INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 2, No. 27
July 4, 2016

IN THIS ISSUE



**Editor's Note**: Due to summer breaks, *International Devices & Diagnostics Monitor* will not be published July 11. The next issue will be published July 18.

## Industry and FDA One Step Closer On Case for Quality Guidance

FDA anticipates releasing its draft guidance on quality metrics for medical device firms in the next few months, the agency said.

The quality metrics initiative will allow firms to determine how products are performing in real-world scenarios during all three lifecycle stages: premarket, production and post-production. By developing metrics across the total product lifecycle, companies will be able to better assess their critical quality practices.

In 2014, the Medical Device Innovation Consortium created a quality forum in collaboration with the FDA and Xavier Health to develop key quality metrics (*IDDM*, Sept. 25, 2015).

Representatives from the consortium presented results from an initial pilot project during a June 28 MDIC meeting in Washington, D.C.

*(See* **MDIC**, *Page 2)*

## FDA Proposed Rule Requires More Data on Imported Devices

The FDA is proposing that devicemakers importing products into the U.S. submit additional product identification information to allow the agency to better focus on products that pose greater risks and to speed up "May Proceed" determinations.

The FDA wants product identification data from the time of entry into a U.S. Customs and Border Protection (CBP) database, including:

- The country of production where the product was last manufactured;
- The complete FDA product code;
- The total value of an entry or the total value of the articles in each import line;
- The quantity of the product in each import line, including each layer of packaging;
- The registration and listing numbers of the domestic manufacturer (DDM), foreign manufacturer (DEV) and/or foreign exporter (DFE) for each medical device; and

*(See* **Rule**, *Page 4)*

**MDIC**, *from Page 1*

The goal of the pilot was to determine which metrics would be most indicative of quality.

Abbott, Baxter, Biomerieux, Boston Scientific, J&J, Meridian Bioscience, Stryker and WL Gore participated in the pilot program.

Participants collected data from October through March, and conducted a two-year retrospective analysis on three specific metrics. Only in-company comparisons were made at this point, since company-to-company comparisons would involve too many variables.

Participants discussed and identified metrics that went beyond compliance, and labeled those as gold and silver activities that could reduce risk.

The pilot began with a focus on the following 11 critical systems:

- CAPA;
- Change control;
- Complaint handling;
- Customer Related;
- Design controls;
- Distribution;
- Management controls;
- Post-launch surveillance;
- Production and process controls;
- Servicing; and
- Supplier controls.

The road to creating meaningful metrics began with identifying activities that set the best companies apart from average companies.

Examples of these include: design controls that ensure minimal quality changes before design transfer, keeping track of trends with no repeat failures and monitoring quality system management.

Pilot companies analyzed which measures could be used to indicate quality and came up with 17 measures that broke down across the total product life cycle as follows: two in enterprise-wide continual improvement, four in the pre-production phase, eight in the production phase and three in the post-production phase.

The top three measures were selected and converted into metrics that included design robustness, right first time (RFT) and post production index. The pilot study examined these top three measures across companies of various sizes with varying products.

The pilot posed six hypotheses for the measures chosen:

- Metrics improve with product lifecycle maturity;
- Higher number of complaints and recalls come from products that have a high number of design changes;
- Low production RFT comes from products that have a higher number of design changes;
- Products with higher non-conformances have a higher volume of complaints;
- Products with higher complaints have greater probability of MDRS and recalls; and
- Risk tolerance.

During analysis of the measures, pre-production was identified as the toughest phase to track changes in improvement due to continuous trial and error which loops back to research and development.

Participants agreed that the goal was to create a self-correcting system across the product life cycle to establish a continuously improving (maturing) system from the earliest point possible.

A number of concerns arose during the pilot project, such as raising awareness and getting approval internally to participate in the program. Other challenges arose due to the complexity of products within portfolios and inconsistency in definitions used. Manufacturers also raised concerns about sharing data between companies and taking company data out of context. Collecting data was also seen to be burdensome on companies.

To drive industry participation in a voluntary program, panelists suggested more incentives were needed beyond being inspected less.

Next steps are a best practices document based on the pilot program to better inform actions in the next few months. — Joya Patel

## FDA, Industry Getting Closer To MDUFA Agreements

The FDA's recent MDUFA counter-proposal suggests a slowly closing gap between the agency and industry negotiations.

Updated meeting minutes from May 16, present the agency's counter-proposal, which presented two options with different levels of performance targets and associated resources needs, with an estimated $30 million difference between the two options.

FDA's proposal included a base of $680 million plus inflation that would be raised by user fees based on current MUDFA III levels (*IDDM*, May 27).

The agency is seeking roughly $160 million more than industry's proposal from the last meeting. Under the lower option, the FDA is asking for $291 million over five years to add 186 full-time employees. On the higher option, the agency is asking for $321.7 million to add 215 FTEs by the end of MDUFA IV.

The counter-proposal includes a reduced FTE hiring plan, with adjusted counts aligned with the agency's low and high proposal options. The FTE's are reserved for pre-submissions, MDUFA quality management framework, supervisors, *de novo* programs and expanding overall reviewer capacity.

The FDA said the lower option should result in a reduction of average decision time to 120 days for 510(k)s and 300 days for PMAs by the end of 2022. The high option proposal should result in a reduction of average decision time to 119 days for 510(k)s and 290 days for PMAs.

Components of the two options could be reorganized to create a hybrid counterproposal, the agency said, noting that its most current counter-proposal requests fewer resources than its previous proposal.

No changes were made to the FDA's proposal on quality metrics, independent assessment and myDevices portal. The agency reduced the cost of its proposal package by removing a plan to establish an "integrated review" process model for the Office of Device Evaluation.

Although gaps remain, both parties are moving closer to agreeing on a proposal package.

In a comparison between FDA's most recent proposal and industry's proposal from April 27:

- Industry and FDA see eye-to-eye on: quality management systems, device submission and review IT portals, independent assessment and standards programs; and
- A gap remains in: third-party 510(k) review programs, recruitment, digital health, pre-submission program, *de novos*, user-fee adjustment mechanisms, real-world evidence, patient engagement, management capacity and incentives, CLIA waiver reviews and shared-decision goals.

The May 16 meeting minutes can be found here: www.fdanews.com/06-30-16-MDUFAMinutes.pdf. — Joya Patel

## FDA Releases Spring Modifications To Recognized PMA Standards

FDA has published its list of spring modifications to the list of standards the agency uses in premarket reviews.

Manufacturers can use the list of recognized standards to ensure conformity with consensus standards. Updates to the list are made in alliance with ISO and ASTM along with industry collaboration from organizations such as AAMI.

FDA publishes the list three to four times per year with major updates published in the spring and fall. The spring 2016 standards list features 32 modifications that include the addition of standards not previously recognized by FDA.

The standards cover an array of device areas including cardiology, anesthesia, quality systems and risk management, electrical safety, surgery, IVD's, medical materials, orthopedics, radiology, sterility, informatics and tissue engineering.

The updated list can be found here: www.fdanews.com/06-27-16-ModificationsList43.pdf. — Joya Patel

## Iontophoresis Device Maker Warned On Complaint Handling, QS Failures

General Medical Company, a maker of devices for excessive sweating, did not keep a record of verbal complaints and had problems with its complaint evaluations, the FDA found during an October 2015 inspection.

The Pasadena, Calif., company manufactures and distributes OTC iontophoresis devices, which use a direct current to treat hyperhidrosis in the underarms, hands and feet.

Two complaints — one involving a customer with a prolonged rash and one where a customer said his daughter's hand was burned by a device — were not evaluated for reportability, says the June 2 letter, posted online June 28.

Out of 136 complaints reviewed during the inspection, the company had not evaluated any to see if an investigation was necessary. "It does not appear investigations were performed for any of these complaints," it adds.

The company apparently did not record verbal complaints at all, the letter said.

General Medical's corrective and preventive action file noted several events where customers were not aware of precautions for the devices. However, the company did not identify actions that would prevent and correct this issue. Several complaints involved customers who were unaware of contraindications for people with metal implants.

According to the letter, the company had not conducted any management reviews or quality audits from 2013 to 2015, despite its procedures requiring these audits annually.

Meanwhile, it failed to conduct adequate revalidations in 2011 after moving certain manufacturing processes from Los Angeles to Pasadena, Calif. The revalidation should have included qualifying the installation and operation of certain equipment.

In addition, the firm failed to maintain a device master record, and it didn't maintain device specifications, including component specifications, production methods and procedures, and quality assurance procedures and specifications.

It also lacked records of receiving, in-process or final acceptance activities for certain devices prior to release for distribution, including documentation that they passed final testing.

Further citations related to process validation, device history records. For example, the firm's device history records didn't include the dates of manufacturing, quantity manufactured and released for distribution, or the unique device identifier.

Additionally, the Drionic Hand/Foot and Drionic Armpit iontophoresis devices lack approval or clearance, and the agency deemed the devices misbranded.

The company declined to provide a comment. The warning letter is available at www.fdanews.com/06-29-16-generalmedical.pdf. — April Hollis

---

**Rule**, *from Page 1*

- The device listing number, premarket number (including PMA, de novo, humanitarian device exemption, 510(k).

The proposed rule also clarified that the same criteria be applied to medical device components (any raw material, substance, piece, part, software, firmware, labeling or assembly intended to be includes as part of the finished, packaged and labeled medical device); electrode lead wires and patient cables intended for use with a medical device; and convenience kits or parts of convenience kits imported or offered for import.

The goal is for this data to feed into the FDA's Operational and Administrative System for Import Support, which is linked to CBP's database and will authorize "May Proceed" determinations for low-risk imported drugs.

Comments are due within 60 days of publication in the *Federal Register*.

Read the proposed rule here: www.fdanews.com/06-30-16-ProposedRule.pdf. — Michael Cipriano

## U.S. Supreme Court to Weigh-in On DNA Test Kit Patent Dispute

The Supreme Court has agreed to review a patent-infringement case between Life Technologies and Promega, involving genetic testing technology.

One month after the federal government urged the high court to review the case, the Supreme Court agreed to grant Life Tech's petition for a *writ of certiorari* stating, "the Federal Circuit's holding is incorrect, and it subjects domestic exporters to the threat of liability for supplying a single staple article into the global stream of commerce."

The Supreme Court's review will shed light on the Federal Circuit ruling from 2014 on whether supplying a single component of a multi-component invention from the United States is an infringing act under patent law that would expose a manufacturer to liability for worldwide sales.

### Component Uncertainty

Life Technologies, part of Thermo Fisher Scientific, manufactures a genetic test kit in the UK to be sold worldwide.

One element of the kit, called a *Taq* polymerase, is made in the U.S. and then shipped to the UK to be combined with the larger product. *Taq polymerase* is used to amplify DNA via the polymerase chain reaction.

In 2010, Promega sued Life Technologies for patent infringement, accusing the company of selling test kits not covered by a 2006 license agreement. Life Tech held a license from Promega to sell DNA test kits used in legal proceedings, but had been accused of allegedly selling the kits for unlicensed uses such as clinical diagnostics.

The kits are used by police for forensic identification, and by researchers for analyzing cancer cells.

Promega Corp. owns four patents and exclusively licenses a fifth related to "short tandem repeats" in DNA sequences, referred to in court documents as the "Tautz patent," which covers methods for determining markers for genetic variations.

The jury determined that Promega was entitled to $52 million in lost profits due to LifeTech's willful infringement of Promega's patents.

Shortly after, the judge overturned the decision after trial, finding that merely shipping the polymerase from the U.S. wasn't enough to warrant such a result because "all or a substantial portion" of an invention's components to be shipped overseas requires that multiple components be involved.

### Awaiting Damages

Promega took its case to the Federal Circuit, where the court did not reinstate the jury award, stating that new damages had to be assessed.

LifeTech petitioned the U.S. Supreme Court for review in 2015, arguing that the Federal Circuit misinterpreted the law when it found Promega was entitled to damages.

The U.S. Solicitor General advised the high court to take up the issue in May, arguing that the ruling was potentially harmful to business, since it "subjects domestic exporters to the threat of liability for supplying a single staple article into the global stream of commerce."

Promega originally asserted five patents against Life Technologies, but four of those were invalidated during the litigation.

Life Technologies asked the Supreme Court to consider the issue of whether the party could "actively induce" itself to infringe a patent or whether that requires the involvement of a third party. The Supreme Court declined to take up that issue and will focus solely on the matter of whether creating a single component can lead to infringement.

Oral arguments will begin in October and end in June 2017. Read the court briefing document here: www.fdanews.com/06-30-16-DNA PatentCase.pdf. — Joya Patel

## CMS Publishes 2015 Analysis Of Vendor-Provider Transactions

Physicians and hospitals in the U.S. accepted $7.52 billion in payments and ownership and investment interests from the drug and medical device industry in 2015, according to data released by the Centers for Medicare & Medicaid Services.

The Open Payments program, also called the Sunshine Act, requires drug and device manufacturers to report payments to healthcare providers.

The data includes payments for items and services such as food and beverage, education, travel, honoraria and research, and is based on information related to 618,000 doctors, 1,110 teaching hospitals and 1,456 companies.

The program reported $2.6 billion in general payments, $3.89 billion in research payments and $1.02 billion of ownership or investment interests.

In its third annual report, the program presents a $3 billion increase over the $7.49 reported in 2014, demonstrating the volume of money flowing from industry to clinicians has slightly changed.

Among companies with the highest payments is J&J owned DePuy Synthes, which made $72.5 million in total general payments and roughly $575,000 in research payments. Stryker made $61.9 million in general payments and $6 million in research payments. Boston Scientific made $30.7 million in general payments and $17.5 million in total research payments. — Joya Patel

## FDA Classifies Electrosurgical Device as Class II

FDA is classifying electrosurgical devices for over-the-counter aesthetic use as Class II, special control devices.

Devicemakers submitting a premarket notification for these electrosurgical devices will need to comply with the special controls named in the final order issued on June 29.

These devices are identified as a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

Read the notice here: www.fdanews.com/06-30-16-ClassifyingElectrosurgicalDevice.pdf.

## French Firm Racks Up Warning Letter for Validation, CAPA Failures

Failure to validate equipment and computer software, and not establishing adequate procedures for implementing corrective and preventive actions, landed French devicemaker Eolane Vailhauques an FDA warning letter.

The Feb. 4 letter cites the firm for failing to validate its galvanic skin response measurement device. During a Sept. 18, 2015 inspection at the Vailhauques facility, inspectors noted that the firm had not established procedures for monitoring and controlling the parameters of validated processes.

Moreover, the firm's CAPA procedures didn't include requirements for verifying the corrective actions didn't adversely affect the finished device. The CAPA procedures also didn't include requirements for making changes in methods and procedures needed to correct or prevent quality problems.

Importantly, the CAPA procedures didn't ensure that information that related to quality issues or nonconforming product was disseminated to the quality unit.

Inspectors discovered the firm also had not validated its computer software. The firm had used the software since 2005 for documenting and monitoring nonconformities with customer complaints, suppliers, internal and external audits; however, it didn't provide validation documentation.

The agency also took issue with the firm's failure to establish procedures to ensure that device history records for each batch of product was made according to the device master record (DMR) as required by 21 CFR 820.184, the warning letter says.

For example, the firm had not maintained copies of primary identification labels used in the DHRs, and some DHRs didn't have identification information for inspection or test equipment used for the finished product acceptance activities.

The agency warned Eolane Vailhauques that premarket approval applications for Class III devices would not be approved until the violations have been corrected.

Eolane Vailhauques Managing Director Steve Bureau told *IDDM* that "all the actions are settled and were sent to the FDA."

Read the warning letter here: www.fdanews.com/06-30-16-EolaneVailhauquesWL.pdf.
— Tamra Sami

## FDA Issues Urgent Recall of Leukotrap RC System Blood Filters

FDA is warning healthcare providers of faulty filters used in Haemonetics' Leukotrap RC System that are associated with higher than expected levels of leukocytes in transfused blood.

The company initially alerted healthcare providers in a recall notice dated June 8, warning of three recent lots of the Leukotrap RC System filtered with its RC2D filter could yield blood products with a high leukocyte count.

The global manufacturer received further reports of higher than expected residual white blood cell counts associated with lot numbers beyond those described in the June 8 recall.

Within two weeks, the company expanded the recall to include additional lots following similar adverse reports, and it issued a voluntary recall of all lots distributed between April and June.

Haemonetics advised healthcare providers to label any blood products collected using affected Leukotrap RC systems as non-leukoreduced, unless the products have been tested and confirmed to be adequately filtering leukocytes.

In its safety advisory, FDA's Center for Biologics Research and Evaluation said such testing should be conducted within 48 hours of filtration, and any alternative procedures for counting leukocytes should be discussed with the agency beforehand.

Both FDA and Haemonetics caution blood collection establishments against re-filtering of affected blood products due to potential for damaging blood cells.

Read the safety alert here: www.fdanews.com/06-27-16-HaemoneticsAdvisory.pdf. — Joya Patel

## FDA Dings Diagnostics Maker Spot On Sciences For Marketing Slips

Spot On Sciences marketed its products for diagnostic testing despite telling the FDA they were intended for research use only, according to a recent warning letter.

In April 2014, the Austin, Texas, company told the FDA that its HemaSpot collection devices are for research use only and are not for use in diagnostic procedures. However, in March of that year, its website had featured a press release about partnering with another company to provide DTC diagnostic testing for various conditions, according to the April 12 letter posted online June 28. The release linked to a website where the devices could be ordered directly by consumers using an online payment service.

Further, statements on the website indicated that the dried blood spot collection devices are used in diagnostic testing. For example, the websites said the devices "greatly increase access to medical testing for chronic diseases and reduce health disparities for underserved and resource-limited populations." It noted that "people who are home-bound or live in remote and rural areas sometimes lack transportation for routine medical screening."

According to the site, the HemaSpot allows people to take their own blood sample with a finger stick and mail it to a testing lab.

The warning letter raps Spot On for marketing the devices without clearance or approval. During an April 2014 teleconference, CDRH gave the company three options to bring the blood collection devices into compliance: submit a 510(k) application, label the devices as research use only or label the devices for investigational use only.

Spot On told the FDA during a May 2014 conference call that it would bring its labeling into compliance by the end of May 2014 and it would remove any non-RUO claims on its website by June 11, 2015. It also pledged to create a "certification program," requiring users to certify they would not use the device for anything other than research.

In the warning letter the FDA asks Spot On Sciences to halt any activities that result in the adulteration and misbranding of the HemaSpot Blood Collection device and HemaSpot SE device.

The company has addressed the FDA's concerns and responded to all the agency's questions, it told *IDDM*. The warning letter can be found at www.fdanews.com/06-29-16-SpotOnWarning.pdf. — April Hollis

## Ireland Issues Safety Notice For Three Rapid Tests

Ireland's Health Products Regulatory Authority is temporarily banning use of Biotest's RightSign rapid tests for HIV, HCV and HBV distributed in the Irish market.

In a Priority 2 warning, HPRA warns providers that the tests manufactured by Hangzhou Biotest Biotech in Hangzhou, China, were being discontinued until further notice. The agency requested that users report any incidents and follow-up with patients tested with any RightSign product.

In a letter dated June 16, Biotest issued a field safety notice after being notified by France's ANSM cautioning on nonconformities. The agency noted that it hadn't received any false results, but it was taking the action to avoid potential risk.

Biotest has issued a recall of the valid batches from the European market. The distributor recommends halting sales of the specified products and disposing of any unused products. Affected products include: 10 lots of the HBsAg Rapid Test Cassette, eight lots of the HCV Rapid Test Cassette, and eight lots of the HIV 1.2.0 Rapid Test Cassette.

Read HPRA's safety notice here: www.fdanews.com/06-30-16-HPRASafetyNotice.pdf. Biotest's field safety notice can be found here: www.fdanews.com/06-30-16-BiotestFieldSafetyNotice.pdf. — Joya Patel

## India Amends 75-Year Old Drug/Device Legislation

Indian regulators have decided to abandon a proposed law that would have amended parts of India's Drugs and Cosmetic Act of 1940, to pursue more extensive revisions to create a separate device regulation.

India's Ministry of Health & Family Welfare has already prepared separate rules for medical devices under the existing act, and has begun drafting separate laws for regulating medical devices, drugs and cosmetics. Draft legislation is expected later this year as the ministry continues to seek input from industry.

"This ushers in times of change and hopefully for the better," said Rajiv Nath, forum coordinator for the Association of Indian Medical Device Industry (AIMED). He told *IDDM* that the association has long asked for separate regulations for devices.

Some of the changes that AIMED had asked for include quality management system requirements that are aligned with ISO 13485 standards, as well as third-party certification bodies to conduct inspections.

The regulator has proposed third party certification bodies, similar to the EU, and is currently considering four tiered risk-based regulations. The government said it was willing to consider third-party certification for low-risk devices but plans on using medical officers for all other device categories.

Nath said the proposed regulatory framework may require changes once complete but the structure would ensure devices are regulated all at once as opposed to being rolled out in stages on a product-by-product basis as was originally proposed.

The most contentious issue is the current definition of manufacturer. CDSCO defines a manufacturer as a person who himself manufactures a medical device and includes any other person who undertakes such manufacturing activity on his behalf.

Nath said this definition could be applied to pseudo-manufacturers, traders, and marketing companies that could be misconstrued as a manufacturer.

AIMED proposed manufacturers be defined as a "person, an enterprise, or an entity who himself makes a product through a process involving raw materials, components, or subassemblies, usually on a large mass production scale with different operations divided among different workers."

He said the issue is important because how legal manufacturers were defined in Europe has hurt its domestic industry as complete products have been farmed out to manufacturers in countries such as China, India and Malaysia and are claimed to be made by European companies.

For this reason, AIMED proposed using Japan's model for defining manufacturers to protect domestic manufacturing and the "Make in India" initiative.

Industry can expect drafted rules within the next six months after which public comments will be integrated into final rules.

Read the draft proposal here: www.fdanews.com/06-30-16-IndiaDraftRules.pdf. India's withdrawal notice can be found here: www.fdanews.com/06-30-16-IndiaWithdrawalNotice.pdf.
— Joya Patel

## BRIEFS

### FDA Approves Corneal Implant for Presbyopia

The FDA approved Revision Optics' Raindrop Near Vision Inlay, which is implanted in the cornea to improve near vision for presbyopia.

The approval marks the second corneal implantable device the agency has approved for near vision in patients who have not had cataract surgery. The device changes the shape of the cornea to improve vision.

The device resembles a contact lens and is made of hydrogel material. It is indicated for

*(See* **Briefs**, *Page 10)*

**Briefs**, *from Page 9*

patients 41 to 65 years old who can't focus clearly on near objects or small print. The device is inserted by a surgeon using a laser to create a flap in the cornea where the device is inserted.

The approval was supported by trials in 373 patients implanted with the device that showed two years after implantation, 92 percent of patients were able to see with 20/40 vision or better at near distances. The device is not recommended in patients who have severe dry eye.

## HeartWare Extends Recall for Batteries

HeartWare is extending a recall to include batteries used in the HeartWare Ventricular Assist Device manufactured between May 2013 to July 2015. The recall extends to 18,631 units nationwide.

The devices help deliver blood from the heart to the body and are used in patients awaiting a heart transplant. The batteries may lose power prematurely due to faulty cells, which could cause serious adverse events. The FDA has identified the move as a Class I recall, the most serious type of recall. Use of the devices may cause serious injury or death.

The firm initiated an initial recall in January, requesting that healthcare providers quarantine the products and return the devices to the manufacturer. Read the recall notice here: www.fdanews.com/06-30-16-HeartWareRecall.pdf.

## FDA Clears Cepheid's Xpert Carba-R Assay

The FDA cleared for marketing Cepheid's Xpert Carba-R Assay, which detects genetic markers associated with bacteria resistant to Carbapenem antibiotics.

Cepheid's assay tests for the presence of five different genetic markers associated with carbapenemase. The test is intended as an aid in infection control, and should be used in conjunction with other clinical and laboratory tests since it does not detect all carbapenemase genes.

The marketing clearance was supported by data from two clinical studies that tested the diagnostic in 755 patients.

## UK Warns on TRUEyou Glucose Strips

The UK's Medicines and Healthcare products Regulatory Agency is warning that certain lots of TRUEyou blood glucose tests strips may give incorrect readings that could lead to hyperglycemia.

MHRA said the issue relates to a small number of home-use blood glucose tests strips, and it is asking patients to return the tests to the manufacturer and discontinue use.

## Medtronic to Acquire HeartWare for $1B

Medtronic will expand its heart failure portfolio with the acquisition of HeartWare International, the maker of circulatory support technologies for treating advanced heart failure.

HeartWare's flagship product is the HVAD System, a miniature ventricular assist device.

Under the terms of the deal announced June 27, Medtronic will pay HeartWare shareholders $58 per share in all-cash deal worth roughly $1.1 billion. The acquisition is expected to close during the second quarter.

FDANEWS

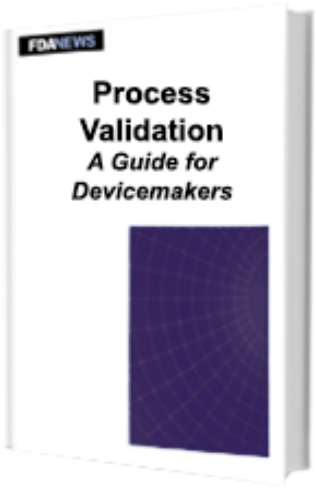
**Customer Service**
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

**Editor:** Joya Patel
(703) 538-7663
jpatel@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:** Michael Cipriano, Anisa Jibrell, José Vasquez
**President:** Cynthia Carter; **Editorial Director:** Tamra Sami; **Managing Editor:** Cameron Ayers




# 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.

16FLYR-N


# Mastering the FDA's Import Rules

U.S. authorities are holding imports more than ever before, particularly at ports that have a history of holding products, and imports from India.

This management report will tell you how to develop a top-notch import compliance program that will keep you in the "safe zone" when it comes to your dealings with the FDA and Customs. You'll gain a clear understanding of the FDA's expectations and qualifications and Customs' operational processes.

You'll also learn:

- The inside scoop from a former FDA import official on the FDA's latest priorities and expectations
- What to do to minimize your risk of delays, detentions and refusals
- How to work closely with suppliers, contract manufacturers and labelers to significantly reduce your hold times
- How to conduct a gap analysis to identify weaknesses in your existing compliance program
- How the FDA operates its import process and uses its main tool — PREDICT
- The importance of proper declarations and other good importer practices to ensure compliance with FDA regulations

Don't take the chance of having your imports held at Customs for reasons that aren't obvious or clear to you.

It's your chance to save your company time … money … and tiresome headaches.

**FOUR EASY WAYS TO ORDER**

1. **PHONE:** Toll free (888) 838-5578
   or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/51352
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 ***Mastering the FDA's Import Rules*** 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)

16FLYR-N