INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

Guidance Seeks to Reduce Cross-Contamination With Gastrointestinal Irrigation Devices

The U.S. Food and Drug Administration wants makers of gastrointestinal irrigation devices to consider risk-mitigation in device design or ensure their devices are reprocessed or discarded after each use to prevent cross-contamination during flexible gastrointestinal endoscopy procedures.

The recommendations, outlined in Tuesday draft guidance, follow reports of backflow from irritation channels into water bottles and tubing when irrigation channels lacked a backflow-prevention mechanism.

According to the FDA, clinicians often use the same water bottle for multiple patients without reprocessing during colonoscopies and upper digestive tract procedures. This increases the risk of cross-contamination from blood or stool that flows up through the endoscope channels and tubing.

Mitigation through device design should prevent this problem, the agency says, adding that there should be at least one device component within the fluid pathway with a one-way valve or other feature to prevent backflow. Manufacturers should test the feature with chemical and/or microbiological assays.

If the device has no such feature, manufacturers should ensure that the water bottle and associated tubing, any component between the patient and the distal valve, and the valve itself are designed to be reprocessed or discarded after each use, the FDA says.

Reprocessing

Devices intended for reprocessing and reuse must be able to withstand multiple cleanings and high-level disinfection or sterilization cycles, according to the guidance. Manufacturers must submit performance data supporting the validation of the reprocessing protocol and inform clinicians that devices must be reprocessed following every procedure.

Irrigation systems with a distal one-way valve may be used in multiple patients over a specified time period, but should then be reprocessed or discarded. In this case, devicemakers should provide the FDA with performance data to show adequate mitigation of cross-contamination risks.

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Valves, *from Page 1*

The guidance also discusses potential cross-contamination from different irrigation channels, such as air/water and auxiliary water/forward water jet.

In the air/water channel, the valve to prevent backflow should be labeled for reprocessing or replacement after every use, the FDA says. For an auxiliary water/forward water jet channel, used on a subset of flexible gastrointestinal endoscopes, a valve to prevent backflow should be located outside the endoscope body.

"For auxiliary water channels with external valves, any device that is directly connected to the auxiliary water inlet ... should be considered contaminated and should be reprocessed or replaced after every patient use," the agency adds.

The guidance also gives recommendations on labeling for irrigation devices.

Comments on the draft are due April 20. View it at www.fdanews.com/01-18-15-Valves.pdf. — April Hollis

U.S. FDA Clarifies Rules on De Novos For Medical Device Accessories

Sponsors hoping to gain de novo status for new medical device accessories should prepare submissions closely mirroring those for stand-alone devices, the U.S. Food and Drug Administration says.

Requests for de novo status should include descriptions of the accessory and its parent device and detailed reasons for any recommended classification for the accessory, recent guidance says. The request should identify all devices with which the accessory can be used, including model numbers or connector types, if appropriate. The request should also identify any potential risks associated with the accessory, proposed mitigation measures and a summary of supporting performance data.

The draft guidance is intended to clarify how the current risk-based regulatory framework applies to accessory devices.

Proposed labeling submitted as part of the *de novo* process should include instructions on how to use the accessory with the parent device and address potential compatibility concerns. Sponsors should also include an executive summary incorporating key information, such as a performance data summary and risk and mitigation information.

The FDA defines an accessory as any device "intended to support, supplement and/or augment the performance of one or more parent devices." An example would be a rechargeable battery used with an automated external defibrillator, because it allows the AED to function. A balloon catheter used to insert an approved transcatheter heart valve into a smaller diseased artery would also be an accessory since it acts as a supplement to the valve's intended use.

Classification of accessories is subject to the same control scheme as that for stand-alone devices, the FDA notes. De novos will be granted if the accessory falls into Class I or Class II. Class III accessories require PMA approval.

Comments are due March 23 to docket no. FDA-2015-D-0025. View the draft at www.fdanews.com/01-19-15-accessories.pdf. — Elizabeth Orr

U.S. FDA Warns Against Using Certain Bone Grafts in Kids

The U.S. Food and Drug Administration is telling doctors not to use artificial bone grafts that contain recombinant proteins or synthetic peptides in pediatric patients because of possible adverse effects on young bodies.

Three such products have been approved for use in adults: Medtronic's Infuse bone graft, Dentsply's PepGen P15 and Osteohealth's Gem21. But a MedWatch notice posted to the FDA's website on Wednesday says the some healthcare providers are using the grafts in patient under the age of 18.

Such use has led to adverse events such as excess bone growth, inhibited bone healing, fluid

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accumulation and swelling, the FDA says. The grafts may also impair skeletal development by altering normal bone formation, the agency adds.

"There is specific language in the labeling warning against the use of these products in this patient population due to concerns about the potential impacts on a developing body," says FDA spokeswoman Jenny Haliski. None of the three grafts has been reviewed by the agency for pediatric use.

The FDA suggests that surgeons consider alternatives such as autograft or allograft bone or bone graft substitutes that do not contain recombinant proteins or synthetic peptides when treating young patients. If the bone graft substitutes listed in the warning are the best alternative, their risks and benefits should be discussed with the patient and their parents or guardians, the agency says.

Known Risks

"It's important to note that the risks cited in the FDA Medwatch notice are known risks of these technologies, are not new observations, and are clearly identified in the Infuse Bone Graft product labeling," says Medtronic spokesman Eric Epperson. He adds that the device's labeling has always been consistent with the guidance issued last week in that the product is contraindicated for patients who are skeletally immature. Infuse was approved in 2002 for certain spine indications and in 2004 for treating orthopedic trauma.

Questions about Medtronic's Infuse have surfaced before. A 2012 Senate Finance Committee investigation revealed dubious payments from Medtronic to researchers and other behind-the-scenes efforts to ensure medical journals portrayed the product favorably, while a 2011 review of Infuse trial data concluded that the device offered little or no benefit over alternatives. The Agency for Healthcare Research and Quality found in 2009 that 85 percent of Infuse use was off-label.

The companies making the grafts did not respond to requests for comment. — Elizabeth Orr

China Prepares for Accreditation Of Device Clinical Trial Sites

China's device authority has released a draft regulation outlining how it will accredit medical institutions that conduct clinical trials for devices.

The move is generally viewed as positive because it will create a separate accreditation system specific to device trials, says John Balzano, special counsel for Covington & Burling's food and drug practice group. Currently, device trials are conducted at sites that have been accredited for drug trials.

The downside of the proposed regulation is that it will restrict trials to sites accredited by the China Food and Drug Administration.

Creation of the trial site accreditation system was mandated by the Medical Device Supervision and Administration Regulation, which took effect last year.

The proposal is broadly phrased, implying that any number of institutions could apply and be accredited, but it remains to be seen how it will work in practice, Balzano tells *IDDM*.

Manufacturing, Supply Controls

Under the draft regulation, the CFDA will make the final decision on accrediting trial institutions after consulting with the National Health and Family Planning Commission, which oversees Chinese hospitals medical practices. Provincial-level counterparts of the CFDA and NHFPC will assist by conducting initial reviews of accreditation applications and site inspections, Balzano explains in a recent Covington & Burling blog.

Clinical trials qualification certificates will be valid for five years.

Separately, the CFDA last week released new guidelines on good supply practices and good manufacturing practices.

The GSP guideline, which took effect in December, requires distributors to apply effective quality control measures for the purchase,

(See **China**, *Page 5)*

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acceptance, storage, sale, transportation and after-sale service of all medical devices.

GSP is a very tough requirement to monitor, and the Chinese device industry needs more time to meet the required standard, says Jack Wong, director of regulatory affairs for Asia Pacific in TerumoBCT's Singapore branch. He advises companies to perform internal audits to ensure compliance.

Balzano notes that not all classes of devices are subject to GSP requirements. Class 2 products don't require a distribution license, but companies must file for the record with local authorities, which is a lighter process than licensing. There is no requirement for Class 1.

The revised GMP guideline, which takes effect March 1, covers personnel, facilities, equipment, document management, design and development, procurement, production management, quality control, sales and after-sales services, control of nonconforming products, adverse event monitoring, analysis and improvement.

Wong says the guideline will benefit industry, particular multinational companies, because it aligns more with global requirements than the current requirements.

Comments on the accreditation proposal are due Feb. 28. View it in Chinese at www.fdanews.com/01-15-Trials.pdf. The GSP guideline is available at www.fdanews.com/01-15-GSP.pdf and the GMP guideline at www.fdanews.com/01-15-GMP.pdf. — Jonathon Shacat

U.S. FDA Regulation of LDTs Would Harm Practice of Medicine: ACLA

A major lobbying organization for clinical lab specialists says the U.S. Food and Drug Administration's proposal to regulate laboratory-developed tests oversteps the agency's legislated authority and threatens to interfere with the way doctors order tests for their patients.

In a white paper released earlier this month, the American Clinical Laboratory Association claims that LDTs are not devices but medical services because they are "developed, validated and performed by highly trained professionals within a single clinical laboratory" and no physical product is developed or sold.

The group dismisses the FDA's claim that LDTs have always been devices under the 1976 medical device amendments, saying the law doesn't mention labs, laboratory tests or laboratory testing services and specifically bars the FDA from regulating the practice of medicine. Allowing labs to develop and use tests as needed without going through FDA premarket review lets physicians respond to patients when the need arises, the white paper says.

The ACLA also argues that by making the change via guidance, the FDA bypassed the notice-and-comment period, circumventing "a cornerstone … of the administrative state." LDTs currently are regulated under the Clinical Laboratory Improvement Amendments.

The FDA maintains that stricter regulation of increasingly complex LDTs is necessary to protect patients. Under the agency's proposal, requirements regarding premarket authorization, adverse event reporting and other issues would be phased in over nine years, beginning with the highest-risk tests.

The white paper was prepared by Paul Clement and Laurence Tribe, attorneys hired by ACLA to help fight the FDA proposal. Its release followed on the heels of an FDA public meeting that heard concerns from clinical lab representatives (*IDDM*, Jan. 9).

View the white paper at www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf. — Elizabeth Orr

Integra Closes Second of Three Warning Letters

Integra LifeSciences has resolved the second of three warning letters it received over 15 months, announcing a closeout letter from the U.S. Food and Drug Administration for its Anasco, Puerto Rico, facility.

The Anasco plant, which had been under a quality-related warning letter since Feb. 13,

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Closeout, *from Page 5*

2013, was cleared Jan. 14, based on a September 2014 inspection.

The other closeout letter was given to Integra's Plainsboro, N.J., facility on Sept. 24, 2014. The remaining warning letter is for an Andover, UK, plant that the company is closing. Company officials do not expect to resolve that letter before the closure.

Wells Fargo analyst Larry Beigelsen says the Anasco closeout "removes a slight overhang," but is unlikely to have a significant impact on earnings. "We believe that the Street largely expected the closeout of the Anasco warning letter and the timing is consistent with the message of IART management over the past year," he writes.

The Anasco warning letter cited Integra for shortfalls in complaint investigations and reviews, and for failing to identify corrective actions. In the Plainsboro letter, the investigator noted mold in an equipment room, unclear environmental control procedures and failure to adequately complete cleaning validation processes.

Integra CEO Peter Arduini says the company has "made significant investments in both people and processes" over the last several years to boost its global quality assurance programs. "The lifting of the warning letter at our Anasco facility is evidence of the progress we have made."

The remaining warning letter, for the Andover plant, relates to corrective and prevention actions, process validation, and quality audits and reviews. — April Hollis

Praxair Warned Over MDRs Related to Fires, Quality Issues

Praxair, a specification developer for gas flow regulators, received a warning letter from the U.S. Food and Drug Administration for MDR failures following fires and other quality issues.

The Tonawanda, N.Y., company had two MDRs suggesting that a device malfunctioned,

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Praxair, *from Page 6*

resulting in a flash fire and that the O-ring may have contributed to each event, according to the Jan. 7 letter posted recently online. However, Praxair did not submit malfunction MDRs within the FDA's 30-day timeframe.

In one case, information in a company document described an incident where an oxygen cylinder ruptured while it was unloaded from a truck, causing a fire that burned the arm of the truck driver's helper, the letter says. The document points to an O-Ring as a possible contributing factor, but Praxair did not submit a malfunction MDR for the event. A malfunction that leads to a fire is a reportable event, the warning letter notes.

The FDA investigator reviewed the company's MDR procedure and found that there were no definitions for what Praxair will consider a reportable event. The company also had not established internal systems for a standardized review process for events and for the timely transmission of complete MDRs.

Supplier Agreement Lacking

In addition, Praxair lacked a supplier agreement requiring notification of changes to a product or service. As a result, the supplier made chances that were not approved by Praxair's management before implementation, the warning letter says. The warning letter followed a July 29 through Aug. 8, 2014, inspection by investigators from the FDA's New York district office.

Meanwhile, complaint files that reported leaks with high-pressure medical grade oxygen cylinders failed to include device identification and control numbers, investigation results or replies to complainants. Praxair's procedure did not ensure that a full complaint investigation would be conducted, and the company did not forward complaint information to a supplier to ensure an adequate investigation, the letter says.

Praxair also lacked corrective and preventive action procedures with adequate provisions for the following: analysis and handling of audit reports, service reports, product returns, trend analysis of complaints and trend analysis of nonconformances. And the company did not require verification or validation of CAPAs.

Praxair did not respond to a request for comment by press time. The warning letter is available at www.fdanews.com/01-20-15-Praxair.pdf. — April Hollis

South Korea to Expand Device Tracking System, Revise Quality Standards

The South Korean government has drafted a regulation that would expand its medical device tracking system to include 24 additional types of products.

According to a pre-legislation notice released by the Ministry of Food and Drug Safety, manufacturers of vascular grafts, implantable insulin pumps and artificial joints and 21 medtech products will now have to submit tracking information to an electronic MFDS database. The aim is to allow high-risk devices to be recovered quickly in the event of a product failure or adverse event, says Young Kim, CEO of Synex Consulting in Seoul.

The move is drawing criticism from industry quarters. U.S. industry group AdvaMed says South Korea's regulatory officials already audit manufacturers and importers to verify sales and other information and check if they are complying with relevant device tracking regulations. The proposed regulation would add burdensome administrative processes without commensurate benefits, spokesman John Dobson tells *IDDM*.

MFDS also plans to update its manufacturing and quality control standards to establish screening methods for on-site inspections, including conformity assessments.

The change would allow the ministry to issue interim certificates of compliance with Korean

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good manufacturing practices following a document review, in the event that an on-site inspection on device factories is necessary but unfeasible due to a natural disaster or war, explains Kim.

With an interim certificate, companies could distribute devices manufactured at a KGMP-expired factory on the condition that the products were tested in Korea and that the test reports were submitted to MFDS. Investigators would inspect the factory once the hindrance was eliminated, Kim adds.

AdvaMed called the proposal a positive step, saying it would ease the cost of on-site audits by switching to a paper format.

The comment period the revised tracking regulation, Posting No. 2014.391, has closed. Comments on the draft manufacturing and quality control standards, Posting No.2014-392, are due by March 2. — Jonathon Shacat

Texas Court Upholds $350M Judgment in BD Sharps Case

Becton, Dickinson & Co. must pay a competitor more than $350 million for attempting to monopolize the safety syringe market, a Texas federal court says.

In a final ruling handed down earlier this month, Judge Leonard Davis of the U.S. District Court for the Eastern District of Texas found BD guilty of illegally striving to monopolize the market and false advertising. He awarded the plaintiff, Little Elm, Texas-based Retractable Technologies, $340.5 million in damages plus $11.7 million in attorney fees and pre- and post-judgment interest and costs.

RTI filed suit against BD in May 2010, claiming that ads touting BD's needles as the sharpest in the world were false and misleading. BD also falsely told customers that its syringes saved medication when compared to RTI's products.

A November injunction ordered BD to stop running the ads and inform customers that the marketing was false. The company was also instructed to retrain employees and distributors to ensure that they no longer maker the false claims. A Jan. 14 follow-up order requires BD to comply with the injunction by Feb. 14.

RTI had also asked the court to limit BD's contracting practices, which it said promoted unfair competition, and to bar the company from advertising its products' safety features. On both of those counts, the judge ruled in BD's favor, saying RTI had not proven its case.

BD plans to appeal the judgment.

The appeal is no surprise, says Douglas Cowan, vice president and chief financial officer at RTI. He notes BD is also still appealing a $7.7 million verdict in a patent infringement case against RTI.

Still, he's optimistic about the case. "It upheld what the jury found as far as damages go, and it also provided injunctive relief," he tells *IDDM*. — Elizabeth Orr

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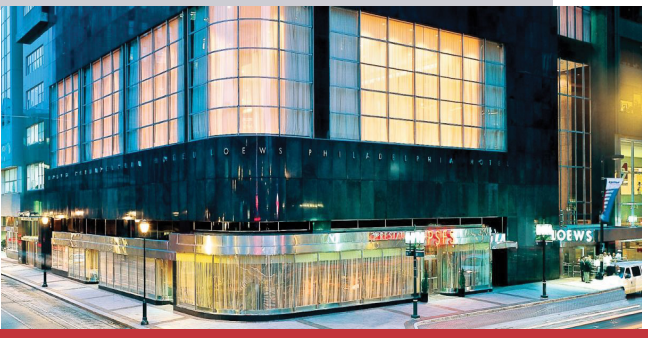

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DAY ONE

8:00 a.m. – 8:30 a.m.
REGISTRATION/CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m.

Understanding The Basics of Human Error On The Manufacturing Floor

- How human errors intersect with manufacturing regulations
- Examples of applicable FDA requirements and what the FDA expects companies to be complying with
- A review of other industry standards that apply to drug and device manufacturing
- What FDA investigators look for during inspections and the most common violations found in Form 483s and Warning Letters
- Which violations tied to human errors and manufacturing are trending up
- The various types of human errors are commonly found on manufacturing floors
- How we got here — why is human error reduction such an important topic

Interactive Exercise! Do we also err? Attendees will be broken into groups and asked to describe the most common human errors within their facilities. The workshop will then reconvene and break-out group leaders will describe what they uncovered. A list of the most common problems will be tallied to help focus the future discussion.

10:00 a.m. – 10:15 a.m. BREAK

10:15 a.m. – 12:00 p.m.

Human Error In Context — What Are the Factors That Drive Human Errors?

- The taxonomy of human error; how and why drug and device companies need to focus on this in their investigation processes
- Why administrative and management systems factor so prominently into deviations and non-conformances
- The role of innovative operational controls and their role in reducing human errors
- Simple procedures that prevent human error -- how they should be described and presented to maximize human error reduction
- Common examples of poor human factors engineering and workplace conditions that contribute to human error
- When training is appropriate and when we should stop
- Learn how common day-to-day communication gaps contribute to human error
- How supervision can be one of the best human error reduction strategies at your site
- When is individual performance responsible for human error and when does it become a root cause
- How to address cognition, attention, and memory failures at your site

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:30 p.m.

Internal vs. External Factors

- How our biology affects our thinking process and individual performance
- Understanding the latest on cognitive load and attention, memory, and decision making errors — how they commonly occur on the manufacturing floor
- How our senses control how we react — it's more important that you think
- Best practices for controlling human factors for optimum people performance
- How to create an organizational environment that supports human error reduction initiatives — from senior management to floor level staff
- Why our culture with regards to human error has to change; it's not an easy process but vitally necessary for drug and device companies

2:30 p.m. – 4:30 p.m.

Corrective and Preventive Action (CAPA) — FDA's #1 Manufacturing Compliance Problem

- How to develop corrective actions that make sense —what's working and not working
- Creating preventive actions that truly prevent; how to stop errors that have not yet happened
- Understanding the human error prediction process and tools
- Prevention and human error control: proven ways to measure improvement and on-going trend analysis
- When to use detection mechanisms instead of preventive mechanisms — the pros and cons of each
- Human error detection and recovery rate — are you really uncovering all the errors within your facilities?
- Assuring for the FDA your CAPA program is effective and you've adequately focused on human error

Interactive Exercise! When to do what?

DAY TWO

8:30 a.m. – 10:00 a.m.

Human Error Reduction Techniques

- Discussion of insights from day 1
- When is human error a human resources issue?
- How and when to apply engineering controls to correct and prevent human error deviations
- What to do when individual performance is the major contributor
- Human error and documentation: from design, construction, change management and implementation
- Additional Contributors for human errors will be discussed

Interactive Exercise! Practice identifying techniques to be applied

10:00 a.m. – 10:15 a.m. BREAK

10:15 a.m. – 12:00 p.m.

Human Error Investigation

- Human Error investigation process defined from beginning to end
- How to gather data in the human error investigation process
- How to perform an effective interview
- Important steps foe effective human error investigations

- How to report issues to mae sure management listens

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:30 p.m.

Root Cause Analysis Tools

- A brief review of common tools used in determining root cause
- Hierarchy and use of the root cause determination tool for human error investigations
- How to perform a cognitive load assessment
- The interview process and interview techniques for human error root cause analysis
- When and how to use the human error prediction tool
- When to perform a Process vs. procedure analysis and why it is so important to do so before establishing procedure revision as a CAPA for human error

Interactive Exercise! Brainstorm root causes for real cases with peers. Using the situations identified in the first exercise we will try and apply the applicable tool.

2:45 p.m. – 4:45 p.m.

Metrics and Human Error

- KPI's
- Human Error rate
- 1st time pass rate
- Overall equipment effectiveness (OEE)
- Trending /Tracking

Interactive Exercise! Work with various common metrics and benchmarks. Determine what constitutes acceptable and non-acceptable results.

4:45 p.m. – 5:00 p.m.

Review and Key Insights/Materials

- Copies of the presentations
- Current FDA regulations
- Pertinent guidance documents
- Articles on Human Error
- Manual Tools
- Interviewing guide
- Report Example
- Root Cause Determination Tool

5:00 p.m. WORKSHOP ADJOURNS

WHO SHOULD ATTEND

- QA/QC directors and managers
- Process improvement/excellence professionals
- Training directors and managers
- Manufacturing operations directors
- Human factors professionals
- Device engineering
- Compliance officers
- Regulatory professionals
- Executive management

COURSE BINDER MATERIALS

- Root cause determination tool
- Interviewing guide – you can take back and use immediately
- Example of well-documented HE report
- Complete copy of slide deck materials
- Copies of applicable FDA regulations referenced in the course
- Copies of pertinent FDA guidance documents
- Articles focused on human error reductions

YOUR EXPERT SPEAKER

GINETTE COLLAZO, PH.D., — has spent more than 15 years in technical training, organizational development and human reliability. She has worked with Bristol-Myers Squibb, Johnson & Johnson, Schering-Plough, Wyeth and Medtronic, and many more small and mid-sized drug and device companies. An active researcher in specialized studies related to human reliability, she is the author of numerous publications on these topics.

"The topic is very relevant to the needs of our business at the moment. I learned several things associated with how to train and use lean techniques to reduce the opportunity for human error. It also reaffirmed the things we are doing well that are working."

—Richard Leach, Director of Quality, Nosco

"[Ginette is] very passionate [and] high energy. A lot of take aways. Reduction of human error has been a challenge and the tools provided will be put to the test."

—Alex Masso, QA In-Process Supervisor, Mylan Institutional Inc.

"[Ginette is] very knowledgeable with great industry examples. Very spunky! Great delivery."

—Irene Rockwell, Manufacturing Compliance, Biogen Idec

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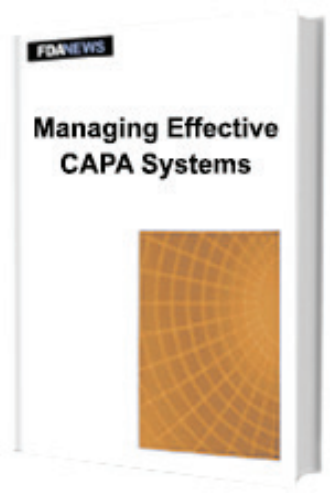

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