transition happen smoothly, timely budgeting for internal and external capacity will be of essence, as is an early start in analysis, way before the regulation is finalized and published.

Singapore Issues Revised Guidance On Change Notification System

Singapore's Health Sciences Authority has updated its guidance on how manufacturers should notify the agency of modifications to registered medical devices.

The new *Guidance on Change Notification for Registered Medical Devices* contains several revisions, all of which took effect Dec. 1.

When changes arise from adverse events or field safety corrective actions, devicemakers now should submit information — such as field safety notices, health hazard evaluations, root cause analysis and corrective and preventive actions, the guidance says.

Upon approval of a change notification application, devicemakers may now concurrently supply both the original registered device along with the changed device only if both versions conform to the Essential Requirements for Safety and Performance, the document says.

"This concurrent supply of the unchanged original device may not be applicable for changes to medical devices implemented as a consequence of reportable AEs or FSCAs," the HSA says.

In addition, the new guidance says that adding devices with proprietary names that are different from the registered product in a listing will not qualify for change notification. Instead, they require submission of a new premarket registration.

Also, adding new models to a registered device listing now requires HSA approval prior to implementing the changes.

Read the guidance here: www.fdanews.com/12-15-HSA-Guidance.pdf. — Jonathon Shacat

FDA Hits WalkMed With Warning Letter For Failing to Investigate Complaints

Failure to conduct adequate investigations of complaints related to its volumetric infusion pumps and not providing corrective action documents are among the issues that have landed WalkMed Infusion an FDA warning letter.

In a Nov. 2 warning letter that resulted from a May 18 to June 11 inspection of the company's Centennial, Colo., facility, the FDA takes the WalkMed to task for not adequately investigating complaints related to the failure of air-in-line detection systems in the Triton and Triton FP infusion pumps, or air being infused into patients. In addition, the company received complaints involving patient infusion-related reactions during use of the Triton administrations sets.

Inadequate Responses

Although the company issued responses dated July 1 and Aug. 31 to the 483, the FDA has deemed them inadequate.

"You state that complaints related to the air-in-line detection system were re-evaluated; however, you did not provide a justification for your failure to review all complaints cited on the Form FDA 483," the letter states.

Further, the company refers to a corrective action report to explain why it hasn't conducted additional investigation, but that report does not include an assessment for the adequacy of the testing equipment used or an explanation of the sufficiency of the overall testing parameters.

WalkMed also is taken to task for failing to detail how it will address particulate nonconformances with a certain unnamed supplier. "You also failed to provide a retrospective assessment on the scope of the problem and the potential impact on marketed product," the letter states.

The FDA also finds fault with the company's complaint handling procedure. "This record includes a drop-down completion form with no explanation to the employee on how to appropriately assess the question being asked (in all cases), nor does it specify which employee(s) (with or without specialized training) will perform certain assessments in the Complaint Handling Record," according to the letter.

In addition, the company failed to analyze and identify the existing and potential causes of nonconforming product and implement corrective actions, the FDA says.

The warning letter also dings the company over procedural failures relating to validating and verifying device design, validating device software and calibrating for accuracy and precision.

The FDA notes that the company has sent a third response, which, along with proposed field corrections, is pending review.

WalkMed did not respond to a request for comment by press time. Read the warning letter here: www.fdanews.com/12-15-WalkMed-WarningLetter.pdf. — Jonathon Shacat

Boston Scientific Recalls Arterial Guidewires

Boston Scientific is recalling 600 units of its RotaWire Elite guidewire and wireClip Torquer guidewire manipulation device, components of the Rotablator rotational atherectomy system, because they may break and separate, causing serious injury or death.

The company initiated a voluntary recall of the product on Oct. 9, and the FDA subsequently classified it as Class 1. The recall affects products manufactured from June 26 to Sept. 10 and distributed from July 9 to Oct. 1. Boston Scientific has received three reports of this issue, including one patient death following medical intervention to remove the broken wire, the FDA says.

"Although the recall is ongoing, we have been in touch with all the hospitals that have received these items, and they have been sequestered from inventory," Tom Keppeler, a spokesman for Boston Scientific, tells *IDDM*. — Jonathon Shacat

Robust Simplicity.

EtQ features the most comprehensive Compliance Solution that is completely configurable to your business needs

- Automated processes such as Corrective Action, Audits, Risk Management, Complaint Handling, Document Control, and more
- Flexible to adapt to unique business processes, without programming
- Scalable solution that integrates with other business systems
- Make any application mobile and access your data from anywhere, anytime

EtQ | info@etq.com
800.354.4476
http://www.etq.com/fda

Alcon Recalls More AcrySof Intraocular Lenses in Japan

Novartis' Alcon unit is recalling more than 43,000 units of its AcrySof IQ Toric, expanding a previous recall of more than 45,000 intraocular lenses earlier this year in Japan.

The Class 1 recall, which affects 43,651 units, was initiated following continued reports of postoperative inflammation in patients who received the device, according to an FDA recall notice issued Nov. 25.

Alcon sent an FDA notification letter Oct. 1 to its consignees in Japan who have received certain models, instructing them to stop using the products immediately and wait for a sales representative to visit their sites for withdrawal.

The company had sent a similar letter April 16 regarding 45,391 of its AcrySof IQ ReSTOR and IQ ReSTOR Toric intraocular lenses. That Class 1 recall followed reports of postoperative inflammation and toxic anterior segment syndrome after cataract surgery, according to an Aug. 7 FDA recall notice.

The FDA has determined that both recalls were caused by process design problems at Alcon in Fort Worth, Texas.

Read the recall notice here: www.fdanews.com/11-15-FDA-Recall.pdf. — Jonathon Shacat

GSK, Propeller to Collaborate On Custom Sensor for Ellipta

Pharma titan GlaxoSmithKline is jumping into the "smart" inhaler space, inking a deal with Propeller Health covering the drugmaker's Ellipta.

Under the terms of the nonexclusive agreement, Propeller will develop and manufacture a digital sensor for the drugmaker's Ellipta inhaler for use in certain clinical studies in asthma and chronic obstructive pulmonary disease. GSK will retain an option to negotiate exclusive commercialization rights to the sensor for use with its portfolio of respiratory medicines administered using Ellipta.

The companies declined to share details on the financial terms of the deal, or the timelines for product development. "This is an early-stage technology deal in an area where we are keen to do more," GSK spokeswoman Mary Anne Rhyne tells *IDDM*.

In the clinical studies, the sensor will collect and record data — such as the date and time of the inhaler's use — and wirelessly transmit the information to a central data repository for analysis by GSK researchers.

"Using innovative sensor technology to improve the quality of adherence data collected during our studies will advance our understanding of disease and inform our decision-making in the development of new medicines," says Dave Allen, GSK's senior vice president of respiratory R&D.

Earlier this year, Madison, Wisc.-based Propeller won expanded FDA 510(k) clearance of its digital health platform for use with medications incorporating GSK's Diskus dry powder inhaler for asthma and COPD. The move followed the Propeller platform's 510(k) clearance in March for use with medications associated with Boehringer Ingelheim's Respimat inhaler for chronic obstructive pulmonary disease (*IDDM*, July 23). — Jonathon Shacat

Report: Medical Devices, Wearables Will Fall Prey to Hackers

Hackers will target medical devices for cyber extortion next year, taking advantage of the rise of virtual currencies and the number of victims who are willing to pay to regain access to their data, a new research report warns.

Consumer-generated health data hold value for patients as well as healthcare providers, insurers, public health researchers and policy makers — from GPS-enabled asthma inhalers to wearable tech-tattoos that monitor vital functions. Cybercriminals also see value in the data, according to *Predictions 2016: Cybersecurity Swings to Prevention* by Forrester Research.

(See **Ransomware***, Page 8)*

Ransomware, *from Page 7*

A partial electronic health record sells on the black market for roughly $50, and health credentials sell for $10 each, many more times the value of a credit card number, the report says. Health information is not only the target of theft, but also extortion, as cybercriminals seek to gain access to the data and demand ransom.

To protect data, the report advises facilities take the following steps:

- Ensure employees are able to identify phishing scams;
- Identify data assets that hackers may want to attack;
- Secure the data chain; and
- Re-examine security functions through an "Internet of Things" lens.

Experts Weigh In

Cybersecurity expert Billy Rios says he believes that attacks against devices will occur in the near future.

"Given the mass adoption of devices, there is now incentive for attacking these devices. Also, the poor security associated with these devices makes it so attackers can actually pull off brazen attacks like ransomware," he tells *IDDM*.

Ken Hoyme, distinguished scientist with Adventium Labs, says it's possible that these new vectors will be applied in the healthcare space — and potentially in the next year — although he wouldn't expect it to begin with implantable devices or wearables.

For data theft, attackers want to get into an organization and remain undetected for a long period of time so they can obtain a lot of data. Many devices are poor targets as they are rarely connected to networks, or may be on/off at random intervals. Better candidates would be large machines like MRIs, CAT scanners, or equipment in blood lab — systems that directly interact with the electronic health record, he says.

"The other risk to devices in the data theft category is being a 'pivot' to insert malware into other systems on the hospital," Hoyme says. "If a poorly patched/maintained medical device can be breached, it may be used as an attack vector to place monitoring malware on better secured systems inside the hospital, if those systems place trust in the medical device because it is inside the hospital walls."

In terms of devices that are hacked and unlocked, they may have adulterated software and should not be used, says Hoyme. If a hacker demands a ransom to unlock MRI system or CAT scanner, facilities should take them off the network and reprogram them from scratch to remove the ransomware and be assured that the device was unadulterated.

Still, as Hoyme points out, there are many uncertainties. "Predicting the future when it comes to cybersecurity is mostly guesswork," he tells *IDDM*. "You are trying to put an estimate on something that involves human behavior and motivation. Predicting which sector and which vector may be used is always easier in hindsight than foresight."— Jonathon Shacat

FDA Panel to Discuss Medtronic's Spinal Stabilization System

The FDA's Orthopedic and Rehabilitation Devices Panel will meet Feb. 19 to discuss Medtronic's premarket application for the DIAM spinal stabilization system.

The implantable device is indicated for skeletally mature patients with low back pain secondary to moderate lumbar degenerative disc disease.

DDD is confirmed radiographically with one or more of the following factors:

- Patients must have greater than 2 millimeters of decreased disc height versus the adjacent level;
- Scarring/thickening of the ligamentum flavum, annulus fibrosis or facet joint capsule; or
- Herniated nucleus pulposus.

Read the *Federal Register* notice here: www.fdanews.com/11-15-FDA-AdCom.pdf.
— Jonathon Shacat

FDA Issues 483 to Del Medical For Repeat Reporting Failures

Del Medical, a radiography and medical imaging devicemaker, has been hit with a 483 that includes three repeat observations cited during previous inspections — specifically, failure to report complaints.

During a July 8 to Sept. 23 inspection of Del's facility in Bloomingdale, Ill., an FDA investigator noted that a correction made by the company — conducted to reduce a risk to health — was not reported in writing to the agency. After receiving six complaints about failing counterweights on wall stands for radiography machines, the company released instructions in a service bulletin to "improve mechanical operations" of these stands.

The company required product preventive maintenance to be performed on two models of wall stands, but did not report the field correction to the FDA. This was a repeat observation from a Sept. 15, 2006, inspection, the 483 says.

During the past two years, Del received six complaints of its VS200 wall stand malfunctioning, causing the receptor to fall to the floor and one complaint of an overhead tube crane malfunctioning, causing the x-ray tube to fall to the tabletop. The incidents were not reported to the FDA, and this observation was also a repeat from the September 2006 inspection.

Further, procedures for corrective and preventive actions have not been adequately established, an observation that was also made during a Dec. 17, 2012, inspection and the 2006 inspection, the 483 says.

Del's CAPA activities and results also went undocumented — specifically, only one CAPA was opened after the company received six complaints about the VS200. Risk analyses were also inadequate, the investigator says.

UMG/Del Medical did not return a request for comment. Read the Form 483 at www.fdanews.com/12-01-15-DelMedical.pdf. — Kellen Owings

Senate Votes to Repeal Device Tax

Despite a promised presidential veto, the U.S. Senate voted 52 to 47 Thursday in favor of a bill that contains a provision to repeal the medical device excise tax.

Passage of H.R. 3762, also known as the Restoring Americans' Healthcare Freedom Reconciliation Act of 2015, follows an Oct. 23 House vote of 240 to 189 to pass the measure.

Although proposals to eliminate the 2.3 percent excise tax have garnered support from both sides of the aisle, no Democrat voted in favor of H.R. 3762, which would repeal a number of other Affordable Care Act provisions. Further, two members of the GOP— Sens. Susan Collins (R-Maine) and Mark Kirk (R-Ill.) broke ranks and voted against the bill.

President Barack Obama has vowed to oppose any attempt to repeal parts of the ACA. "If the president were presented with H.R. 3762, as amended by the Senate amendment, he would veto the bill," according to a White House Statement of Administration Policy.

Last month, House members were pushing for medical device tax repeal provisions to be included in a larger legislative package by the end of the calendar year (*IDDM*, Nov. 25). The group says the tax threatens innovation.

The House voted 280 to 140 on June 18 to repeal the device excise tax under H.R. 160, known as the Protect Medical Innovation Act of 2015.

Three other bills have been introduced in the House and Senate, including the Medical Device Tax Elimination Act (H.R. 1533), the Medical Device Access and Innovation Protection Act (S. 149) and A Bill to Repeal the Medical Device Excise Tax, and for Other Purposes (S. 844).

H.R. 1533 was referred to the House Ways and Means Committee, while S. 149 and S. 844 were referred to the Senate Finance Committee. The bills have failed to get out of committee. — Jonathon Shacat

BRIEFS

St. Jude Launches SCS System in Europe

St. Jude Medical has launched its Proclaim Elite spinal cord stimulation system — a non-rechargeable system designed to deliver burst stimulation — in Europe. The approval includes conditional magnetic resonance, enabling patients to safely undergo head and extremity MRI scans. The device doesn't need to be recharged and features Bluetooth wireless technology and Apple mobile digital devices to allow for more effective management of chronic pain treatment. It also is equipped with an upgradeable platform, so patients can more easily access future therapies and software upgrades.

New Director Starts at Croatia's Agency

Sinisa Tomic began a four-year term as the new director of the Croatian Agency for Medical Products and Medical Devices on Dec. 1. He was chosen for the position on Nov. 25 by the agency's governing council. Tomic served as head of the agency from October 2003 to November 2011.

Covalon Wins Clearance for Catheter

The FDA has granted Covalon Technologies clearance for its SilverCoat Silicone Foley catheter, which is designed to allow clinicians to drain a patient's bladder. By draining the bladder, the catheter helps reduce the likelihood of a patient developing a catheter-related urinary tract infection. The U.S. Centers for Disease Control and Prevention taps catheters as the primary cause of urinary tract infections. The 100 percent silicone catheter features a permanent lubricious coating with silver ions, which provides a zone of inhibition to bacteria around the catheter surface. The silver also resists microbial colonization on the device's surface, the Canadian company says.

FDA Approves Boston Scientific Catheter

Boston Scientific has won FDA approval and CE Mark for its AngioJet ZelanteDVT thrombectomy catheter designed to treat deep vein thrombosis in large-diameter upper and lower limb peripheral veins. The catheter is built to remove large venous clots and facilitate rapid restoration of blood flow, providing four times the thrombus removal power of existing AngioJet catheters, the company says. Deep vein thrombosis occurs when a blood clot forms in one or more of the deep veins — frequently in the legs. The device is designed to break apart and remove these clots from iliofemoral and lower extremity veins greater than or equal to 6.0 mm in diameter.

HiberGene Wins CE Mark for Test

Dublin, Ireland-based HiberGene Diagnostics has won CE marking for its HG Meningococcus test for Meningococcal disease, a severe form of bacterial meningitis. While current testing methods of growing the bacteria in a culture medium can take several days, HG Meningococcus — featuring loop-mediated isothermal amplification — provides results in less than an hour, the company says. The test can be performed using a sample of whole blood, cerebrospinal fluid or from a nasopharyngeal swab. The test will be available through a number of national distributors.

FDANEWS

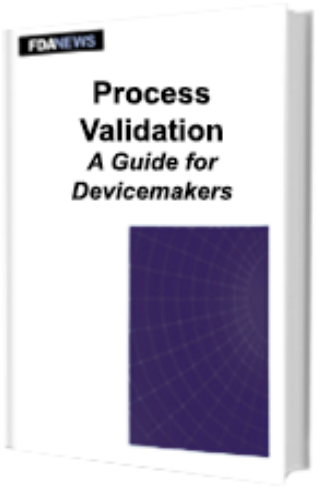
Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Jonathon Shacat
(703) 538-7663
jshacat@fdanews.com

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

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: Kellen Owings, Michael Cipriano, Victoria Pelham, Cameron Ayers
President: Cynthia Carter; **Editorial Director:** Tamra Sami; **Managing Editor:** Elizabeth Hollis



Process Validation
A Guide for Devicemakers

When must a process be validated? That is the first crucial question devicemakers must answer. But with no clear guidance from the CDRH, finding the answer can be difficult.

The new FDAnews management report — **Process Validation: *A Guide for Devicemakers*** provides you with the answers. This report will walk you through each point in the decision-making process, including how to determine if a product can be "fully verified," and how FDA inspectors define that term.

In it, you'll also find a valuable in-depth overview of all of the currently applicable regulatory guidelines that have an impact on process validation for devices, including those from three key sources: the FDA, the International Organization for Standardization (ISO) and the Global Harmonization Task Force (GHTF).

Process Validation: *A Guide for Devicemakers* teaches the proper application of the regulatory requirements that lead to successful process validation, and also offers advice on the practical issues confronting validation compliance by using real-life anecdotes and scenarios.

You also get invaluable extras, such as checklists for IQ, OQ and PQ — and hundreds of pages of appendices, including the invaluable *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, which is no longer available from the FDA.

But, most importantly, throughout the report, you'll find real-life examples that illustrate relevant concepts … show when processes need to be validated … identify the kinds of evidence you need to collect and maintain to demonstrate proper validation … and actual FDA warning letters to help you learn from others' mistakes.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/50705
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 ***Process Validation: A Guide for Devicemakers*** at the price of $397 each for the format I've selected: ❑ Print ❑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)

Add $10 shipping and handling per book for printed books shipped to the U.S., or $35 per book for books shipped elsewhere. Virginia customers add 6% sales tax.

15FLYR-N

FDANEWS

Managing Data and Documentation for FDA Inspections

Do you understand the FDA's document access authority? Is your company's data and documentation organized and ready for your next FDA inspection?

If not, your next inspection could become a scavenger hunt.

Managing Data and Documentation for FDA Inspections will help you get control of your data by using industry best practices and SOPs.

You will also learn:

- Documentation the FDA is entitled to see;
- Documentation the FDA is not entitled to see;
- How to create unique naming conventions to handle masses of data;
- How to prioritize data that might be requested during an inspection;
- The "Top 10" questions to ask about your archival process;
- What to do when documents are not in the general archives;
- When does email count as documentation;
- If source data is electronic, how to provide access to the regulatory authority;
- If source data is paper that was scanned, what to do with the originals; and
- Tips for dealing with more than one "original."

Order your copy of **Managing Data and Documentation for FDA Inspections** TODAY!

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578
   or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/51287
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 **Managing Data and Documentation for FDA Inspections** at the price of $397 each for the format I've selected:
❑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)

Add $10 shipping and handling per book for printed books shipped to the U.S. or $35 per book for books shipped elsewhere. Virginia customers add 6% sales tax.

15FLYR-N